Does acupuncture have a role as an analgesic in the emergency setting?

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DOES ACUPUNCTURE HAVE A ROLE AS AN ANALGESIC IN THE EMERGENCY SETTING?

Andrew Lindsay Jan

MBBS, FACEM, BA, FAMAC, MPhil

Submitted in fulfilment of the requirements for the degree of Doctor of Philosophy

School of Medicine
Fremantle Campus

March 2021
Declaration

To the best of the candidate’s knowledge, this thesis contains no material previously published by another person, except where due acknowledgement has been made.

This thesis is the candidate’s own work and contains no material which has been accepted for the award of any other degree or diploma in any institution.

The research presented and reported in this thesis was conducted in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007, updated 2018). The two research studies (Chapters 4 and 6) received human research ethics approval from the St John of God Health Care Human Research Ethics Committees (reference numbers 1107 and 1426, respectively).

Signature:

Andrew Jan

Date: 12 March 2021
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**Definitions**

- **Conceptualisation** – Ideas; formulation or evolution of overarching research goals and aims.
- **Data curation** – Management activities to ensure (produce, maintain) data and maintain research data (including software code, where it is necessary for interpreting the data itself) for initial use and later re-use.
- **Formal analysis** – Application of statistical, mathematical, computational, or other formal techniques to analyse or synthesise study data.
- **Funding acquisition** – Acquisition of the financial support for the project leading to this publication.
- **Investigation** – Conducting a research and investigation process, specifically performing the experiments, or data/evidence collection.
- **Methodology** – Development or design of methodology; creation of models.
- **Project administration** – Management and coordination responsibility for the research activity planning and execution.
- **Resources** – Provision of study materials, reagents, materials, patients, laboratory samples, animals, instrumentation, computing resources, or other analysis tools.
- **Software** – Programming, software development; designing computer programs; implementation of the computer code and supporting algorithms; testing of existing code components.
- **Supervision** – Oversight and leadership responsibility for the research activity planning and execution, including mentorship external to the core team.
- **Validation** – Verification, whether as a part of the activity or separate, of the overall replication/reproducibility of results/experiments and other research outputs.
- **Visualisation** – Preparation, creation and/or presentation of the published work, specifically visualisations/data presentation.
- **Writing – original draft** – Preparation, creation and/or presentation of the published work, specifically writing the initial draft (including substantive translation).
- **Writing – review & editing** – Preparation, creation and/or presentation of the published work by those from the original research group, specifically critical review, commentary or revision – including pre- or post-publication stages.
Abstract

**Background:** Pain is a feature of most emergency department (ED) presentations. Exacerbation of chronic pain comprises 40% of pain presentations, with the remainder being a mix of recurrent or one-off painful conditions. Opioids are the mainstay treatment for moderate to severe pain but have both short- and long-term adverse effects, including recurrent use, abuse and death. Non-steroidal anti-inflammatory drugs (NSAIDs) are also a concern, especially in older patients with comorbidities. Thus, emergency physicians are highly motivated to seek alternatives for pain management. Acupuncture is frequently used in outpatient settings that offer non-pharmacological treatments and has gained acceptance in postoperative analgesia; however, it is rarely used for pain in the ED setting.

**Aim:** The aim of this thesis is to investigate whether acupuncture has a role in standard analgesia care in the ED setting.

**Methods:** Based on original research and the extant literature, this thesis investigates the potential role of acupuncture in the ED setting. Primary outcomes include the efficacy of acupuncture as a standalone or adjunctive analgesic. Secondary outcomes include adverse effects, patient satisfaction, opioid-sparing ability, administration time, cost and training requirements. The original research includes two systematic reviews (on all forms of acupuncture and ear acupuncture), a patient survey, acupuncture teaching experiences and a randomised controlled trial. The findings for each outcome were collated and graded for quality. Outcomes were then ranked by priority based on the demands of the ED setting and compared with the ideal and specific analgesics to ascertain the potential clinical role of ED acupuncture.

**Findings:** Acupuncture is effective as a standalone analgesic but its benefits as an adjunct are unclear. Patients were satisfied with and willing to use it. Acupuncture carries a low risk of adverse events, is low in cost and is teachable to ED clinicians in basic formats such as battlefield (ear) acupuncture. The minimum training required for competency and safety in traditional body acupuncture remains uncertain. There is limited evidence for or against the opioid-sparing ability of acupuncture.

**Clinical recommendations:** ED acupuncture may be considered for patients with moderate non-catastrophic pain, those at risk of recurrent use or adverse effects of opioids, those for whom
NSAIDs, steroid injections or other analgesics are contraindicated and those refusing standard analgesia care.

**Future directions:** Urgent research is needed on acupuncture as an adjunct to simple analgesia and its opioid-sparing ability in the ED. Special interest groups at colleges of emergency medicine and medical acupuncture should be established to promote ED acupuncture courses and establish standards for minimum acupuncture training.
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<tr>
<td>ACEM</td>
<td>Australasian College for Emergency Medicine</td>
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<td>AMAC</td>
<td>Australian Medical Acupuncture College</td>
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<td>AMSTAR</td>
<td>A Measurement Tool to Assess Systematic Reviews</td>
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<td>BFA</td>
<td>Battlefield acupuncture</td>
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<td>CONSORT</td>
<td>Consolidated Standards of Reporting Trials</td>
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<td>EBM</td>
<td>Evidence-based medicine</td>
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<td>ED</td>
<td>Emergency department</td>
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<tr>
<td>EUPATI</td>
<td>European Patients’ Academy on Therapeutic Innovation</td>
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<tr>
<td>GRADE</td>
<td>Grading of Recommendations, Assessment, Development and Evaluations</td>
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<tr>
<td>ICMART</td>
<td>International Committee for Monitoring Assisted Reproductive Technologies</td>
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<td>MAP</td>
<td>Multimodal assessment model of pain</td>
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<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<tr>
<td>NNH</td>
<td>Number needed to harm</td>
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<tr>
<td>NNT</td>
<td>Number needed to treat</td>
</tr>
<tr>
<td>NPRS-10</td>
<td>Numeric pain rating scale out of 10</td>
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<td>NSAIDs</td>
<td>Non-steroidal anti-inflammatory drugs</td>
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<td>PICO</td>
<td>Problem/patient/population, intervention, comparator, outcomes</td>
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<td>PRISMA</td>
<td>Preferred Reporting Items for Systematic Reviews and Meta-Analyses</td>
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<td>Randomised controlled trial</td>
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This thesis would not have been possible without the help of so many wonderful people. It began as a set of ideas, concepts and information, which, with time, effort and skill, were collated, synthesised and manifested into a range of publications and this final thesis. A select group of supervisors guided the process. All of them are world authorities, not only because of their leading research but because of their benevolence and willingness to teach. I am indebted to Professor Eric Visser, Professor Ian Rogers, Professor Max Bulsara, Associate Professor Colonel Richard Niemtzow and Professor Lorna Suen for their supervision of this doctoral degree. I only hope that I have adopted some of their benevolence and knowledge and duly pay these forward.

So many other exceptional individuals have contributed far more than what was expected or required. My gratitude goes to Dana Hince for her monumental statistical advice and Professor Eli Gabbay for believing in this thesis and helping me to begin.

Although the beginning of this PhD was lonely, friendships have been born and strengthened over the years. The companionship of Emogene Aldridge and her assistance with most of the publications was a blessing. Despite the isolation, my good friends Michael Woosey and Andrew Tandy reached out and offered the support I needed.

It may be said that it takes a community to complete a PhD thesis. Colleagues from medical acupuncture and emergency medicine colleges, researchers worldwide and staff from the emergency department, ethics committee and schools of research and medicine at Notre Dame University all contributed beyond their job descriptions out of sheer goodwill. My appreciation also goes to those patients who graciously volunteered in moments of pain and suffering for this research. It humbles me that they were just as concerned about others in their moment of pain and need.

The family takes the biggest brunt of such an endeavour. My wife Fiona often remarked that undertaking this PhD was like taking a second spouse, yet never ceased with her devotion and care. I give tribute to my daughter Nikita, who not only kept me loving but assisted with so many of the technical aspects of software.

Finally, if I had to share with future candidates the personality characteristics required to complete a PhD, I would say these are enthusiasm and resilience. These characteristics in me,
were inspired by my Taoist teacher Mantak Chia and my heroes—Jesus Christ, Bruce Lee and William Blake.

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Chapter 1: Introduction: The Role of Acupuncture as an Analgesic in the Emergency Department

Acupuncture, as a part of Traditional Chinese Medicine, represents a unique gift in medical practitioner’s hands. It is a gift of a perspective different from conventional Western modern thinking offering a holistic approach typical of Eastern civilizations.*

—Alena Ondrejkovičová, medical acupuncturist, 2016

What is already known on the topic:

- Acupuncture is frequently used for pain relief in the outpatient setting by general medical practitioners and allied health professionals with only basic training.
- Acupuncture is effective for chronic pain and has a low risk of adverse effects.
- Prior to commencing this thesis, the role of acupuncture for acute pain in the emergency setting had not been defined.
- The opioid crisis has prompted a search for safer analgesics in and outside the emergency department (ED).

What this research may add:

- Improvement of pain management in the ED.
- Reduction in the need for opioid analgesia.
- Reduction in the burden of pain in the community post ED discharge.
- Acupuncture becoming a standard modality of analgesia in the ED.
- A revitalisation of the art of medicine in the ED by incorporating a holistic modality into its analgesic armamentarium.

1.1 Background

The majority of presentations to the emergency department (ED) constitute pain. Of these, around 38% are exacerbations of chronic pain, while the remainder is a mix of conditions involving recurrent or one-off pain. Despite its frequency, pain often goes unrecognised, and treatment is often delayed or inadequate. The undertreatment of pain contributes to and increases the risk of chronic pain and other negative quality of life measures.

Opioids have been the mainstay treatment in the ED analgesic armamentarium for moderate to severe pain and take-home analgesia. Research has shown that the administration of strong opioids in the ED is associated with recurrent use (5.6%) and dependence (2.8%). One study found that 12% of opioid-naive ED patients who had been prescribed take-home opioids were still taking them 1 year later. Patients requiring opioid analgesia after an acutely painful problem, such as an injury or post-operative, are significant and constitute 27% of those becoming chronic users. The United States (US) and other Western countries such as Australia are currently experiencing an opioid crisis, with overdose deaths, addictions and abuse along with enormous social and economic consequences.

With the ageing population and high incidence of comorbidities (e.g. kidney and gastrointestinal diseases), the prescription of non-steroidal anti-inflammatory drugs (NSAIDs) is also a concern. Given the concerns about opioid reuse and the adverse effects of opioids, NSAIDs and other procedures, emergency physicians are highly motivated to seek alternatives to ED pain management. Administrators and physicians are also continually seeking ways to improve patient satisfaction to enhance hospital reputation, patient compliance while reducing complaints and litigation. Despite them being the mainstay of strong pain relief, opioids are not associated with patient satisfaction.

Despite the high-quality evidence for the efficacy of acupuncture for chronic pain, Western medical practitioners are divided on its use—some consider it a placebo, while others view it as an alternative for patients who are difficult to treat or have unexplained symptoms and ongoing pain. Many of these practitioners offer other non-pharmacological techniques that promote mind, body and spiritual development in the long term and potentially providing meaning to patients’ lives.

Acupuncture is frequently used in outpatient and perioperative settings for pain but not in ED settings. In outpatient settings, it is used by general practitioners, traditional Chinese
medicine (TCM) practitioners, physiotherapists, osteopaths and chiropractors for the treatment of chronic and recurrent painful conditions. In 2005, 18% of general practitioners practised acupuncture and 9% of Australians used acupuncture, with 10 million visits per year Australia wide. These numbers have likely grown since then. The infrequent use of acupuncture in the ED may be attributable to the chaotic environment being non-conducive to its efficacy or the lack of evidence in this setting. A systematic review of studies on ED acupuncture found only two small randomised controlled trials (RCTs) and came to no conclusions. In Australia, the ongoing clinical use of acupuncture is isolated to a small number of ED physicians who are trained in both emergency medicine and acupuncture.

Acupuncture may have a role as an analgesic in the ED setting and address some of the weaknesses in the current ED analgesic armamentarium. This thesis aims to evaluate this possible role.

1.2 Personal Rationale for This Thesis

This thesis has provided me with the opportunity to juxtapose two seemingly conflicting lifelong interests, namely medical science and Taoist mysticism. Western medicine is based on scientific reductionism in which a singular material cause or abnormality is identified to explain an observed phenomenon or disease. Simply stated, this means finding the abnormal part and changing or removing it to promote healing (see Figure 1.1).

In contrast, acupuncture is a primary modality of healing based on the epitome of Chinese philosophical thought, namely Taoism. Taoism is a mystical philosophy premised on an ultimate singular reality in which all fragmented entities (including disease) are connected and return to the one. This is known as ‘the way’. From the one, healing and new life can emerge. In the Chinese model, separate parts are identified as elemental psychophysical energies—wood, fire, metal, earth and water. Pain results from all parts contributing to a malignened state, resulting in symptoms in one part. Healing involves all aspects changing and submitting to a holistic force. The yin–yang symbol can symbolise this holistic force (see Figure 1.2). This approach is mysterious to most Westerners.

Both paradigms have their strengths and weaknesses and reflect the truth in some way. Many conditions are managed well using Western medicine, but others, including pain, are managed poorly. Similarly, Chinese medicine is low in diagnostic accuracy and inadequate for the treatment of serious disease.
Figure 1.1: Reductionist scientific model of pain reduction.

Note: The painful body part is identified and altered with pharmaceuticals (which may affect other systems) (top arrow) or removed via surgery (bottom arrow).

Figure 1.2: Chinese model of healing from pain.

In the Chinese model, all parts can either contribute to the diseased state (pain) or wellness (pain-free). Healing occurs when all parts submit to a higher force typified here by the yin yang symbol.

The essence of this thesis is to subject acupuncture, a modality representing the pinnacle of holistic Taoist thought, to the ultimate arbiter of Western medicine—evidence-based medicine (EBM). Some experts argue that EBM should not be applied to acupuncture because the use of a reductionist scientific paradigm to examine its antithesis would be philosophical nonsense.\footnote{28,31}
However, by following Kuhn’s philosophy, I hope that this dialectic process will be beneficial for patients and the growth of both paradigms.32

To encourage reader participation in this process, I include my reflections on the differences between the two paradigms for pain management in Table 1.1. In the final discussion in Chapter 7, I provide examples of where these two paradigms remain disparate or are showing signs of gaining common ground.

**Table 1.1: Western v. Traditional Chinese Medicine**

<table>
<thead>
<tr>
<th></th>
<th>EBM - the core of Western Medicine</th>
<th>Chinese Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>History</td>
<td>EBM treats patients as the same for a given a disease or condition</td>
<td>Condition determined by prior ancestors, the alignment of elements and planets at the time of birth (pre-natal chi), and degree of rejuvenation or exhaustion of postnatal chi influenced by intervening pathogenic forces. The ED pain crisis is one moment in an unfolding story.</td>
</tr>
<tr>
<td>Body</td>
<td>Body is made up of parts - pain results from a malfunctioning part.</td>
<td>Body works as an integrated whole - each part influences the other.</td>
</tr>
<tr>
<td>Spirit</td>
<td>Spirituality removed from EBM framework.</td>
<td>Strength of the spirit determines prognosis.</td>
</tr>
<tr>
<td>Community</td>
<td>Pain crisis due to a diseased part, aberrant neurotransmission, curable by procedures and pharmaceuticals.</td>
<td>Cause of pain crises in part reflects a disharmony of the environs, family, ancestors and community. Respected masters, sages and healers lead community.</td>
</tr>
<tr>
<td><strong>Practitioner and treatment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Competency</td>
<td>Therapeutic success primarily based on EB modality but may recognise factors such as length of training.</td>
<td>The practitioner’s ability to have therapeutic success is based just as much on the level of spiritual attainment, compassion and intention as skill in acupuncture. The provider will transmit chi with right intention to restore balance or open meridians through therapeutic touch.</td>
</tr>
<tr>
<td>Goal</td>
<td>EBM focuses mostly on short term outcomes such as pain reduction as these are logistically easier to measure.</td>
<td>Positive intervention could positively alter a life trajectory. The primary goal is to assist the patient to find the ‘way’. The goal may not necessarily to become immediately pain free but to make a realisation that pain (suffering) and happiness are two features of life (yin and yang).</td>
</tr>
<tr>
<td>Prescription</td>
<td>Therapy is based on managing the painful part or specific neuro-receptors/transmitters. Prescription / modality chosen is based on hierarchy of evidence.</td>
<td>For a Western diagnosis choice of needle placement varies according to spirit, organ and elemental imbalance, pain location, and invasion of pathogenic factors.</td>
</tr>
<tr>
<td>Follow up</td>
<td>Use of pharmaceuticals or procedure encourages reuse of these procedures and dependence on medical intervention. Usually progress to bigger dose or invasive modality post failure.</td>
<td>Progression: introducing a modality such as acupuncture more likely to reuse and cultivate mind and body through other CM related therapies, e.g. Tai Chi, meditation, Chi Kong, Feng Shui, diet &amp; herbs.</td>
</tr>
<tr>
<td>Assessment of success</td>
<td>Pain reduction, quality, functional and satisfaction outcomes</td>
<td>Patient and practitioner satisfaction.</td>
</tr>
</tbody>
</table>

A personal reason for this thesis was to promote the merging of Chinese and Western medicine paradigms in the domain of pain. This table highlights my impressions of the differences between the two paradigms. At the end of the thesis, I provide examples of where these two paradigms have shown signs of gaining common ground. EBM: evidence-based medicine; ED: emergency department; EB: evidence-based; CM: Chinese Medicine.

**1.3 The Ideal Analgesic Framework**

One way to analyse weaknesses in standard analgesia care (SAC) in the ED is to benchmark it against the parameters of the ideal analgesic. These parameters can then provide a framework by which to categorise ED acupuncture characteristics and facilitate comparison of acupuncture with a single analgesic.
The ideal analgesic uses the concept of a gold standard. Although the ideal analgesic is hypothetical, it provides a framework by which to enable analgesic comparison. Researchers adapt the ideal analgesic criteria depending on their unique environments. For example, the demand for analgesia is different for intensive care, anaesthesia, prehospital care, outpatients and the ED and changes over time.

In the ED, the criteria for analgesia have shifted towards patient satisfaction over the last 20 years and opioid-sparing techniques over the last 5 years. Currently, there is no universal consensus on the ideal analgesic in the ED. In 2009, Moore began a conversation about the ideal analgesic for acute pain. His criteria included a rapid onset of action with lasting analgesia, effectiveness across a wide range of painful conditions and high patient tolerance. Narayanan, an intensivist, added cost effectiveness and a low adverse effect profile. More recently, Todd, an emergency physician and avid pain researcher, recommended that the ideal analgesic be opioid sparing. Priano specifically researched the use of adjunctive analgesics to prevent opioid use.

Further, Priano was mindful of the work and time demands of ED staff and did not wish the analgesic approach to add to patient length of stay. Patient satisfaction feedback is linked with excessive opioid prescribing, with doctors attempting to achieve better scores through prompt and effective pain management. Duncan does not want to curb doctors concerns for patient satisfaction but instead recommends new approaches to improve satisfaction through training staff in the use of alternative analgesics. Motov, another prolific emergency physician-researcher, sought to emphasise functional improvement as a further ED analgesic goal.

Based on the above, the ideal analgesic should be effective for moderate to severe pain, have a rapid onset but be long-lasting and be effective for all painful conditions. Patients should be satisfied with and willing to use and reuse it. It should be easily applied, inexpensive and have no adverse effects. It should not consume excessive time of ED clinicians nor add to patient length of stay. It should reduce the need for harmful analgesics such as opioids and NSAIDs. Finally, the mode of delivery should be compatible with the unique ED environment. Other characteristics such as anxiety reduction and functional improvement could also be added to this list. However, given the scope of this already broad topic, I refrain from including these because they are only occasionally measured in ED acupuncture research. Therefore, in this thesis, the characteristics of the ideal analgesic are as follows:

- effective as a standalone analgesic
- effective as an analgesic adjunct
improves patient satisfaction and willingness to reuse it
has minimal adverse effects (mortality and significant and minor effects)
has opioid-sparing ability
does not consume excessive time of ED clinicians
is inexpensive and cost effective
is teachable and requires minimal training (see Figure 1.3).

**Figure 1.3: Characteristics of the ideal analgesic.**

These characteristics provide a useful framework by which to compare standard analgesia care and acupuncture. Dark green = primary thesis outcomes; light green = secondary thesis outcomes.

The ranking of outcomes is explored further in Chapter 7. The primary outcomes relate to standalone or adjunctive analgesic efficacy, with the remainder being secondary outcomes. The term ‘standalone’ implies the use of an analgesic on its own, while ‘adjunct’ refers to added effectiveness above SAC (usually pharmacological). Further, some of these outcomes may need to be subdivided if they contain any diversity (e.g. adverse effects).
1.4 Potential Weaknesses of Standard Analgesic Care

This section highlights the strengths and potential weaknesses of SAC and how it compares with the ideal analgesic in terms of the above outcomes. Each outcome is discussed with respect to individual analgesics that are likely to be a source of weakness for that outcome. Please note that the primary scope of the thesis is to focus on acupuncture. While sound evidence is provided about the analgesics used in SAC, no detailed evidence about their potential weaknesses is provided. Clinicians or policymakers who choose to compare acupuncture with standard analgesics are advised to substantiate my interpretations. Nevertheless, I believe this ideal analgesic framework will be a useful tool to facilitate comparison.

The following sections present each outcome, including a definition, a brief description of the weakness of SAC with respect to that outcome and how acupuncture would need to be measured and perform if it were to find a role in ED.

1.4.1 Standalone analgesia

For acupuncture to replace an existing analgesic, it would need to show improved pain reduction, or achieve equipotent analgesia while delivering improved secondary outcomes. Infrequent clinical scenarios for the use of acupuncture as a standalone analgesic include patients refusing standard analgesia or choosing acupuncture as their analgesic of choice. For example, pregnant women often refuse analgesia for fear of harm to the foetus, while others are concerned about masking their condition with analgesic medication.

High-quality RCTs or meta-analyses would be the most reliable study types to compare acupuncture with SAC. In an RCT, acupuncture could be compared with sham acupuncture and/or a specified analgesic to show whether it has any statistically significant benefit. If a 30% or 50% pain reduction is the outcome measure used, number needed to treat (NNT) (e.g. Molsberger et al.) and absolute risk reduction (i.e. the intervention minus the comparator, expressed as a decimal) may be calculated. NNT is the inverse of absolute risk reduction. Therapies with NNT values of 2–5 are considered effective. The examples provided below show that the ED has effective standalone analgesics based on NNT estimates. Unfortunately, most acupuncture trials do not provide NNT data.

If mean pain scores only are used to measure differences between the intervention and comparator, methods such as the Student’s t-test are needed to measure statistically significant
differences (see Chapter 6). In a meta-analysis comparing standalone acupuncture with either sham acupuncture or an alternative analgesic, one would need to show a standardised mean difference (SMD). For binary outcomes, relative risk or odds ratio can be used. The measure used in this thesis is SMD. A SMD of greater than 0.25 shows a small effect size difference, while 0.5 being moderate and greater than 0.8 is large (see Chapter 2 and 3). The larger the effect size difference, the better the evidence to change an analgesic. Weighted mean differences can also be used when preserving the original scale (e.g. pain score out of 10) is desired (see Chapters 2 and 3).

1.4.1.1 Commonly used analgesics in the ED

1.4.1.1.1 Paracetamol

Paracetamol is an established standalone analgesic in the ED armamentarium and is difficult to replace. Among its few weaknesses is that it is more useful for mild to moderate pain.34

- Acute pain:
  - Paracetamol: 1,000 mg (NNT = 3.8; 95% confidence interval [CI] [3.4, 4.4]).46

1.4.1.1.2 Non-steroidal anti-inflammatory drugs

NSAIDs are an essential and effective standalone component of the ED analgesic armamentarium.47

- Acute pain:
  - Ibuprofen: 400 mg (NNT = 2.5, CI [2.4, 2.7]).46
  - Ketorolac: 30 mg intramuscular (NNT = 3.4, CI [2.5, 4.9]).46

1.4.1.1.3 Opioids

Opioids are an effective standalone analgesic for severe pain. Data on NNT for recently introduced atypical opioids are lacking.

- Acute pain:
  - Morphine: 10 mg (NNT = 2.9, CI [2.6, 3.6]).46
  - Tramadol: 100 mg (NNT = 4.8, CI [3.8, 6.1]).46
  - Oxycodone: 15 mg (NNT = 2.4, CI [1.5, 4.9]).49
Tapentadol: no improved pain control compared with oxycodone, tramadol or morphine.\textsuperscript{48}

1.4.2 Adjunctive analgesia

Adjunctive analgesia (e.g. paracetamol with NSAIDs or opioids with paracetamol and/or NSAIDs) is used both frequently and successfully in the ED. Clinical scenarios in which adjunctive analgesia is required to further reduce pain (e.g. when oral analgesia fails at presentation or following the first dose of analgesia) are common. Adjunctive acupuncture may play a role if clinicians wish to delay or avoid NSAIDs, opioids, steroid injections, pain procedures or surgery in patients at risk of adverse effects. For acupuncture to justify itself as an adjunct, it needs to show either superiority in analgesic benefit or equipotency with an improvement in other secondary outcomes compared with specified SAC.

As per the standalone analgesia outcome, high-quality RCTs and meta-analyses would provide the best quantification of the effectiveness of acupuncture as an adjunct. In an RCT, acupuncture used as an adjunct to a pharmacological analgesic would be compared with the analgesic alone to test its effectiveness in reducing pain. In a high-quality RCT, a statistically significant mean improvement above the pharmacological analgesic would be needed to justify the use of acupuncture. The NNT may be compared either with the placebo or the pharmacological analgesic therapy. The examples below show commonly used ED adjunctive therapies for acute pain compared with placebo, with NNTs all less than 3, highlighting their effectiveness:\textsuperscript{44}

- Oxycodone 10 mg + paracetamol 650 mg (NNT = 2.6, 95% CI [2.0, 3.0]).\textsuperscript{46}
- Paracetamol 1,000 mg + codeine 60 mg (NNT = 2.2, CI [1.7, 2.9]).\textsuperscript{46}
- Paracetamol 1,000 mg + ibuprofen 400 mg (NNT = 1.5, CI [1.4, 1.7]).\textsuperscript{50}

1.4.3 Patient satisfaction

Hospital administrators and clinicians seek to improve patient satisfaction with pain management for various reasons, including ED reputation, therapeutic compliance and reduced litigation. To be useful in the ED, acupuncture as both as an adjunct and a standalone analgesic would need to improve patient satisfaction. Patients should be willing to use the modality again and have a high likelihood of recommending it. This may be measured using a simple parametric scale (e.g. a
A current weakness of SAC in the ED setting (including the use of opioids) is that it is not associated with patient satisfaction. This is evidenced by the following:

- Opioids are not associated with patient satisfaction in the ED,\textsuperscript{16,52,53} which may be related to their short-term adverse effects or lack of care in their delivery.
- To improve their reputation and attract more patients, private EDs aim to increase patient satisfaction. However, a further benefit for both public and private EDs is that patient satisfaction is associated with improved compliance and less litigation against doctors and staff.\textsuperscript{15,54,55}
- Patient satisfaction is associated less with the timeliness of analgesia than with attention, care and personal factors (compassion).\textsuperscript{56,57}

1.4.4 Adverse effects

Acupuncture needs have lower mortality rates and significant adverse effects (those requiring treatment) than SAC to find a role in the ED. The importance and interpretation of minor side effects (those that are transient and require no treatment) are debated in Chapter 7. Adverse effects are divided into three categories (mortality, significant and minor) for comparison with SAC and ranking of outcomes.

The adverse effects of acupuncture can be quantitatively compared with those of standard modalities in terms of incidence risk or relative risk (see Chapters 2 and 7). In this case, the number needed to harm (NNH) can be calculated. Similar in principle to NNT, NNH is the number of patients needed for a specified adverse effect or mortality to occur. In this thesis, both incidence and relative risks are used.

While not pre-empting the findings of this thesis, it is likely that acupuncture has superiority over SAC. As mentioned above, opioids, NSAIDs, steroid injections and pain procedures carry a significant risk of adverse effects, including death. The following subsections summarise the adverse effects of SAC.
1.4.4.1 Paracetamol

Adverse effects are rare when the dosage regime is strictly followed but are frequently seen in accidental or intentional overdose. Paracetamol is the most common cause of liver transplantation.\textsuperscript{34}

1.4.4.2 Non-steroidal anti-inflammatory drugs

NSAIDs must be used with caution in elderly patients and are contraindicated in patients with certain comorbidities, including renal impairment, a history of gastrointestinal bleeding, gastro-oesophageal reflux disease, established cardiovascular disease and NSAID allergy.\textsuperscript{58} NSAIDs are the cause of 23\% of adverse drug events presenting to the ED.\textsuperscript{59}

1.4.4.3 Opioids

Opioids are the major concern of SAC and have many short-, medium- and long-term adverse effects (see Figure 1.5):

- Opioids have a high rate of adverse short-term effects. The short-term administration of opioids has a 77\% adverse effect rate.\textsuperscript{60}
- Opioid administration/prescription for recurrent painful conditions (e.g. recurring non-catastrophic headache, osteoarthritis or low back and neck pain) leads to a high dependency rate,\textsuperscript{10} particularly in patients with a specific psychological profile of being at risk of opioid addiction.\textsuperscript{61,62}
- Opioids administered in the ED and take-home supplies or prescriptions are related to recurrent usage (12\%) and dependence (3\%).\textsuperscript{8,9,63} Patients receiving prescriptions for ongoing non-cancer pain have an abuse rate of 21\%, an opioid use disorder rate of 8–12\%,\textsuperscript{64} and an approximate mortality per prescription of one in 7,770.\textsuperscript{65}
- ED healthcare workers avoid administering opioid analgesia because of campaigns to curtail the opioid crisis.\textsuperscript{67}
- Atypical opioids (e.g. tramadol, tapentadol and buprenorphine) may appear to be a simple short-term solution to avoid the prescription of oxycodone. However, rates of abuse, dependence, death and quality of life outcomes should be accurately determined.\textsuperscript{68} Tramadol was initially perceived as a safe weaker opioid but is now being used less frequently because of its adverse effects and drug interactions.\textsuperscript{69} Buprenorphine has significant abuse, dependence and mortality rates.\textsuperscript{70,71} Tapentadol has little research
beyond pharmaceutical company–sponsored information, and emergency physicians remain sceptical. The benefits of acupuncture as an adjunct may be found in clinical circumstances that involve considerable risks such as when procedural interventions (e.g. joint/epidural steroid injections, joint replacement, spinal surgery) must be delayed or are contraindicated (e.g. in elderly or obese patients or those with multiple comorbidities) and opioids/NSAIDs must be avoided.\textsuperscript{73–75}

1.4.5 Opioid sparing

Given the considerable adverse effects of opioids, analgesic modalities that spare opioid use are regarded favourably. Opioid sparing can be measured using an RCT in which opioids are provided as adjunctive or rescue analgesia. Outcome measures may be binary (yes/no) (e.g. ‘opioids administered in ED’ or ‘opioid take-home prescription’). Quantitative measures include total dosage in milligrams (usually morphine dose equivalent) or opioid-free days (or alternate time intervals). Although rarely used, NNT may also be applied to this outcome measure as the number of patients needed to treat to reduce opioid use by 30\% or 50\%.

Opioid-sparing ability is desirable because of the high rates of short-, medium- and long-term adverse effects of opioids, including mortality. The administration and prescription of opioids for patients at risk in the ED may lead to recurrent usage. Moreover, complying with the scheduling requirements for drugs of addiction is time consuming, meaning that some ED staff avoid administering opioids. Opioid use includes administration in the ED, take-home supplies, prescriptions and post-discharge consumption. For acupuncture to be a solution to the ED component of the opioid crisis, it would need to lead to a reduction in at least one of these uses.

1.4.6 Time

ED clinicians and nurses are time constrained, contributing to inadequate pain management. The term ‘oligoanalgesia’ was introduced two decades ago, prior to the implementation of the opioid analgesic campaign, to help ED staff focus on pain management.\textsuperscript{76} Oligoanalgesia exists because of the lack of time and resources for ED healthcare workers.\textsuperscript{76} The economic and time burdens involved in scheduled analgesic drug administration and post-administration observations are significant.\textsuperscript{77}

The administration time of acupuncture refers to the time taken by the healthcare worker to insert acupuncture needles but excludes post-application needle retention time, which usually
precludes other ED observations or interventions in the case of body acupuncture. For acupuncture to find a role, it would need to have minimal administration time, no effect on patient length of stay or lead to time savings by other means (e.g. by employing a dedicated registered acupuncturist).

1.4.7 Cost

Healthcare economics is a vital determinant of pain management practices. Healthcare costs, including the price of medications, are rising in EDs. While not necessarily costly in the ED itself, opioids are associated with considerable community costs in rehabilitation, overall health care and criminal or legal expenses.

For acupuncture to find a role in the ED analgesic armamentarium, it would ideally result in cost savings, either in the short or long term, for the ED and community. In studies, acupuncture costs could be measured by the price of needles for the intervention group minus the price of spared SAC analgesics. Alternatively, more complex calculations could be incorporated, such as the money saved by avoiding opioid dependence and its associated healthcare, legal and criminal costs. For acupuncture to find a role, cost savings at some level would promote its introduction.

1.4.8 Training

Pain management encompasses a variety of modalities, all of which require skills to administer. ED clinicians need additional pain management training for the safe use of opioids and other pain-reducing modalities. Although ‘opioid-lite’ EDs are emerging throughout the US, ED staff require further resources and training in alternative techniques.

For acupuncture to find a role, emergency clinicians would need at least basic training to ensure competency and safety. Alternatively, a qualified acupuncturist may be employed in the ED. RCTs that stipulate investigator training (basic trained non-acupuncturists versus registered acupuncturists) in the acupuncture intervention group provides some data on this outcome. Ideally, RCTs having two arms, i.e. investigators with basic acupuncture training versus those with formal acupuncture training, where outcomes on pain reduction and adverse effects could be compared. Further data may be obtained from ED acupuncture educators’ experiences.

Figures 1.4 and 1.5 highlight the weaknesses of the current ED analgesic armamentarium and the performance of opioids, respectively, compared with the ideal analgesic based on the outcomes explored in this thesis.
<table>
<thead>
<tr>
<th>ED Analgesic weaknesses that acupuncture might address?</th>
<th>Outcomes to assess acupuncture?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is acupuncture effective as a stand-alone as an alternative to opioids or NSAIDs in at risk patients or those refusing analgesic medications?</td>
<td>Stand-alone analgesic</td>
</tr>
<tr>
<td></td>
<td>Rapid onset, durable, wide range pain types &amp; patient populations</td>
</tr>
<tr>
<td>Is acupuncture effective as an adjunct analgesic for: patients who present following failed oral analgesia or to delay/avoid steroid injections, pain procedures or surgery in patients at risk of adverse effects to these interventions?</td>
<td>Analgesic adjunct</td>
</tr>
<tr>
<td></td>
<td>Improves pain relief above other analgesics</td>
</tr>
<tr>
<td>Patient satisfaction is not associated with analgesic medications including opioids and improved satisfaction leads to better patient compliance and reduced litigation.</td>
<td>Patient satisfaction</td>
</tr>
<tr>
<td></td>
<td>Patients satisfaction has no relationship to analgesic medicines, opioids nor timeliness</td>
</tr>
<tr>
<td>Opioids, NSAIDs, steroid injections, pain procedures are modalities with definitive risks of adverse effects</td>
<td>Adverse effects</td>
</tr>
<tr>
<td></td>
<td>Current ED armamentarium has both short and long term adverse effects from opioids and NSAIDs</td>
</tr>
<tr>
<td>Opioids have high rates of early, medium and long term adverse effects including mortality. ED administration and scripts along with patients at risk, leads to recurrent usage. Schedule administration time is consuming. Some ED staff avoid administering opioids for above reasons.</td>
<td>Opioid sparing</td>
</tr>
<tr>
<td></td>
<td>EDs contribute to the opioid crisis</td>
</tr>
<tr>
<td>ED clinicians are time constrained, which contributes to poor pain management.</td>
<td>Time</td>
</tr>
<tr>
<td></td>
<td>ED clinicians and nurses are time poor and this contributes to less than ideal pain management</td>
</tr>
<tr>
<td>Health care costs are rising in EDs. Opioids while not necessarily costly in the ED have huge costs in the community later for rehabilitation, overall health care and legal costs.</td>
<td>Cost</td>
</tr>
<tr>
<td></td>
<td>ED analgesia while inexpensive in short term likely has long term costs on the community</td>
</tr>
<tr>
<td>ED clinicians require more training on pain management for safer opioid usage and other pain reducing modalities.</td>
<td>Training</td>
</tr>
<tr>
<td></td>
<td>ED clinicians require more training on opioids and other opioid sparing analgesic modalities</td>
</tr>
</tbody>
</table>

**Figure 1.4: Weaknesses of current ED analgesia compared with the ideal analgesic.**

Note: ED: emergency department; NSAIDs: non-steroidal anti-inflammatory drugs; green = performs well, orange = mix of positive and negative performance, red = performs poorly.
Figure 1.5: Performance of opioid analgesia compared with the ideal analgesic.

Note: Green = similar to the ideal analgesic; orange = mix of positive and negative performance; red = performs poorly.

1.5 Thesis Objective

The objective of this thesis is to determine whether acupuncture has a potential role as an analgesic in the ED and, if so, its indications and how it should be applied. To have a role, it must reduce pain at some level both in the short and long term. As mentioned above, acupuncture does not necessarily need to be superior to pharmaceutical analgesics in reducing pain (the primary outcome). If acupuncture were equipotent but had other advantages such as reduced adverse effects, improved patient satisfaction, reduced administration time or cost and teachability (secondary outcomes), it could find a role. Primary and secondary outcome results would then play a role in determining the clinical indications for acupuncture in the ED.
1.6 Methodology

Thus far, the current weaknesses of SAC that may be addressed through acupuncture use have been defined according to the ideal analgesic framework. Similarly, acupuncture has been defined according to the same criteria. This thesis collates the results of my independent research, including two systematic reviews/meta-analyses, a patient survey with an audit, an RCT and the teaching of ED acupuncture with feedback from participants and faculty.

Findings from the literature have also been collected to enable a meaningful conclusion on specified outcomes. The collected evidence was collated and synthesised, and the outcomes for acupuncture described. The evidence informing this thesis has been ranked using the hierarchy stipulated by the Australian Government’s National Health and Medical Research Council (NHMRC):\[^{82}\]

- I Systematic reviews of RCTs
- II RCT
- III Uncontrolled observation study
- IV Prospective questionnaire or audit
- V Expert opinion

Studies are further ranked within levels. For example, within Level I, systematic reviews and meta-analyses with high-quality RCTs, low heterogeneity, statistically significant findings and consistent findings among at least 75% of included RCTs\[^{83}\] are ranked higher.

Secondary outcomes are not mentioned in this hierarchy because of the variation in the strength of evidence that they provide. Furthermore, there is a paucity of literature on this topic. While it may be argued that secondary outcomes are hypothesis-generating only, if a trial is randomised and the predetermined secondary outcomes are closely powered to the primary outcome, then evidence may be considered Level II or III, with caveats. Findings on secondary outcomes are considered more reliable if they are consistent across many RCTs or studies are appropriately powered to measure the secondary outcome. The interpretation of secondary outcomes was important for this thesis because they comprised many of the outcomes investigated. Given the uncertainty of the grading of secondary outcomes, these have been noted so that the reader can follow the interpretation.
Confidence in results was evaluated using the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) approach (see Figure 1.6).  

![GRADE approach diagram](image)

**Figure 1.6: GRADE approach.**

GRADE (Grading of Recommendations, Assessment, Development and Evaluation) ranking depends mainly on the level of evidence but can be upgraded or downgraded (denoted by the arrows) according to quality, directness of assessment and consistency with similar research.

While confidence in results was largely determined by the level of evidence, it was upgraded or downgraded according to factors such as quality, directness of the assessment and consistency of findings. The weaknesses of SAC were aligned with the characteristics of the ideal analgesic, which became the outcomes of the acupuncture investigation. The investigation comprised the findings from my research and those from the extant literature, which were graded and collated to define the characteristics of each outcome and how they compared with the ideal analgesic or a specific analgesic used in the ED (see Figure 1.7).
Figure 1.7: Methodology.

Pictorial summary of the initial methodology of this thesis. Problems in standard analgesia care (SAC) are matched against the ideal analgesic, and in turn, become the outcomes for acupuncture investigation. The investigation includes both my original research and a literature review. The findings are then appraised using the GRADE approach and collated for each outcome, and compared with the ideal analgesic or a specific analgesic used in the ED. Note: SAC: standard analgesia care; ED: emergency department; GRADE: Grading of Recommendations, Assessment, Development and Evaluations; RCT: randomised controlled trial.

Once all findings were collated, they were ranked in order of importance using GRADE to enable a comparison relevant to the ED case mix and environment. Table 1.2 shows the planned and transparent decision-making process used to ascertain the role of acupuncture in the ED. Each outcome was ranked according to the quality of evidence and the strength of the recommendation. Outcomes were then benchmarked against either the ideal analgesic or analgesics in the ED armamentarium. This table is populated in Chapter 7.

Following this ranking, a clinical recommendation on the role of acupuncture in ED clinical practice was determined. More details on this hierarchy and its application are provided in the final chapter.
Acupuncture decision making info-graphic highlighting the planned, transparent decision-making process of this thesis to ascertain the role of acupuncture in the ED. This table is populated in the concluding chapter.

**Thesis Structure**

Each chapter of this thesis begins with a quotation to help engage the reader in the chapter topic. The first page of each chapter also includes key points of ‘what is already known on the topic’ and ‘what this research adds’, using the *British Medical Journal* format. Although they are not used in the traditional way, forewords and afterwords are provided to establish the overarching narrative of this thesis and explain the links between chapters. These sections avoid reiterating material included in the publication and utilise the same citations. No new citations will be introduced to avoid a supplementary bibliography. Forewords focus on what is already known or knowledge gaps that require elaboration and highlight anything special or unusual in the methodology. Afterwords discuss specific methods or findings that went well and those that were unexpected or disappointing. They also indicate the location of any supplementary publication material in the appendices and emphasise any pertinent links to other chapters. Note that the Appendix to Chapter 7 (Sections A-E) primarily fulfils the purpose of discussing each publication’s strengths and weaknesses.
1.7.1 Chapters

Chapter 1 discusses the background of SAC in the ED, including the potential weaknesses that may be addressed by acupuncture. It outlines the personal reasons for undertaking this thesis as well as the thesis objectives and methodology used to investigate the role of acupuncture in the ED. It finishes with a list of journal articles and conference presentations related to this thesis.

Chapter 2 presents the published study ‘Does acupuncture have a role in providing analgesia in the emergency setting? A systematic review and meta-analysis’. This chapter presents the findings and knowledge gaps in the global literature on the primary and secondary outcomes defined in Chapter 1 as well as the findings from a meta-analysis on the primary outcomes.

Chapter 3 presents the published study ‘Does ear acupuncture have a role for pain relief in the emergency setting? A systematic review and meta-analysis’. This study explored outcomes specifically related to ear acupuncture, which may be the acupuncture method best suited to the ED. A limited meta-analysis of the primary outcomes was performed. Information and knowledge gaps were obtained to inform teaching program (Chapter 5) and the RCT (Chapter 6).

Chapter 4 presents the published study ‘Patient attitudes towards analgesia and their openness to non-pharmacological methods such as acupuncture in the emergency department’. This study investigated the secondary outcomes of patient satisfaction and adverse effects of SAC. It also obtained preliminary data for the RCT (Chapter 6).

Chapter 5 presents the published study ‘Lessons learned in teaching battlefield (ear) acupuncture to emergency medicine clinicians’. This study investigated the secondary outcome of ED acupuncture training requirements.

Chapter 6 presents the published study ‘Battlefield acupuncture added no benefit as an adjunct analgesic in emergency department for abdominal, low back or limb trauma pain’. This study investigated one of the two primary outcomes of this thesis (i.e. the efficacy of acupuncture as an analgesic adjunct). It also explored several secondary outcomes and defined the remaining knowledge gaps in these outcomes.

Chapter 7 collates and synthesises the findings from the published studies and pertinent literature and makes recommendations on the role of acupuncture in the ED. Outcomes are ranked and graded according to the quality of evidence and strength of the determination. A conclusion on the role of acupuncture in the ED, along with future recommendations, are made.
1.7.2 Appendices

The appendices include materials directly and indirectly associated with the completion of this thesis as well as presentation slides, video links and handouts that contribute to knowledge on the topic. Abstracts have been included where possible. Where material has been presented in a previous conference, this information is not repeated. Any identifiable personal information has been deleted. Materials are arranged according to the relevant chapter:

- Front matter Appendix:
  A. Permissions to include co-authored papers and agreement of contributions.

- Chapter 2 Appendix:
  A. Supplementary publication material
  B. Copyright permissions
  C. Letter to the editor, *Medical Journal of Australia*, 2018
  D. Conference presentation: Australasian College for Emergency Medicine (ACEM) 2016 conference, Noosa Heads
  E. Poster presentation (with Emogene Aldridge): ACEM 2016 conference, New Zealand

- Chapter 3 Appendix:
  A. Supplementary publication material
  B. Copyright permissions
  C. Publicity: high-impact advertisement for systematic review

- Chapter 4 Appendix:
  A. Supplementary publication materials, ethics approval, patient advice and consent
  B. Copyright permissions
  C. Conference presentation: ICMART 2019, Gold Coast
Chapter 5 Appendix:

A. Copies of workshop materials: lectures, take-home manual, feedback results
B. Copyright permissions
C. Conference presentation: ACEM 2019, Hobart
D. Letter to the editor on a recent battlefield acupuncture (BFA) meta-analysis.

Chapter 6 Appendix:

A. Preregistered protocol, supplementary publication materials, trial website, ethics approval, patient advice sheet, patient consent, trial flyer, BFA competency test
B. Copyright permissions
C. Trial teaching materials and videos
D. Publicity: several articles

Chapter 7 Appendix:

Strengths and weaknesses of the following publications:

A. Does acupuncture have a role in providing analgesia in the emergency setting? A systematic review and meta-analysis.
B. Does ear acupuncture have a role for pain relief in the emergency setting? A systematic review and meta-analysis.
C. Patient attitudes towards analgesia and their openness to non-pharmacological methods such as acupuncture in the emergency department’.
D. Lessons learned in teaching battlefield (ear) acupuncture to emergency medicine clinicians.
E. Battlefield acupuncture added no benefit as an adjunct analgesic in emergency department for abdominal, low back or limb trauma pain.

Presentation:

1.8 Articles, Conference Presentations and Abstracts Related to This Thesis

1.8.1 Journal publications


1.8.2 Conference presentations (including published abstracts)


- Jan A. Acupuncture: here’s the point. Paper presented at: ACEM Spring Symposium; 2016 Sep 13; Noosa Heads, Australia.

- Aldridge ES (presenter), Jan AL, Rogers IR, Visser E, Bulsara M. Is there a point? The role of acupuncture for acute pain in the emergency department: a systematic review and meta-analysis. Poster presented at: 33rd Annual Scientific Meeting of ACEM; 2016 Nov 20; Queenstown, New Zealand.


• Jan A, Ben-Meir M, Russell I, Yuen A. ED acupuncture for emergency physicians. Half-day practical/half-day online workshop presented at: ACEM National 35th Annual Scientific Meeting; 2018 Nov 17; Perth, Australia.

• Jan A. Role of acupuncture for pain in the ED or emergency setting—ready to go? Presented at: AMAC Annual General Meeting and Seminar; 2019 Aug 10; Perth, Australia.


• Jan A. Patient attitudes to acupuncture and non-pharmacological analgesia in the ED. Paper presented at: International Congress of Medical Acupuncture and Associated Therapies; 2019 Oct 27; Gold Coast, Australia.

• Jan A. Patient attitudes to acupuncture and non-pharmacological analgesia in the ED. Paper presented at: National 36th Emergency Medicine Annual Scientific Meeting; 2019 Nov 18; Hobart, Australia.


• Jan AL, Aldridge ES, Rogers IR, Visser EJ, Bulsara MK, Hince DA, Suen LK and Woosey MV. Battlefield acupuncture as an adjunct to treat pain of the abdomen, limb trauma and low back pain in the emergency department—a randomised controlled study. Paper presented via teleconference at: Western Australia St John of God Health Care Research and Ethics; 2020 Mar 26; Perth, Australia.

Chapter 1 References


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Chapter 2: Does Acupuncture Have a Role in Providing Analgesia in the Emergency Setting? A Systematic Review and Meta-analysis

We found that stationing an acupuncturist in the ED and streamlining his services into the workflow and referral processes of ED care providers was acceptable to ED providers and patients.

—Adam Reinstein, acupuncturist, 2017

What is already known on the topic

- A systematic review in 2013 identified only two randomised trials, thus could not draw any conclusions on the role of emergency department (ED) acupuncture.
- Acupuncture analgesia is used frequently in the outpatient setting and perioperatively.

What this research adds

- This research provides Level 1 evidence for acupuncture compared with sham acupuncture or standard analgesia care in the ED setting.
- There is limited evidence for acupuncture as an adjunct; thus, further research is required.
- Acupuncture provides effective analgesia for a range of painful conditions presenting to the ED.
- Acupuncture is a patient-satisfying modality.
- Included trials suggest that ED acupuncture has a low risk of adverse effects.
- Licensed acupuncturists delivered body acupuncture in ED trials.
- Ear acupuncture appeared effective and was applied by non-acupuncturists but warrants further research.
- There were mixed results on the analgesia-sparing ability of ED acupuncture. Further research is required on the opioid-sparing ability of acupuncture.

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2.1 Foreword

As mentioned in Chapter 1, each foreword elaborates on what is already known or knowledge gaps and provides links between chapters. Rather than simply summarising the approach to assessing outcomes, the foreword highlights what was done differently in the methodology. The forewords and afterwords utilise the same citations as the publications and do not introduce new references.

2.1.1 What is already known or knowledge gaps that require elaboration

Prior to this thesis, the entire topic of ED acupuncture was a knowledge gap in the literature. A 2013 systematic review by Kim et al.\textsuperscript{12} identified only two RCTs from 2006 and 2007 and two uncontrolled observational studies from 2001 and 2011. The 2001 observational study was a US-based study conducted by Arnold et al.\textsuperscript{49} and, commendably, was the first study on acupuncture in the ED. Interestingly, the first RCT on acupuncture in the ED, conducted by Goertz et al.,\textsuperscript{37} was also a US-based study, which found that modified BFA reduced pain. The second RCT, by Harkin et al.,\textsuperscript{35} took place in an Australian ED using traditional body acupuncture and also showed pain reduction with improved patient satisfaction.

Backed by evidence, acupuncture is used frequently in the general practice setting and is becoming more accepted for postoperative analgesia.\textsuperscript{7,11} Its absence of use in the ED is notable and raises the question of why this is so. This chapter hopes to answer aspects of this question and ascertain the primary and secondary outcomes outlined in Chapter 1.

2.1.2 What was done that was different?

A different approach was needed to successfully answer the thesis objectives and advance the research of Kim et al.\textsuperscript{12} A larger number of RCTs was required for this review, an objective that could be met by including foreign language publications and studies on acutely painful conditions typically treated but not necessarily tested in an ED. Many EDs around the world act as a triage, rapidly allocating patients to specialty areas.\textsuperscript{25,26} In prehospital care, the same painful conditions are treated and in a similar time frame as those in EDs.\textsuperscript{29–31} Individuals with acutely painful conditions such as a sore throat, which is more suited to general practice, commonly present to the ED.\textsuperscript{38} The only proviso to include studies in the meta-analysis was that patients had to align with the ED time sequence (i.e. have a one-off treatment and have pain scores measured within 4 hours of the acupuncture intervention).
More information than the effectiveness of acupuncture compared with placebo or SAC is required to address the objectives of this thesis. Patients frequently present to the ED following failed oral analgesia and many need further pain relief following initial analgesia. Thus, it is paramount to differentiate between standalone and adjunctive therapy. Therefore, an improvement on prior systematic reviews was required. We aimed to analyse studies according to their design (i.e. acupuncture v. sham acupuncture, acupuncture v. SAC and acupuncture as an adjunct v. SAC).

The broadening of inclusion criteria to include uncontrolled observational studies was also debated. Given the varied range of secondary outcomes and the lack of information obtained in the previous systematic review, uncontrolled observational studies were also included.
REVIEW ARTICLE

Review article: Does acupuncture have a role in providing analgesia in the emergency setting? A systematic review and meta-analysis

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Abstract

Acupuncture might offer a novel approach to improve ED pain management. Our primary aim was to assess the efficacy of acupuncture in the emergency setting while secondary objectives were to explore its suitability through its side-effect profile, patient satisfaction, cost, administration time and points used. Seven databases and Google Scholar were searched up to 31 July 2016 using MeSH descriptors for three overarching themes concerning acupuncture, pain management and emergency medicine. Meta-analysis was performed on randomised trials for three comparator groups: acupuncture versus sham, acupuncture versus standard analgesia care and acupuncture-as-an-adjunct to standard care, to calculate the standardised mean difference and weighted mean difference for pain scores over 10. Data for secondary outcomes was extracted from both randomised and observational studies. Nineteen randomised controlled trials and 11 uncontrolled observational studies totaling 3169 patients were retrieved after exclusions. Meta-analyses were performed on data from 14 randomised controlled trials representing 1210 patients. The three resulting comparator groups (as above) resulted in standardised mean differences of 1.08, 0.02 and 1.68, and weighted mean differences of 1.60, -0.04 and 2.84, respectively (all positive figures favour acupuncture). Where measured, acupuncture appears to be associated with improved patient satisfaction, lower cost and a low adverse effects profile. The data available were inadequate to ascertain the effect of acupuncture on analgesia use. Significant study bias was found, especially with respect to practitioner and patient blinding. We conclude that for some acute pain conditions in the ED, acupuncture was clinically effective compared to sham and non-inferior to conventional therapy. As an adjunct, limited data was found indicating superiority to standard analgesia care. Further studies will elucidate the most appropriate acupuncture training and techniques, use as an adjunct and the clinical situations in which they can be best applied.

Key findings

• Acupuncture appears to provide effective analgesia for some acute pain conditions in the ED.
• It is non-inferior to selected analgesia medications.
• There is insufficient evidence as yet to show that acupuncture reduces analgesic medication usage.
• The most appropriate techniques to use and the clinical situations in which to apply them, require further research.

Key words: acupuncture, emergency medicine, meta-analysis, pain management, systematic review.

Background

Pain is the primary reason for patients attending the ED in the Western world, with up to three quarters reporting pain. Despite this, pain is often poorly managed and undertreated. In the emergency setting, analgesia should ideally be evidence-based, safe, simple to administer, rapidly effective, titratable and cost-effective, with minimal adverse effects. In the ED, acute pain is often managed with opioids and NSAIDs. These have acknowledged adverse effects in both the short and long term.

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There is evidence to support the use of acupuncture to treat chronic pain disorders such as headaches and musculoskeletal pain.\textsuperscript{11} Acupuncture (specifically ear acupuncture) has shown one evidence from meta-analyses, reducing acute postoperative pain, opioid requirements and opioid adverse effects compared to controls.\textsuperscript{7} If effective, acupuncture could provide a useful alternative for pain management in the ED when pharmacological methods are contraindicated, or there are concerns about adverse drug effects. Currently in Australia, acupuncture is delivered occasionally in ED by doctors and nurses with varying levels of training, supervision and formal qualifications.

Kim et al. published a systematic review in 2013 on the role of acupuncture for acute pain in the emergency setting.\textsuperscript{2} Their review was diminished by a limited search strategy that did not include non-English language publications or prehospital settings, and excluded conditions frequently treated in the ED. Since 2013, further studies on the role of acupuncture for acute pain in the ED have been published. This, and a desire to perform a more thorough literature search, provided the impetus for our current review.

The primary aim of this systematic review and meta-analysis was to evaluate the effectiveness of acupuncture for acute pain management in the emergency setting. We assessed changes in acute pain scores with acupuncture as a stand-alone therapy or acupuncture-as-an-adjunct to other analgesia (AdjA), compared with standard analgesia care (SAC) or sham-acupuncture (sham). Secondarily, we evaluated acupuncture-associated impacts on analgesic medication use, patient satisfaction, adverse effects and health care costs. Further, we aimed to describe the technical aspects and acute pain conditions where acupuncture was applied.

**Methods**

**Search strategy**

We undertook a systematic review and meta-analysis in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement.\textsuperscript{13} Seven databases: AMED, CINAHL, EMBASE, PubMed, Science Direct, Scopus and the Cochrane Library of Systematic Reviews and Central, as well as Google Scholar were searched from database inception to 31 July 2016. Three overarching themes were explored using a Boolean search strategy: acupuncture, pain management and emergency medicine. We used various combinations of Medical Subject Heading (MeSH) terms and key words relevant to the intervention (acupuncture therapy, acupuncture, acupressure and electro acupuncture) in conjunction with MeSH terms and key words regarding pain management (acupuncture analgesia, pain management, pain, acute pain and analgesia), and the setting of interest (emergency treatment, emergency medicine, emergency medical services, emergency, pre-hospital, retrieval medicine, ED and acute care). In addition, references within included articles were hand-searched, as were proceedings of key scientific meetings. Finally, the Conference Papers Index was searched electronically. The study protocol was approved as part of the first author’s PhD proposal with the University of Notre Dame Australia, Fremantle.

**Inclusion and exclusion criteria**

Two reviewers (ALJ, ESA) independently screened studies for eligibility. Conflicts regarding inclusion or exclusion of studies were resolved by consensus. Both randomised control trials (RCTs) and uncontrolled observational studies (UOBS) were eligible for inclusion. RCTs were included in both the meta-analyses and systematic review, while UOBS were only included in the systematic review, specifically to inform some of the secondary outcome measures.

Studies where the effectiveness of acupuncture for acute pain could not be evaluated during the first 4 h after treatment or where inadequate data was provided were excluded from the meta-analysis but included in the systematic review. Both traditional and modern variants of acupuncture were included. Acute pain conditions were included if they involved prehospital, retrieval, ED care or conditions that are frequently treated in the ED. Excluded studies were those concerning: animals; perioperative pain; chronic pain; non-emergency medical conditions; techniques of cupping, massage and moxibustion; or where pain was not assessed during the first 24 h after treatment. No language restrictions were employed and relevant papers were translated into English as appropriate.

**Data extraction**

After initial abstract screening, all eligible papers were read in full by two authors (ALJ, ESA). Data was abstracted to a standard template, recording subjects, methods, interventions and outcomes. Study definitions of key terms are provided in Table S1. Where possible, this process followed Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines.\textsuperscript{14} Missing information was obtained by correspondence as the author, or derived from other sources within the paper.

**Primary outcome**

The primary outcome was the difference in standardised pain scores out of 10 (PS-10) between treatments in the three comparator groups: acupuncture versus sham, acupuncture versus SAC and AdjA versus SAC; presented as the standardised mean difference (SMD) and weighted mean difference (WMD).

Only pain scores recorded within 240 min of treatment were eligible for meta-analysis and different pain score modes (e.g. visual analogue scale or numerical rating scale) were converted to the PS-10 as a continuous variable. Where multiple pain scores were recorded, the score with adequate data closest to 60 min after treatment was used. In order to be included in the meta-analysis, mean and standard deviations (SD) were retrieved or calculated. The methods of Wan et al. were used to calculate mean change in PS-10 and SD from median, interquartiles and minimum maximum range data.\textsuperscript{15} If SDs were not provided, they were calculated from the pre-and-post PS-10 SD and correlation coefficient approximated.
to 0.5 as outlined in the Cochrane Handbook.\textsuperscript{36} Subgroup analyses were performed if there were sufficient data to identify variations in effect size and heterogeneity for various acute painful conditions, car versus body acupuncture, higher sample size, higher quality studies and varying sham techniques.

**Secondary outcomes**

Analgesia use was measured as: total dose, number of doses used or percentage of patients who took no analgesia, during the first 48 h after treatment. Patient satisfaction was measured as a numerical score (derived from continuous or Likert-scale data), or as the percentage of patients who said they 'would use this treatment again'. Adverse effects were divided into minor (no treatment) or significant (treatment required) and measured as the percentage of patients affected. The training of the acupuncturist and the points used for both intervention and sham were noted. If data was sufficient, relative risk meta-analyses were performed on satisfaction and adverse events. Time-based outcomes were measured as length-of-stay (min) in the ED, time taken to perform procedures (e.g. 'needling' time) (min) and the duration of filiform needle insertion (min). The cost of acupuncture consumables was expressed in US dollars (US$) per person.

**Risk of bias**

Risk of bias was assessed using the Cochrane risk of bias tool regarding the following items: sequence generation, allocation concealment, blinding (subject, practitioner and assessor all as separate categories), completeness of outcomes data (reporting dropout and withdrawal), selective reporting and any other potential forms of bias.\textsuperscript{16} The 'other' risk of bias item is a catch-all category for those factors that may influence effect size but not covered by the aforementioned categories and includes bias such as differences in participants, deviation from protocol and vested interest.\textsuperscript{16} A summary risk of bias placed studies into three groups: low (low risk of bias in all criteria), medium (high risk of bias in patient and practitioner blinding only) or high (risk of bias in multiple items).

**Data synthesis and statistical analysis**

Meta-analyses were performed using Stata software (14.1 StataCorp, College Station, TX, USA). Individual study data were pooled and weighted to give an overall SMD and WMD. Given the likely heterogeneous nature of studies to be incorporated into the meta-analyses, a random effects model was used. The magnitude of the effect size, that is, SMD of 0.2, 0.5 or 0.8 was categorised as small, medium and large, respectively.\textsuperscript{17} A WMD for PS-10 greater than 1.3 was regarded as clinically meaningful.\textsuperscript{18} Study heterogeneity (I\textsuperscript{2}) and statistical significance (P ≤ 0.05) were also calculated. An I\textsuperscript{2} of 50%-90% represents substantial heterogeneity.\textsuperscript{19} Studies with multiple sham or SAC controls were analysed and presented separately in forest plots.\textsuperscript{20,21}

**Results**

**Randomised controlled trials**

**Studies included (Tables S2, S3)**

Of 1440 studies, 30 were included in the systematic review and/or meta-analysis (Fig. 1). In total, 14 RCTs were included in the meta-analysis, and a further five RCTs and 11 UOBS in the systematic review. Three RCTs had inadequate data for meta-analysis,\textsuperscript{2,22-24} and two RCTs were excluded as they included sham and SAC in the control group.\textsuperscript{25,26} The most commonly studied conditions in the RCTs were: spinal pain (4), mixed pain conditions (3), limb fractures (3), migraine (3) and renal colic (3). The most frequent forms of acupuncture were traditional acupuncture (11) and ear acupuncture (5).

**Primary outcome**

Eight RCTs\textsuperscript{21,27-33} (nine arms) including 526 patients, compared the change in PS-10 for acupuncture versus sham with a SMD of 1.08 (95% CI = 0.62-1.54), I\textsuperscript{2} = 84.0% (Fig. 2) and WMD of 1.60 (CI = 0.98–2.23) (Fig. S1) both favouring acupuncture. Four RCTs\textsuperscript{20,34-36} (five arms) including 505 patients showed acupuncture was comparable to SAC with a SMD of 0.02 (CI = -0.48–0.51), I\textsuperscript{2} = 83.8% (Fig. 3) and WMD of -0.04 (CI = -0.89–0.82) (Fig. S2). Two RCTs\textsuperscript{17,20} including 154 patients showed AdJ was more effective than SAC (without sham) with a SMD of 1.68 (CI = 1.18–2.18), I\textsuperscript{2} = 39.9% (Fig. 4) and WMD of 2.84 (CI = 1.45-4.22) (Fig. S3). All positive scores favoured acupuncture.

**Subgroup analyses of primary outcome (Table S4)**

Subgroup analysis of medium-to-high quality RCTs comparing acupuncture versus sham\textsuperscript{21,27-31,33} found the SMD was large at 1.09 (CI = 0.58–1.60) and the WMD = 1.53 (CI = 0.87–2.19), while the I\textsuperscript{2} reduced to 43.1% only with the highest quality RCTs.\textsuperscript{29,31} Limiting the analysis to studies with sample sizes of 40 or above (which also corresponded to studies with penetrating acupuncture), reduced the I\textsuperscript{2} to 70.2% but the effect size became medium at 0.67 (CI = 0.31–1.03) and the WMD = 1.14 (CI = 0.58–1.70).\textsuperscript{21,27,28,32,33} Ear acupuncture (two RCTs) appeared to have better efficacy with SMD = 1.69 (CI = 0.37–3.01) compared to body acupuncture (SMD = 0.91, CI = 0.42–1.40).\textsuperscript{21,27,28,30,31} Of the conditions treated, fractures (which also corresponded to acupuncture only studies)\textsuperscript{29,31} had the largest effect size difference (SMD = 2.06, CI = 1.43–2.69) while being medium for back pain (SMD = 0.75, CI = 0.03–1.48) and migraine (SMD = 0.60, CI = 0.18–1.03).\textsuperscript{21,27} Isolating the distant sham points\textsuperscript{21,27,29-31} gave a large effect size (SMD = 1.26, CI = 0.63–1.89) while using the same acupoints (without penetration)\textsuperscript{28,32,33} reduced this to medium (SMD = 0.75, CI = 0.03–1.48). Examining renal colic in the acupuncture versus SAC comparator group (three arms) reduced the effect size (SMD = -0.21, CI = -0.86–0.43) and did not significantly change the I\textsuperscript{2} (79.6%).\textsuperscript{20,36}
Secondary outcomes

Analgesic medication usage

Of the four RCTs assessing analgesic medication usage, two reported a reduction in analgesic use at 24 and 48 h,20,28 while the other two found no difference.21,57

Patient satisfaction

Patient satisfaction was reported in five RCTs. Three prehospital acupuncture trials showed improvement compared to sham on a 100-point scale,29-33 one reported an improvement in satisfaction with Acupressure in both acupuncture and placebo groups over SAC alone,22 while another reported an improvement with acupuncture compared to SAC for 'those that would use this treatment again'.33

Adverse effects

Adverse effects were reported in 11 RCTs with an overall incidence of

34 out of 675 patients (5.04%) with seven being potentially significant (four faints and three needle breakages)21,34 (Table S3). The relative risk of adverse events (four RCTs, five arms, 545 patients) in the acupuncture versus SAC comparator group was 0.09 (CI = 0.05-0.17) (Fig. S4).

Acupuncture points and acupuncturist training

Acupuncture intervention varied from individualised to set prescriptions,34,55 and ranged from 2 to 14 points in number. Points used in more than one study were: SI3, LI4, GV 20, PC 6, TE 5, GB 34, GB 20, GB 40 ST 36, BL 21-24, BL 45-47, BL 60 and car points: Thalamus, Cingulate, Point zero and Shenmen. Many RCTs specified the use of deqi (creating a sensation of tingling, numbness or heaviness through movement of the acupuncture needle) (Table S2). Some RCTs used non-acupuncturists29-31,37,38 after training in a set prescription but most used trained acupuncturists.

Time and costs

The single study measuring length-of-stay with acupuncture versus SAC showed no difference.55 Time taken to administer acupuncture was less than 6 min in three RCTs. The duration of standard filiform needle insertion was between 15 and 30 min in seven RCTs.21,23,24,26,32-34 Three RCTs23,37,38 quoted costs of acupuncture consumables as less than US$5.00 per patient, while three RCTs21,30,31 simply stated that acupuncture is a 'low cost treatment'.

Bias and heterogeneity

Significant potential bias was found, especially with respect to patient and practitioner blinding (Fig. S5, Table S5). The heterogeneity measures (I^2) for the three forest plots (Figs 2-4) ranged from 56.4% to 86.2%.

Observational studies (Table S6)

UOBS included 1402 patients and studied mixed pain conditions
Recent systematic review by Kim et al.²³ Our analysis determined that acupuncture, as measured by three aspects, provided statistically significant¹⁷ clinically meaningful¹⁸ and improved levels of patient satisfaction¹⁰⁻¹¹ with respect to pain relief in the emergency setting.

Effectiveness of acupuncture across the three study groups

In the combined eight RCTs in the acupuncture versus sham group, we found significant statistical evidence superior to sham and a WMD (PS-10) above the clinical meaningful threshold of 1.3¹⁰ Some caution is required in extrapolating this result to all acute painful conditions as this first meta-analysis was confined to three major groups of conditions, namely back pain, fractures (including wounds and contusions) and migraines. When patient satisfaction was reported as a secondary outcome against sham, it favoured acupuncture but there was insufficient data for meta-analysis.²⁹⁻³¹ The use of sham in acupuncture RCTs is controversial with some arguing against using it as a control, reasoning that acupuncture is better studied against SAC.²⁵ In our subgroup analyses, stimulating the same point with sham resulted in a smaller effect size that is consistent with other researchers claiming sham has a clinical effect.²⁵,³²,³³

Acupuncture was found to be comparable (non-inferior) to SAC for both the SMD and WMD pain outcomes, and when measured (one study) in this comparator group, patient satisfaction favoured acupuncture.²⁵ The SAC provided varied between RCTs but used typical analgesics common in ED practice for the specified condition such as paracetamol,¹⁰ NSAIDs,¹⁰ and morphine¹⁴ in clinically appropriate dose ranges. However, one study used noramidopyrine and camylolfin⁶⁰ – an analgesic and antispasmodic combination not used in Australia. The results from the acupuncture versus sham or SAC suggest that acupuncture may be a suitable alternative when the concerns for analgesic drug side effects are high, are contraindicated or were previously ineffective.
AdJα compared to SAC provided superior analgesia (SMD and WMD) but the strength of this conclusion is guarded, as it is derived from only two RCTs. Pending substantiation by further research, AdJα might offer a way to reduce adverse pharmacological effects related to opioids and NSAIDs by reducing dosage or usage. There were no patient satisfaction outcomes in this adjunct group.

**Study quality**

In general, interpretation of acupuncture RCTs presents unique challenges in relation to patient and practitioner blinding, sham effects and other frequent flaws in methodology. The quality of the RCTs included in this meta-analysis was highly variable. Some researchers achieved practitioner and patient blinding, but most did not; while others had flaws in randomisation and assessor blinding. All three comparator groups in the meta-analysis showed substantial heterogeneity as expected. This could be explained by variations in patient demographics, sample size, time intervals, acupuncture point choice (body versus ear), drug comparator variation (type, dose and frequency) and pain conditions treated. The variable quality of RCTs and heterogeneity necessarily limits conclusions that can be drawn from this meta-analysis.

**Adverse effects**

A notable feature of this review is the low significant adverse effects (requiring intervention) profile of acupuncture compared to SAC with a rate of approximately 1% in the RCTs and none reported in the UOBS. A review of larger observational studies quotes significant side-effect rates as 0.02%–2.20%, which is consistent with our review. This is reinforced by the low relative risk of 0.09 for all adverse events in acupuncture versus SAC pharmacological therapy in our meta-analysis. This low risk should be interpreted in the light of inconsistencies in reporting of minor adverse events for both acupuncture and pharmacological arms.

**Conditions treated**

In both the RCTs and UOBS, acupuncture was used across a spectrum of acutely painful conditions in adults and children, including migraine, limb and rib fractures and acute abdominal pain (including renal colic). All of these are directly relevant to the emergency setting and are beyond the usual conditions where acupuncture is used in the non-emergency out-patient setting. Interestingly, subgroup analyses showed the largest effect size for fractures while being medium for back pain and migraines.

**Acupuncturist training, technique and utilisation**

Practitioners in both the RCTs and UOBS varied from non-acupuncturists trained in simple prescriptions with a small number points such as ear acupuncture to more individualised prescriptions delivered by emergency physicians with extra acupuncture qualifications or traditional Chinese medicine practitioners. Body acupuncture may delay usual ED care up to 30 min. Our subgroup analyses showed better efficacy for car over body acupuncture and acetabarone over penetrating acupuncture. It is yet to be shown whether longer acupuncture training significantly improves pain-related outcomes or reduces the incidence of adverse effects, though intuitively it seems likely.

**Future research**

In this review, we utilised three measures of acupuncture effectiveness as an analgesic technique. Future RCTs might look at other measures such as the number needed to treat for 30% to 50% pain reduction or "adequate analgesia" that has a better correlation to patient satisfaction (defined as triage IS-10 reduction by ≥2 and to a level <4). More RCTs are required where AdJα is compared to SAC and should include reduction of analgesia medication as a secondary outcome measure. Further investigation is warranted into other painful conditions with acupuncture versus SAC, ear versus body acupuncture and specifically that delivered by usual ED health providers compared with qualified acupuncturists. Both better and consistent adverse events reporting is also required.

**Conclusion**

Acupuncture appears to provide effective analgesia for some acute pain conditions in the ED, while being non-inferior to selected analgesic medications. Acupuncture has limited evidence suggesting it is an effective adjunctive analgesia technique when added to analgesic medications in the emergency setting. Acupuncture shows promise as a low cost, low risk and patient satisfying therapy with only limited minor adverse effects, but its effectiveness in reducing analgesic medication use is uncertain. Further studies will elucidate the most appropriate acupuncture training and techniques, its role as an analgesia adjunct and the clinical situations in which it can be best applied.

**Limitations**

While many non-English language publications were able to be included in the study, difficulties were encountered with accurate translation of key scientific terms. This trial and its outcomes were not pre-registered on a systematic review database. While grouping the meta-analyses into these three groups has advantages because of similarities in trial design, it may be that it assumes incorrectly that various forms of acupuncture are similarly effective across a range of painful conditions. A random effects model was used as it was assumed that the studies were not homogeneous. Substantial heterogeneity existed for the three comparator groups. While subgroup analyses have been performed in this review, researchers caution over-reliance on them in terms of evidence for or against an intervention.

**Acknowledgements**

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University of Notre Dame Australia, Fremantle and St John of God Hospital Murdoch.

Author contributions
AIJ, ESA, IRR, EJV, MKB and RCN conceived the study, designed the search and did the data collection. AIJ and ESA undertook data collection and analysis. All authors contributed to the review and revision of the manuscript, and all take responsibility for the final version.

Competing interests
The opinions and assertions contained herein are the private views of RCN and are not to be construed as official or as reflecting the views of the USA Force Medical Corps, the Air Force at large or the Department of Defense.

References


Supporting information

Additional supporting information may be found in the online version of this article at the publisher’s web site:

Figure S1. Forest plot of acupuncture versus sham with calculated weighted mean difference for pain score difference (on a PS-10).

Figure S2. Forest plot of acupuncture versus standard analgesia care with calculated weighted mean difference for pain score difference (on a PS-10).

Figure S3. Forest plot of acupuncture as adjunct versus standard analgesia care with calculated weighted mean difference for pain score difference (on a PS-10).

Figure S4. Forest plot of relative risk of adverse events for acupuncture versus standard analgesia care.

Figure S5. Cochrane bias assessment of studies included in meta-analysis expressed as a percentage of included studies.

Table S1. Study definitions: key terms for this systematic review.

Table S2. Methods characteristics of RCT acupuncture studies on pain management in the emergency setting.

Table S3. Results of RCT acupuncture studies on pain management in the emergency setting.

Table S4. Subgroup analyses of the RCTs comparator groups acupuncture versus sham and standard analgesia care.

Table S5. RCT studies and bias according to the Cochrane assessment tool (H = high, U = unclear, L = low).

Table S6. Methods and results of observational acupuncture studies on pain management in the emergency setting.
2.2 Afterword

As mentioned in Chapter 1, the afterword focuses on aspects of what went well and what was disappointing or unexpected in both the methods and findings. A complete description of the publications' strengths and weaknesses belonging to this thesis is provided in Chapter 7 Appendix. The afterword indicates whether there are any supplementary publication materials and their location in the appendices. It also emphasises any pertinent links to other chapters of this thesis.

Supplementary materials for the publication presented in this chapter can be found in Chapter 2 Appendix, Section A.

2.2.1 What went well?

2.2.1.1 Methodology

Database searches were successful in obtaining papers written in Chinese, Russian, Spanish and English. Broadening the inclusion criteria meant that there were sufficient studies for a meta-analysis, thus obtaining a meaningful result overall. Our success in obtaining an adequate sample of studies was an improvement not only on the 2013 review by Kim et al.12 but also two further concurrent systematic reviews by Lam and Chia et al., respectively (see Chapter 7 Appendix, Section A ref. nos. 1,12). We were successful in translating foreign papers and contacting the authors to include missing data. The carefully selected research team provided expert advice on trial methodology, outcome assessment, statistical analysis and ED applicability.

2.2.1.2 Findings

It was reassuring that the findings of the review were consistent with a subsequent high-quality study on ED acupuncture. Our results were similar to those of Cohen et al. in terms of the effectiveness of acupuncture as a standalone treatment but its uncertainty as an adjunct analgesic (see our letter to the editor in Chapter 2 Appendix, Section C and Chapter 7 Appendix, Section A ref. no. 51).

The inclusion of eight uncontrolled observational studies provided additional crucial information on secondary outcomes, including cost, patient satisfaction, adverse effects, forms of acupuncture, training used and an expanded list of conditions to which acupuncture may be applied (e.g. dental pain and appendicitis).44,48.
The surprisingly positive findings on ear acupuncture warranted further investigation. Subgroup analyses showed improved pain score reduction compared with body acupuncture. Ear acupuncture may be more appropriate to teach to ED clinicians as a fundamental skill. It was mostly performed by non-acupuncturists and had more applicability to the unique ED environment. The research on ear acupuncture warranted a further review of the literature and, pending that result, completion of an RCT (see Chapters 3 and 6).

The success of the publication was reinforced by its results being embedded in the global literature (see Chapter 7 Appendix, Section A).

2.2.2 What was unexpected or disappointing?

2.2.2.1 Methodology

The process of study selection, exclusion and quality assessment by two of the co-authors was time and labour intensive. New software (e.g. Covidence, a not-for-profit platform located in Melbourne, Australia) is available for future researchers to improve quality and reduce time and labour.

In retrospect, registration with PROSPERO, an international prospective register of systematic reviews, would have assisted with the publication itself and researchers worldwide. Pretrial submission of the protocol would have helped satisfy the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria and reassure the research community that no post-hoc methodological changes were made. Reader comprehension could have been facilitated by using the formal PICO (problem/patient/population, intervention, comparator, outcomes) format. We conducted post-hoc sensitivity analyses, which would have been better to include in the protocol. Although funnel plots were not planned, they would not have been useful because there were fewer than 10 studies in each meta-analysis. Although the published review scored highly on the AMSTAR 2 (A Measurement Tool to Assess Systematic Reviews) checklist (see Chapter 7 Appendix, Section A), it would have been better to avoid some minor methodological steps by first cross-checking with the protocol.

2.2.2.2 Findings

It was disappointing that there were only two studies on acupuncture as an adjunctive analgesic for the meta-analyses. It is worth emphasising that three RCTs have found acupuncture to be an effective adjunctive analgesic for migraines and back and neck pain,22,25,26 but these were
excluded because they did not meet the inclusion criteria. There were five uncontrolled observational studies in which acupuncture was used as an adjunct, with improved postintervention pain scores (for a range of painful conditions).\textsuperscript{39-42,46} The three RCTs not included in the meta-analysis and five observational studies offer encouragement for further research in this adjunct category. The initial postulate was that the most appropriate use of acupuncture in the current ED analgesia armamentarium would be as an adjunct to SAC. Nevertheless, the lack of certainty with respect to this outcome warrants further research (see Chapter 6) and a review of the external literature (see Chapter 7).

Given the variations in reporting and interpretation of pain score reduction, we propose that future researchers use the recognised analgesia effectiveness parameters of 30\% and 50\% reduction in pain scores. This information would help clinicians and policymakers in the calculation of NNT and comparison with other analgesics (see Chapter 1). We also proposed another effectiveness indicator—adequate analgesia—because previous researchers have found that this correlates well with patient satisfaction.\textsuperscript{59} These outcome measures were considered and included in our RCT (see Chapter 6).

It was disappointing that the findings for analgesia reduction and the opioid-sparing ability of acupuncture in the ED were inconsistent. Two ED acupuncture studies (i.e. on the use of acupuncture with NSAIDs for sore throats and aspirin for migraines, respectively) showed analgesia reduction,\textsuperscript{26,38} while two (any medication for migraine and mixed pain) did not.\textsuperscript{21,37} Opioid sparing was not explicitly assessed, thus there is a significant knowledge gap that requires further investigation (see Chapters 6 and 7).

While this review elicited some information on adverse effects, the studies were insufficiently powered to provide accurate adverse effect rates. A large prospective study is required to obtain a realistic estimate because this information is unlikely to be obtained from an RCT powered to ascertain analgesia effectiveness only (see Chapter 7).
Chapter 3: Does Ear Acupuncture Have a Role for Pain Relief in the Emergency Setting? A Systematic Review and Meta-Analysis

Ear acupuncture is well-suited as an adjunctive treatment to the conventional pain management administered to a wounded patient.

—Dr Stephen Burns, US Airforce, 2013

What is already known on the topic

- Reviews of studies on ear acupuncture, primarily in the post-operative period, show Level 1 evidence for the effectiveness of acupuncture for pain and analgesic reduction.
- In our prior systematic review, subgroup analyses showed that ear acupuncture was a standout form of acupuncture that improved analgesic effectiveness and required less training for providers.

What this research adds

- This review provides limited evidence for ear acupuncture either as an adjunct or standalone analgesic for painful conditions presenting to the emergency department; however, further research required.
- Ear acupuncture is suitable for emergency department settings because it allows access to the body for observations and procedures and takes only 2–10 minutes to apply.
- Battlefield (ear) acupuncture is easy to learn, may be used by non-acupuncturists and can be used for a wide range of painful conditions.

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3.1 Foreword

3.1.1 What is already known or knowledge gaps that require elaboration

In the previous chapter, ear acupuncture was identified as being potentially more efficacious than body acupuncture and mostly performed by non-acupuncturists in trials. Non-acupuncturists included ambulance officers who had no prior knowledge or experience before being trained for the study\cite{16} and physicians who were not qualified acupuncturists.\cite{30-32} This form of acupuncture may be ideal for ED clinicians, who can be trained in this technique alone and do not need to commit the time to becoming fully qualified acupuncturists.

Previous meta-analyses of studies on ear acupuncture have shown that it can provide immediate and prolonged (2-day) pain relief and reduction of analgesics (including opioids).\cite{15,17} Unfortunately, included RCTs were predominantly on postoperative pain.

Murakami et al.\cite{17} argue that sham ear points are likely to be effective for pain relief, thus problematic for sham acupuncture controls. This issue warrants further exploration, especially because an RCT on ear acupuncture was entertained as part of this thesis.

3.1.2 What was done that was different?

By completing a database search 9 months later, we anticipated that more studies would be identified than those found for the review presented in Chapter 2. If not, study designs (i.e. acupuncture v. sham acupuncture, acupuncture v. SAC and acupuncture as an adjunct v. SAC) would need to be amalgamated for the meta-analysis, as done in previous systematic reviews by other acupuncture researchers.

Rather than submitting this publication to an Australian journal, we chose to submit to an American acupuncture journal given the severity of the opioid crisis there and the consequent interest in alternatives, particularly BFA. This publication was the first systematic review on the use of ear acupuncture for acute pain in the ED setting.
Does Ear Acupuncture Have a Role for Pain Relief in the Emergency Setting? A Systematic Review and Meta-Analysis

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ABSTRACT

Objective: Ear acupuncture might be the form of acupuncture best suited to improving acute pain management in the emergency department (ED). The primary aim of this review was to assess the analgesic efficacy of ear acupuncture in the ED. Secondary outcomes included measures of patient satisfaction, adverse effects, cost, administration techniques, and reduction of medication usage.

Methods: Seven databases and Google Scholar were searched up to April 27, 2017, using MeSH descriptors for three overarching themes (ear acupuncture, pain management, and emergency medicine). Meta-analyses were performed in 3 comparator groups: (1) ear acupuncture versus sham; (2) ear acupuncture-as-adjunct to standard care; and (3) ear acupuncture (both as sole therapy and adjuvant) versus control to calculate the standardized mean difference (SMD) and weighted mean difference (WMD) for pain scores out of 10.

Results: Six randomized controlled trials and 2 observational studies, totaling 458 patients, were retrieved after exclusions. The meta-analysis used data from 4 randomized studies representing 286 patients. The above 3 comparator groups resulted in SMDs of 1.69, 1.68, and 1.66, and WMDs of 2.47, 2.84, and 2.61 respectively, all favoring acupuncture. Battlefield (ear) acupuncture was the most commonly used technique. There were no significant adverse effects and patient satisfaction improved. Results regarding if acupuncture reduced medication use were equivocal. Significant study bias and heterogeneity were found.

Conclusions: While study numbers are limited, ear acupuncture, either as stand-alone or as-an-adjunct technique, significantly reduced pain scores and has potential benefits for use in the ED. Further studies will define acupuncture’s role and if it reduces use of analgesic medications.

Keywords: ear acupuncture, auriculotherapy, emergency medicine, pain management, systematic review, meta-analysis

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INTRODUCTION

Pain is the most common presenting symptom in patients presenting in an emergency department (ED). ED pain management is often characterized by delays in analgesia as well as inadequate pain-score reduction. Furthermore, EDs continue to seek improved patient satisfaction with pain management. The current mainstay of pain management is medication. However, medications have significant side-effects in both the short- and long-term. Of particular concern is recurrent opioid use, which, in part, can lead to a reluctance to prescribe and administer such medications. Nonsteroidal anti-inflammatory drugs (NSAIDs), another mainstay of ED pain management, also have side-effects especially in the gastrointestinal system and kidneys in the elderly.

Characteristics ideally required for any new analgesic modality are: efficacy, rapidity of administration, low side-effects, minimal post-administration monitoring, improved patient satisfaction, and low cost. A novel modality such as ear acupuncture might offer a solution for these issues.

In 2014, Yeh et al. performed a meta-analysis of pain score reduction, using ear acupuncture for acute and chronic pain in a variety of comparator groups and settings. The researchers concluded that ear acupuncture is useful as an adjunct therapy for pain management. This conclusion was based on a meta-analysis of 13 randomized controlled trials (RCTs), totaling 806 patients with a mixture of pain types. The researchers reported a standardized mean difference (SMD) in pain reduction of 1.59, indicating a large effect-size. Further subgroup analyses of immediate pain score reduction under 15 minutes in 4 studies with 193 patients reported an SMD of 2.84. For acute pain relief at 12–24 hours, there were 4 studies including 314 patients and, here, the SMD was 1.71. When reviewing various modalities (i.e., acupuncture versus acupressure versus electroacupuncture [EA]), the researchers found that EA was the least effective. Unfortunately, most of the studies were on perioperative and not on ED pain and, furthermore, an emergency setting RCT was missed in this review.

Murakami et al. did a further review in 2016 on ear acupuncture for acute pain relief, particularly looking at analgesic use up to 48 hours. The researchers' meta-analysis of 6 studies included 303 patients and showed a statistically significant reduction in analgesia usage with an SMD of 1.08. Again, the studies were predominantly perioperative and not in the emergency setting.

The current authors performed a prior review that analyzed both body and ear acupuncture together in the ED setting and concluded that acupuncture was superior to sham and non-inferior to standard analgesic care (SAC) in selected conditions, with limited evidence for analgesia as an-adjunct. This conclusion was based on meta-analyses of 14 RCTs involving 1210 patients.

Therefore, unlike other prior reviews, which focused on perioperative pain, the current authors identified a need for a specific systematic review that focused on the effectiveness of ear acupuncture for acute pain in the emergency setting, while asking further questions about applicability and best technique.

OBJECTIVES

The primary aim of the current systematic review and meta-analysis was to specifically evaluate the effectiveness of ear acupuncture for acute pain management in the emergency setting. Changes in acute pain scores were assessed with ear acupuncture as a stand-alone therapy or ear acupuncture as an-adjunct to other analgesia (AdjEA), compared with SAC. Secondly, acupuncture-associate effects were evaluated on analgesic medication use, patient satisfaction, adverse events, and health care costs. Furthermore, the current authors aimed to describe the specific acupuncture techniques and acute pain conditions for which acupuncture was applied. See Table 1 for explanations of terms.

METHODS

The methodology for this study was closely aligned to that of the current authors' previous systematic review and meta-analysis of all forms of acupuncture and was approved as part of the first author's PhD proposal by the University of Notre Dame Fremantle, in Fremantle, Western Australia. The current systematic review and meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement. Seven databases were searched from database inception to April 27, 2017: AMED, CINAHL, EMBASE, PubMed, Science Direct, Scopus, and the Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Trials (CENTRAL). Additional studies were identified by hand searches of the proceedings of key scientific meetings, the Conference Papers Index, relevant systematic reviews, and Google Scholar. Three themes were explored using a Boolean search strategy: (1) ear acupuncture; (2) pain management; and (3) emergency medicine. The search used MeSH terms and keywords relevant to: the intervention (auricular acupuncture, ear acupuncture, battlefield acupuncture, auricolocupuncture, auriculotherapy, auricular therapy); pain management (pain, acute pain, analgesia); and the setting (emergency medical services, emergency, prehospital, retrieval medicine, emergency department, acute care, military).

Inclusion and Exclusion Criteria

All potentially eligible articles identified were screened for appropriate RCTs and uncontrolled observational
Table 1. Key Terms and Study Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
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| Acute pain                                  | "Acute pain is defined as pain of recent onset and probable limited duration. It usually has an identifiable temporal and causal relationship to injury or disease."  
   "Acute pain management occurs in a variety of patient-care settings (e.g., prehospital, emergency department, and perioperative environments)."  
   "In all settings, patients may suffer from acute and chronic pain simultaneously.”                                                                 |
| Ear acupuncture                              | Ear acupuncture or auriculotherapy includes: ear acupuncture with needle skin penetration, electroacupuncture stimulation, laser acupuncture, and acupressure.  
   Unless otherwise specified, ear acupuncture includes all forms of auriculotherapy.                                                                                                                      |
| Sham ear acupuncture                         | "Sham is the term used to refer to a faked operative intervention used in the same manner as a placebo to enable blinding and reduce bias."  
   "1. same treatment on ear acupoints that are not theoretically effective for the condition;  
   2. same treatment on non-acupoints on the ear; 3. placebo needles or adhesive patches without pellet/seed on the same ear acupoints as experimental group; 4. pseudo-interventions (e.g., switched-off laser acupuncture devices, electro-acupuncture devices with minimum emission, Vaccaria seeds without pressing) on the same ear acupoints as the experimental group.”  
   "The current authors would also include pharmacologic placebo techniques in this pseudo-intervention group.”                                                                                                 |
| Sham ear acupuncture trial (sham)            | This is a trial comparing ear acupuncture alone against sham ear acupuncture alone.                                                                                                                       |
| Standard analgesia care (SAC) trial          | This is a trial that use the SAC of pain care designated by the local institution, researcher, or guidelines as the comparator against acupuncture.                                                                 |
| Ear acupuncture-as-an-adjunct to other analgesia (AdjEA) trial | This is a trial in which SAC is combined with ear acupuncture versus SAC alone.                                                                                                                          |

53 Ref. 15.  
54 Ref. 40.

studies (UOBS) independently by the first 2 authors (A.L.J., E.S.A.) for inclusion or exclusion. Any discrepancies were resolved by consensus or discussion with the other coauthors. RCTs were eligible for both the systematic review and meta-analysis, while UOBS were included in the systematic review for information on secondary outcomes. Studies on acutely painful conditions treated by ear acupuncture were included if they involved the following settings: prehospital, retrieval, ED, or other settings if the condition is frequently managed in the ED. Studies on painful conditions were excluded if they were: not assessed within the first 24 hours; not involved with ear acupuncture; chronic conditions; involving animals; or concerned with perioperative pain. No language restrictions were applied.

Data Extraction

All of the eligible studies were read by the first 2 authors (A.L.J. and E.S.A.), who extracted data from the articles according to a predefined standard template based on the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines.29 This data for each article included information regarding: condition, setting, subjects, methods for both intervention and control groups, and data for both the primary and secondary outcomes, including relevant statistical information. Any missing data were derived from within the article, other sources, or by contacting the authors.

Data Synthesis

Primary outcome. While all clinical endpoints were considered, the primary outcome measure in this review was the pain score out of 10 (PS-10) difference in 3 comparator treatment groups: (1) ear acupuncture versus sham; (2) AdjEA versus SAC; and (3) ear acupuncture (sole therapy and AdjEA) versus control presented as the SMD and WMD.

To be included in the meta-analysis, a converted PS-10 mean score change along with standard deviations (SDs) needed to be retrieved or calculated. Different pain-score modes and scales (e.g., visual analogue scale 100 or 10) were converted to a standard numerical pain-rating scale, the PS-10, as a continuous variable. Pain scores closest to 60 minutes after treatment were used. For those SDs that were not provided, they were calculated from the pre-and-post PS-10 SD, using the correlation coefficient approximated to 0.5 as outlined in the Cochrane Handbook.21 In one study, the SDs were approximated from similar studies by the same authors under similar trial circumstances.16,22,23
Secondary outcomes. Medication usage included opioids and nonopioids, the frequency of usage both during and post ED stay, and the rate of discharge analgesic dispensing and prescriptions. Patient satisfaction was measured either on a continuous scale out of a 100 or percentages chosen for specified Likert categories. Adverse effects were coded as minor (required no treatment) or significant (required treatment) for both acupuncture and control groups. Ear acupuncture techniques were described regarding: training of the acupuncturist, acupoints used, methods of point location, whether unilateral or bilateral, needle types (or acupressure alone), duration of application, EA, and needle retention times. Time-based outcomes were measured as: time taken to perform procedures (e.g., needling time in minutes) and the duration of needle insertion. The cost of acupuncture consumables was expressed in U.S. dollars per person if specified.

Risk of bias. The risk of bias was assessed, using the following criteria from the Cochrane Classification: sequence generation, allocation concealment, subject, practitioner, and assessor blinding, completeness of outcomes data (reporting dropouts and withdrawals), selective reporting, and any other potential forms of bias.\textsuperscript{21} Using the same method as the current authors’ prior review on all forms of acupuncture,\textsuperscript{18} bias was categorized into low (low risk of bias in all criteria), medium (high risk of bias in patient and practitioner blinding), or high (risk of bias in multiple items). Again, any discrepancies between data abstractors were resolved by consensus or discussion with the other coauthors.

Meta-analyses. Stata software (14.1 StataCorp,\textsuperscript{24} College Station, TX, 2015) was used to perform the statistical analyses and calculate the SMD and WMD from the pooled RCT data. The magnitude of the effect-size was categorized as small (SMD of 0.2), medium (SMD of 0.5) or large (SMD of 0.8).\textsuperscript{25} A WMD for the PS-10 of >1.3 was regarded as clinically meaningful.\textsuperscript{26} Study heterogeneity ($I^2$) was provisionally assigned as low ($I^2$ of 25%), moderate ($I^2$ of 50%), or high ($I^2$ of 75%).\textsuperscript{27} Probability values ($P$) were considered to indicate statistical significance if $P<0.05$.\textsuperscript{27}

RESULTS

Of the 149 studies found, 8 were included in the systematic review and/or meta-analysis (Fig. 1). In total, 4 RCTs were included in the meta-analysis, and a further 2 RCTs and 2 UOBS were used in the systematic review.

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![FIG. 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) chart explaining study selection and exclusions. RCTs, randomized controlled trials; UOBS, uncontrolled observational studies.](image-url)
Table 2. Included Studies Detailing Acute Pain Type, Setting & Study Design

<table>
<thead>
<tr>
<th>First author, year &amp; ref.</th>
<th>Acute pain type</th>
<th>Study setting</th>
<th>Study type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allais, 2011^33</td>
<td>Migraine</td>
<td>Ward</td>
<td>RCT ear acupuncture vs. sham</td>
</tr>
<tr>
<td>Barker, 2006^16</td>
<td>Hip fractures</td>
<td>Ambulance</td>
<td>RCT ear acupressure vs. sham</td>
</tr>
<tr>
<td>Goertz, 2006^14</td>
<td>Pain not requiring medical intervention</td>
<td>ED</td>
<td>RCT AdjEA &amp; SAC vs. SAC alone</td>
</tr>
<tr>
<td>Gu, 1993^29</td>
<td>Biliary colic</td>
<td>ED</td>
<td>RCT ear acupuncture vs. SAC</td>
</tr>
<tr>
<td>Moss, 2015^32</td>
<td>Sore throat</td>
<td>GP Military</td>
<td>RCT ear acupuncture &amp; SAC vs. SAC alone</td>
</tr>
<tr>
<td>Fox, 2016^8a</td>
<td>Low-back pain</td>
<td>ED</td>
<td>RCT ear acupuncture &amp; SAC vs. SAC alone</td>
</tr>
<tr>
<td>Burns, 2013^30</td>
<td>All types</td>
<td>Retrieval</td>
<td>Observational study of ear acupuncture &amp; SAC</td>
</tr>
<tr>
<td>Graff, 2016^44</td>
<td>Migraines</td>
<td>ED</td>
<td>Observational study of ear acupuncture alone</td>
</tr>
</tbody>
</table>

Abstract only.
RCT, randomized controlled trial; AdjEA, ear acupuncture-as-an-adjunct to other analgesia; SAC, standard analgesia care; ED, emergency department; GP, general (family) practice.

(Table 2). Two of the RCTs had inadequate data for meta-analysis. The studied conditions included mixed pain types (2 studies), migraine (2 studies), hip fractures, low-back pain, sore throats, and biliary colic. The most frequent forms of ear acupunture were BFA (4 studies) 28,30,32 and ear acupuncture using a point finder (skin conduction and algometer; 2 studies), 33,34 (Fig. 1 and Table 2)

Primary Outcome

Four RCTs, representing 281 patients, were eligible for meta-analyses. Two RCTs with 127 patients compared the change in PS-10 for ear acupuncture (including 1 acupressure study) versus sham with an SMD of 1.69 (confidence interval [CI]: 0.37–3.01), I² = 87.0%, and P < 0.01 (Fig. 2); and and a WMD of 2.47 (CI: 1.79–3.16) and P = 0.22 (Supplementary Fig. S1; Supplementary Data are available online at www.liebertpub.com/acu). Two RCTs with 154 patients compared AdjEA to SAC without sham; the SMD PS-10 was 1.68 (CI: 1.18–2.18), I² = 39.9%; P = 0.20 (Fig. 3); and the WMD was 2.84 (CI: 1.45–4.22), P = 0.01 (Supplementary Fig. S2). When combining all 4 RCTs as ear acupuncture (both sole and adjuvant) versus control, the SMD PS-10 was 1.66 (CI: 1.13–2.19), I² = 71.3%, and P = 0.02 (Fig. 4); and the WMD was 2.61 (CI: 2.00–3.22), P = 0.05 (Supplementary Fig. S3).

Secondary Outcomes (Tables 3–5)

Medication usage. One RCT showed a reduction in NSAID usage for sore throats, with a reduced mean number of doses at 6 hours (0.4 versus 1.1), 24 hours (1.4 versus

FIG. 2. Forest plot of ear acupuncture versus sham with calculated standardized mean difference (SMD) for pain score difference on a pain score out of 10 (PS-10). CI, confidence interval.
2.6), and 48 hours (2.2 versus 4.1), with all \( P < 0.05 \). Another RCT showed no difference in overall medication usage regarding frequency or obtaining of analgesics via prescription. One small pilot study (abstract only) showed no difference in ED opioid use but, upon discharge, fewer analgesia prescriptions were given to the control group. The statistical significance of these differences for this latter pilot study was not reported.

**Patient satisfaction.** Two studies measured patient satisfaction. In the prehospital acupressure RCT there was a quoted improvement over sham but no quantitative data was available.
<table>
<thead>
<tr>
<th>First author, year &amp; setting</th>
<th>Condition</th>
<th>Study design (acupuncture practitioner qualification)</th>
<th>Experimental group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migraines</td>
<td>2 arms, acupuncture (n=46) &amp; sham (n=48) (not specified)</td>
<td>Acupuncture 24 h</td>
<td>Several (not specified): Ear: Thalamus (bilateral)</td>
<td>Sham: Four: Nonsensitive sciatic point on antihelix inferior crus x 2 bilateral</td>
</tr>
<tr>
<td>Hip fractures</td>
<td>2 arms, acupressure (n=18) &amp; sham (n=20) (paramedics inexperienced in acupuncture)</td>
<td>Acupressure N/A</td>
<td>3 ear: Shenmen; Hip point; &amp; Tranquilizer point (bilateral)</td>
<td>Sham: 2 ear: Stomach point bilateral (concha ridge)</td>
</tr>
<tr>
<td>Mixed</td>
<td>2 arms, AdjEA (n=50) &amp; standard care (n=50) (medical acupuncturist)</td>
<td>AdjEA 4–6 d</td>
<td>4 ear: Cingulate, Thalamus (bilateral)</td>
<td>SAC: SAC</td>
</tr>
<tr>
<td>Biliary colic</td>
<td>2 arms AdjEA (n=30) &amp; standard care (n=18) (not specified)</td>
<td>Acupuncture 20 min</td>
<td>2 ear: Point Zero, De Qi every 3–5 min (bilateral)</td>
<td>SAC: 0.5 mg atropine &amp; 25 mg promethazine</td>
</tr>
<tr>
<td>Sore throat</td>
<td>2 arms AdjEA (n=27) &amp; standard care (n=27) (certified acupuncturist and physicians inexperienced in acupuncture)</td>
<td>AdjEA 48 h</td>
<td>Up to 10 ear: Cingulate; Thalamus; Omega 2; Point Zero; Shenmen (bilateral)</td>
<td>SAC: Ibuprofen or equivalent PRN</td>
</tr>
<tr>
<td>Low-back pain</td>
<td>2 arms, AdjEA (n=15) &amp; standard care (n=15) (certified acupuncturist and physicians inexperienced in acupuncture)</td>
<td>AdjEA Not specified</td>
<td>Up to 10 ear: Cingulate; Thalamus; Omega 2; Point Zero; Shenmen (bilateral)</td>
<td>SAC: SAC</td>
</tr>
</tbody>
</table>

aAbstract only.

RCT, randomized controlled trial; h, hours; N/A, not applicable; AdjEA, ear acupuncture-as-an adjunct to other analgesia; d, days; SAC, standard analgesia care; ED, emergency department; min, minutes; PRN, pro re nata (as needed).
<table>
<thead>
<tr>
<th>First author, year, ref. &amp; condition</th>
<th>Experimental group</th>
<th>Control group</th>
<th>Mean pain score change difference between intervention &amp; control</th>
<th>Bias</th>
<th>Secondary outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean age yrs with SD or P-value (% female)</td>
<td>Mean age yrs with SD or P-value (% female)</td>
<td>Mean age yrs with SD or P-value (% female)</td>
<td>Mean age yrs with SD or P-value (% female)</td>
<td>Mean age yrs with SD or P-value (% female)</td>
</tr>
<tr>
<td></td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>2.1</td>
<td>Medium</td>
</tr>
<tr>
<td></td>
<td>35.9; range: 15–60 yrs (100%)</td>
<td>32.2 range: 16–58 yrs (100%)</td>
<td>Not specified</td>
<td>Low</td>
<td>Anxiety 38/100 change vs. 3/100; P&lt;0.001; Lower HR; more satisfied than sham.</td>
</tr>
<tr>
<td>Allais, 2011&lt;sup&gt;33&lt;/sup&gt;</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>2.8</td>
<td>Low</td>
</tr>
<tr>
<td>migraine</td>
<td>Barker, 2006&lt;sup&gt;16&lt;/sup&gt;</td>
<td>86.5 ± 4.0 yrs (83%)</td>
<td>86.0 ± 4.8 yrs (90%)</td>
<td>Not specified</td>
<td>Not specified</td>
</tr>
<tr>
<td>hip fractures</td>
<td></td>
<td></td>
<td></td>
<td>2.8</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Goertz, 2006&lt;sup&gt;31&lt;/sup&gt;</td>
<td>30.4 ± 9.7 yrs (42%)</td>
<td>32.8 ± 7.5 yrs (64%)</td>
<td>Not specified</td>
<td>Not specified</td>
</tr>
<tr>
<td>mixed</td>
<td>30.4 ± 9.7 yrs (42%)</td>
<td>32.8 ± 7.5 yrs (64%)</td>
<td>Not specified</td>
<td>2.18</td>
<td>Medium</td>
</tr>
<tr>
<td></td>
<td>Gu, 1993&lt;sup&gt;29&lt;/sup&gt;</td>
<td>47 ± 8.8 yrs (53.3%)</td>
<td>42 ± 6.6 yrs (42.7%)</td>
<td>Not specified</td>
<td>Not specified</td>
</tr>
<tr>
<td>biliary colic</td>
<td>47 ± 8.8 yrs (53.3%)</td>
<td>42 ± 6.6 yrs (42.7%)</td>
<td>Not specified</td>
<td>2.18</td>
<td>Medium</td>
</tr>
<tr>
<td>source left</td>
<td></td>
<td></td>
<td></td>
<td>2.18</td>
<td>Medium</td>
</tr>
<tr>
<td></td>
<td>34 yrs; P &lt; 0.48 (74%)</td>
<td>31 yrs; P &lt; 0.48 (56%)</td>
<td>Not specified</td>
<td>3.6</td>
<td>High</td>
</tr>
<tr>
<td>source right</td>
<td>34 yrs; P &lt; 0.48 (74%)</td>
<td>31 yrs; P &lt; 0.48 (56%)</td>
<td>Not specified</td>
<td>3.6</td>
<td>High</td>
</tr>
<tr>
<td>source mixed</td>
<td></td>
<td></td>
<td></td>
<td>3.6</td>
<td>High</td>
</tr>
<tr>
<td></td>
<td>Fox, 2016&lt;sup&gt;30a&lt;/sup&gt;</td>
<td>Not specified</td>
<td>2 events: pain at needle site</td>
<td>Not specified</td>
<td>Not specified</td>
</tr>
<tr>
<td>low-back pain</td>
<td>Not specified</td>
<td>2 events: pain at needle site</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Post pain score: 1.7</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Post pain score: 1.7</td>
<td>High</td>
</tr>
</tbody>
</table>

*Abstract only.

RCT, randomized controlled trial; yrs, years; SD, standard deviation; HR, heart rate; h, hours; ROM, range of movement; LOS, length of stay; ED, emergency department; BFA, Battlefield Acupuncture.
The table below provides the methods and results of included observational ear acupuncture studies on pain management in the emergency setting.

<table>
<thead>
<tr>
<th>First author, year, ref. &amp; setting</th>
<th>Condition (sample size)</th>
<th>Intervention</th>
<th>Acupuncturist qualification</th>
<th>Method/ acupuncture points</th>
<th>Length of time needles retained</th>
<th>Mean age years with ± SD (± SD female)</th>
<th>Adverse events from acupuncture</th>
<th>Mean pain score out of 10 pre-post with SD or P-value (change)</th>
<th>Secondary outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burns, 2013, 30</td>
<td>Varied pain types (75)</td>
<td>AdjEA SAC</td>
<td>Nonacupuncturists: Nurse-practitioners (2) Physician (1) trained in BFA</td>
<td>Up to 10 Ear: Cingulate, Thalamus, Omega 2, Point Zero &amp; Shenmen (bilateral)</td>
<td>Not specified</td>
<td>55.4% ages 21-30 (14.9%)</td>
<td>Not specified</td>
<td>4.07 to 2.17 (1.89)</td>
<td>P &lt; 0.0001</td>
</tr>
<tr>
<td>Graff, 2016, 34</td>
<td>Migraine (19)</td>
<td>Acupuncture</td>
<td>Physician</td>
<td>Up to 6 (3 in each ear): Thalamus &amp; miregaine line (bilateral)</td>
<td>2 weeks or till needles fell out</td>
<td>14 ± 2.9 yrs (89%)</td>
<td>0</td>
<td>7.63 ± 1.2 – 0.55 ± 0.4 (7.08 ± 1.0)</td>
<td>Nil</td>
</tr>
</tbody>
</table>

SD, standard deviation; AdjEA, ear acupuncture-as-an-adjunct to other analgesia; SAC, standard analgesia care; BFA, Battlefield Acupuncture; ED, emergency department; yrs, years.

**DISCUSSION**

The most important conclusion of this review is that ear acupuncture has some important clinical evidence of effectiveness for the management of pain in all treatment groups. This review concluded that the evidence for ear acupuncture was not as strong as for other methods of acupuncture, such as traditional acupuncture. However, it is important to note that the effectiveness of ear acupuncture has not been adequately studied in the past.

**Time-based outcomes and costs**

The time required to apply ear acupuncture was specified for 6 of the 8 studies and ranged from 2 to 10 minutes (see Table 5). The costs of ear acupuncture were also mentioned in 2 of the studies.

**Adverse effects**

Adverse events were not specifically measured in all the studies, with 4 studies providing data on adverse events. However, in all studies, the adverse events were not significant.

**Ear acupuncture techniques (points and training)**

Ear acupuncture techniques have been used in the past, but the effectiveness of these techniques has not been adequately studied.

**Conclusion**

Ear acupuncture has some clinical evidence of effectiveness for the management of pain, but further research is needed to determine the optimal method and techniques for its use.

**Conclusion of the Overall Study**

The overall study concluded that ear acupuncture has a potential role in the management of pain, but further research is needed to determine its optimal use.

**References**

1. Burns, 2013
2. Graff, 2016
3. Other studies

**Appendix**

See Table 6 for a summary of the included studies.

**Table 6. Methods & Results of Included Observational Ear Acupuncture Studies on Pain Management in the Emergency Setting**

<table>
<thead>
<tr>
<th>First author, year, ref. &amp; setting</th>
<th>Condition (sample size)</th>
<th>Intervention</th>
<th>Acupuncturist qualification</th>
<th>Method/ acupuncture points</th>
<th>Length of time needles retained</th>
<th>Mean age years with ± SD (± SD female)</th>
<th>Adverse events from acupuncture</th>
<th>Mean pain score out of 10 pre-post with SD or P-value (change)</th>
<th>Secondary outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burns, 2013, 30</td>
<td>Varied pain types (75)</td>
<td>AdjEA SAC</td>
<td>Nonacupuncturists: Nurse-practitioners (2) Physician (1) trained in BFA</td>
<td>Up to 10 Ear: Cingulate, Thalamus, Omega 2, Point Zero &amp; Shenmen (bilateral)</td>
<td>Not specified</td>
<td>55.4% ages 21-30 (14.9%)</td>
<td>Not specified</td>
<td>4.07 to 2.17 (1.89)</td>
<td>P &lt; 0.0001</td>
</tr>
<tr>
<td>Graff, 2016, 34</td>
<td>Migraine (19)</td>
<td>Acupuncture</td>
<td>Physician</td>
<td>Up to 6 (3 in each ear): Thalamus &amp; miregaine line (bilateral)</td>
<td>2 weeks or till needles fell out</td>
<td>14 ± 2.9 yrs (89%)</td>
<td>0</td>
<td>7.63 ± 1.2 – 0.55 ± 0.4 (7.08 ± 1.0)</td>
<td>Nil</td>
</tr>
</tbody>
</table>

SD, standard deviation; AdjEA, ear acupuncture-as-an-adjunct to other analgesia; SAC, standard analgesia care; BFA, Battlefield Acupuncture; ED, emergency department; yrs, years.
on ear acupuncture in the emergency setting, compared to prior reviews.\textsuperscript{15,17,18,39} These prior reviews provided evidence from meta-analyses that all forms of acupuncture were effective in the ED environment and that ear acupuncture is effective for acute perioperative pain, but did not address the specific role of ear acupuncture in the ED setting.

Effectiveness Across Study Groups

\textit{Ear acupuncture versus sham.} In the ear acupuncture versus sham group, there was a large statistical effect size significance favoring ear acupuncture. The clinical significance of a pain score change of 2.47 of 10 should be interpreted with caution, as the \( P \)-value for the WMD was 0.22. One study measured patient satisfaction and documented improved satisfaction, compared with sham.\textsuperscript{18} Patient satisfaction is an important aspect to quantifying analgesia effectiveness and is not necessarily captured by pain-score reduction.\textsuperscript{7,36}

Some researchers argue against the use of sham in acupuncture trials, as, in these researchers’ view, simply piercing the skin is likely to have a therapeutic effect and they would prefer to compare acupuncture against SAC.\textsuperscript{58,39} The analgesic effects of sham ear acupuncture needing nonactive or irrelevant acupoints (types 1 and 2; see sham ear acupuncture definition in Table 1) is perhaps more therapeutic, compared to body sham, as the ear is small and has >93 documented active acupoints,\textsuperscript{40} and, furthermore, each point has active neighboring zones.\textsuperscript{41} Thus, attempts to show efficacy of ear acupuncture above sham using supposedly inactive ear acupoints is theoretically more difficult. However, Zhang et al. in their review of sham

\begin{table}[h]
\centering
\caption{Bias Assessment for Included RCTs Judged According to the Cochrane Assessment Tool}
\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|}
\hline
First author, & Adequate & Allocation & Patient & Practitioner & Assessor & Incomplete & Selective & Other & Summary of bias risk \\
year & ref. & randomization & concealment & blinding & blinding & outcome data & reporting & sources & \\
\hline
Allais, 2011\textsuperscript{33} & L & L & L & H & L & L & L & L & Medium \\
Barker, 2006\textsuperscript{46} & U & L & L & L & L & L & L & L & Low \\
Goertz, 2006\textsuperscript{47} & L & L & H & H & L & L & L & L & Medium \\
Gu, 1993\textsuperscript{39} & U & U & H & H & U & U & U & U & Medium \\
Moss, 2015\textsuperscript{52} & L & U & H & H & H & L & L & L & High \\
Fox, 2016\textsuperscript{58a} & U & U & H & H & H & L & U & L & High \\
\hline
\end{tabular}
\end{table}

\textsuperscript{a}Abstract only.

RCTs, randomized controlled trials; L, low; H, high; U, unclear.
control methods in ear acupuncture was not able to demonstrate this.\textsuperscript{40} These researchers found no difference between the needling of nonactive or irrelevant acupoints versus pseudo-interventions (type 4; see sham ear acupuncture definition in Table 1).

While the current authors chose to focus on ear acupuncture in the ED setting, the small number of sham studies and \(P\)-value >0.05 for the overall WMD indicate that further evidence from studies of other non-ED scenarios and body acupuncture is helpful. Yeh et al. in 2014 performed review\textsuperscript{15} of ear acupuncture for immediate pain relief (15 minutes) in non-ED conditions and documented 2 acupuncture versus sham studies involving the changing of burns dressings\textsuperscript{42} and chronic distal extremity pain.\textsuperscript{43} Both studies showed significant but small effect-size differences favoring ear acupuncture (SMD=0.37 and 0.34, respectively).\textsuperscript{15} The current authors’ prior meta-analysis of acupuncture versus sham included both body (6 RCTs) and ear (2 RCTs) acupuncture, and the results also favored acupuncture for a broader range of conditions, with a large effect-size and improved patient satisfaction.\textsuperscript{18} Both of these latter reviews supported the current finding that ear acupuncture is likely to be more effective than sham acupuncture.

\textit{AdjEA compared to SAC.} The current meta-analysis of 2 studies revealed a large statistical effect-size (SMD) that was not statistically significant and a clinically meaningful reduction in a numeric rating scale pain score of 2.84/10 favoring AdjEA. There were no patient-satisfaction measures in this group. Again, because of the limited number of ED studies and a \(P\)-value >0.05 for the SMD, further evidence is required elsewhere to allow useful interpretation. In the perioperative setting in Yeh et al.’s meta-analysis (4 studies),\textsuperscript{15} AdjEA showed a large effect-size difference (SMD=1.71) for pain-score change in a 12–24-hour period. These results are consistent and support the current analysis for this comparator group. Thus, the evidence for ear acupuncture in this group and in the group against sham—albeit with limited numbers of studies—suggest that ear acupuncture might be a suitable adjunct with simple analgesia such as acetaminophen or NSAIDs, or as an alternative when concerns for analgesic drug side-effects are high, contraindicated, or previously ineffective.

\textit{Ear acupuncture alone compared to SAC.} There was only 1 study in this group, dating from 1993.\textsuperscript{29} The drug comparator of atropine and promethazine would no longer be considered standard therapy. In the current authors’ prior review of body acupuncture, a meta-analysis of this group showed that body acupuncture was non-inferior to SAC.\textsuperscript{18} No further studies on ear acupuncture could be found in the perioperative setting for this comparator group.

\textit{Ear acupuncture versus control (all groups combined).} In this group, all eligible RCTs that had adequate data were combined. There was both a large statistical effect-size difference of 1.66 and a clinically meaningful PS-10 of 2.61 (\(P\)=0.05) above the threshold of 1.3, all favoring ear acupuncture.\textsuperscript{25,35} While this meta-analysis combined various style designs, allowing interpretation of acupuncture effects relative to the control, it still should be interpreted with some caution due to these heterogeneous trial designs. Many acupuncture systematic reviews performed this meta-analysis including 3 major reviews on ear acupuncture and pain management. These reviews by Murakami et al. (2017),\textsuperscript{17} Yeh et al. (2014)\textsuperscript{15} and Asher et al. (2010)\textsuperscript{35} all highlighted large effect-size differences favoring ear acupuncture for acute pain (both perioperative and ED pain) with SMDs of 0.96 (3 studies; 333 patients), 2.84 (4 studies; 193 patients), and 1.35 (2 studies; 111 patients), respectively. These 3 meta-analyses were consistent with the current results.

\textbf{Quality of Studies and Heterogeneity}

Like body acupuncture, ear acupuncture RCTs have unique challenges to overcome blinding, sham needling effects, and lack of mainstream support or funding.\textsuperscript{44} The quality of studies in this review was variable. One high-quality study overcame the challenge of practitioner blinding successfully by using acupuncture-naïve paramedics,\textsuperscript{16} as opposed to another 2 studies that did not blind their assessors.\textsuperscript{28,30} Heterogeneity was moderate to high in the current meta-analysis.\textsuperscript{28} The issues of bias and heterogeneity both diminished positive interpretation of acupuncture in these meta-analyses.

\textbf{Adverse Effects}

This current systematic review was not able to extract useful data on adverse effects from the studies selected, due to the inconsistent reporting of such events. Only 2 studies were identified that measured adverse events as a secondary outcome, and no serious adverse events were found in either study.

These results are consistent with the literature. A 2014 review by Tan et al. on adverse events with ear acupuncture collected data on adverse events in 18 studies (RCTs and UOBS) involving 1753 patients.\textsuperscript{45} The researchers recorded no serious adverse events but there were short-term minor events, including pain, nausea, dizziness, local bleeding, and mild inflammation.\textsuperscript{25} Xu et al., in 2013, in their review of case reports noted the more serious adverse event of perichondritis.\textsuperscript{46} A previous review from 2004 estimated the incidence of serious adverse events requiring treatment for all forms of acupuncture at 0.05 per 10,000 treatments, with perichondritis comprising ~5% of these.\textsuperscript{21} Fainting (a vagovagal event) is a potentially more serious complication of
ear acupuncture, as injuries can be sustained from falling. In 1 survey, the incidence of fainting was quoted as 0.1%, but this incidence included both ear and body acupuncture.48 Needle-stick injuries to staff from indwelling ear needles falling out are another reported and preventable complication.49

Medication Usage

One of the adjunct studies showed a reduction in medication use,32 while the other 2 did not.31,34 Therefore, no conclusions could be drawn in this current review on whether or not ear acupuncture reduced medication use in the emergency setting. However, the periprojective meta-analyses provided some indirect evidence that ear acupuncture could reduce medication usage. Murakami et al. performed a meta-analysis on medication usage in 6 RCTs with a total 303 patients.17 There, the SMD was 1.08 favoring AdjEA for medication reduction.17

Technique and Applicability to the ED Setting

There were two predominant styles of ear acupuncture in the current review. One style was developed by Marco Moroli, FISA (2 studies) and the other was developed by Richard C. Niemtzw, MD, PhD, MPH (4 studies). The former style relies on more skills, with identification of ear points through a combination of: anatomical location, localized tenderness (including use of an algometer), and trial of improvement (needle-contact test) or electrical skin resistance. The latter style, BFA, uses up to 5 set points that are only anatomically located. There were inadequate studies in this review to evaluate which of these two styles was most effective for pain-score reduction.

The BFA technique is attractive—as it can be applied in a wide spectrum of conditions, using the same point prescription—and is extensively used by nonacupuncturists. BFA has already been taught to more than 2800 nonacupuncturist military providers (personal written communication with coauthor Dr. Niemtzow on September 15, 2016). In the current review, there were 4 BFA studies that utilized noncertified acupuncturists.

Application time for ear acupuncture in the current review was under 10 minutes. It is noteworthy that body acupuncture has not been shown to be more efficacious and might delay usual care for up to 30 minutes because of the need for widespread needle placement.18 Ear acupuncture, however, allows body access for observations, intravenous access, imaging (except magnetic resonance imaging), and procedures.

Future Research

The current review highlighted issues in the methodological quality of the RCTs, encouraging future researchers to address basic requirements such as assessor blinding. Adverse events were only reported sporadically, so the current authors recommend uniform reporting standards be used for minor adverse events. More studies with a comparator group of acupuncture versus SAC would allow the relative risk of adverse events to be calculated. Patient satisfaction is an important determinant of acupuncture efficacy, and more studies require this as a secondary outcome. Other painful conditions besides those to date are needed for BFA assessment to show that it is efficacious across all painful conditions. Further studies are required to assess the various techniques of ear acupuncture, ear versus body acupuncture, and utilization of certified acupuncturists versus nonacupuncturists. The acceptance of acupuncture in the ED setting is likely to be partially dependent on proving medication-usage reduction; thus, further testing using AdjEA versus SAC with medication usage as a secondary outcome is required.

Limitations

While this review and its outcomes were preapproved as part of a PhD proposal, it was not preregistered on a systematic review database. This review was limited by the numbers of patients and studies, substantial study heterogeneity, limited statistical significance within the meta-analyses, and quality issues within the RCTs. Further research is likely to have an effect on the results of this review. While grouping of the studies is advantageous because of trial design (i.e., ear acupuncture versus sham, AdjEA versus SAC, and ear acupuncture versus SAC), this is fraught with assumptions that ear acupuncture is effective across a range of conditions. Grouping all RCTs together into 1 meta-analysis variant study designs compiles together and should be interpreted with caution. Finally, a random-effects model was used, as it was assumed that the studies were not homogeneous and there might have been studies that were missed or unpublished.

CONCLUSIONS

Based on this systematic review, there is limited evidence that ear acupuncture (as stand-alone or adjunct therapy) can provide effective analgesia for some acute pain conditions in the ED. Until further research occurs, it is necessary to interpret the effectiveness of ear acupuncture—at least in part—in the light of prior reviews on perioperative studies and body acupuncture. ED clinicians may consider ear acupuncture as an adjunct to SAC or as an alternative when concerns about analgesic drug side-effects are high, contraindicated, or previously ineffective. While ear acupuncture has been shown to reduce medication usage in perioperative pain, this has not yet been established in the ED setting. However, ear acupuncture has additional potential features that make it suitable to the emergency
setting. These features are: low risk, low cost, reasonable application time, improved patient satisfaction, and allowing body access for other dimensions of ED care.

ACKNOWLEDGMENTS

Support for this research was provided by the University of Notre Dame, St. John of God Hospital Murdoch, and the Australian Government Research Training Program Scholarship.

All of the authors conceived the study and designed the search and data collection. A.L.J. and E.S.A. undertook data collection and analysis. All of the authors contributed to review and revision of this article, and all take responsibility for the final version.

AUTHOR DISCLOSURE STATEMENT

No competing financial interests exist.

REFERENCES


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3.2 Afterword

Supplementary materials for the publication presented in this chapter can be found in Chapter 3 Appendix, Section A.

3.2.1 What went well?

3.2.1.1 Methodology

The research team included a statistician, a co-author of one of the included RCTs, a pain medicine specialist, an emergency physician and an acupuncturist (see Chapter 7 Appendix, Section B). These experts enabled the delivery of timely expert advice for various aspects of the publication.

3.2.1.2 Findings

The publication was well received and declared a high-impact article by the journal. Given the interest in ear acupuncture in the US, the choice of an American journal was justified (see Chapter 3 Appendix, Section C). The popularity of the article was surprising given the lack of decisive conclusions. It is possible that defining the knowledge gaps was just as crucial as producing definitive results.

We identified two predominant ear acupuncture styles in the review, namely that developed by Marco Moroli and the other by Richard Niemtzow. Ultimately, Niemtzow’s BFA was chosen for the RCT (see Chapter 6) because it seemed the easiest to learn and the most investigated.

Although we were unable to gain further insights from the individual RCTs into a suitable sham for the upcoming trial (Chapter 6), a systematic review on sham techniques (included in the discussion section of this publication) provided the answer.\(^{40}\) Zhang et al. argued that there are so many active ear points that a sham ear point is likely to be active.\(^{40}\) Further, stimulation of active points with mere touch or pressure is also likely to result in analgesia. Therefore, using information from Zhang et al., we chose a pseudo-intervention, i.e. a piezoelectric device for our RCT.

As highlighted in Chapter 7 Appendix, Section B, the findings from this review are already embedded in the literature.
3.2.2 What was unexpected or disappointing?

3.2.2.1 Methodology

The review on ear acupuncture used a similar methodology to that of the study presented in Chapter 2, thus had similar room for improvement. In retrospect, it would have been desirable to utilise the AMSTAR checklists and preregister the protocol using the PICO format. The use of specialised software (e.g. Covidence) (see Chapter 7 Appendix, Section A) would have reduced errors and assisted in compliance with PRISMA.

3.2.2.2 Findings

Despite the 9 months since the first systematic review, we identified only one extra article, a conference abstract by Fox et al., which offered limited data. At the time of this review, Fox et al. had chosen not to release further data to us until formal publication.

Similar to the first review, there were insufficient studies to perform a separate meta-analysis on each study design, i.e. acupuncture v. sham acupuncture, acupuncture v. SAC and acupuncture as an adjunct v. SAC. Therefore, as anticipated, to enable a meaningful result, the various design types were combined into one meta-analysis. Further, the discussion was supplemented with findings from studies on postoperative analgesic acupuncture because of the limited evidence produced. We needed to utilise findings from previous reviews on ear acupuncture to reinforce our results and provide encouragement for further research on opioid reduction.
Chapter 4: Patient Attitudes Towards Analgesia and Their Openness to Non-Pharmacological Methods such as Acupuncture in the Emergency Department

‘Acupuncture worked for my back, so I am very positive about ED acupuncture’.
‘Don’t like drugs, so open to anything’.
‘I am very agreeable to acupuncture as opioids make me sick, hot and strange’.
‘Depending on the skill of the acupuncturist, I would be agreeable to acupuncture’.
‘I work with clients with drug addiction issues, so very supportive of acupuncture’.
‘I don’t want acupuncture as I’m scared of needles’.
‘I would only agree to acupuncture if I was given pain medicines as well’.
‘I’m not that agreeable to acupuncture as it didn’t work for me in the past’.

—Sample of patient comments from this chapter’s survey

<table>
<thead>
<tr>
<th>What is already known on the topic</th>
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<tbody>
<tr>
<td>• Based on observational studies in Australia and the US, patient willingness to use acupuncture ranges from 50 to 90%.</td>
</tr>
<tr>
<td>• Patient satisfaction improves when acupuncture is used in the emergency setting.</td>
</tr>
<tr>
<td>• Surveys show that approximately 60% of patients in the US are concerned about opioid addiction as a result of take-home opioid prescriptions.</td>
</tr>
<tr>
<td>• Opioids administered or prescribed in the emergency department (ED) do not improve patient satisfaction.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>What this research adds</th>
</tr>
</thead>
<tbody>
<tr>
<td>• About 90% of patients were willing to use non-pharmacological methods for pain reduction.</td>
</tr>
<tr>
<td>• 68% of patients were willing to receive acupuncture as an analgesic.</td>
</tr>
<tr>
<td>• There was no association between opioid administration and patient satisfaction.</td>
</tr>
<tr>
<td>• About 20% of patients suffered adverse effects to standard analgesics in the first hour, and 50% of these would not use that analgesic again.</td>
</tr>
<tr>
<td>• Only 10% of patients in a private Australian ED were concerned about addiction to administered opioids.</td>
</tr>
<tr>
<td>• About 58% of patients were administered opioids as part of standard analgesia care, of which atypical opioids constituted a minority (~3%, predominantly tramadol).</td>
</tr>
<tr>
<td>• Patients with fewer concerns about opioids were more likely to receive them.</td>
</tr>
</tbody>
</table>
4.1 Foreword

4.1.1 What is known or knowledge gaps that require elaboration

In response to the opioid crisis, non-pharmacological methods for analgesia are gaining interest. Acute low back pain guidelines recently collated by Almeida et al. recommend non-pharmacological methods for first-line management (see Chapter 7 Appendix, Section C ref. no. 44). However, research on patient attitudes to such analgesic modalities in the ED is lacking.

As mentioned in Chapter 1, this thesis explores two aspects for the patient satisfaction outcome: satisfaction with acupuncture treatment and willingness to use acupuncture. To date, the only information on patient willingness to use acupuncture is from observational studies, which show a consent rate of approximately 70% in Australian public EDs and 50–90% in the US (see Table A7-5 in Chapter 7 Appendix). This rate may be different in the private ED used in our study, and data from this survey aided in planning the completion time for our upcoming trial via consent rates (see Chapter 6).

Patient satisfaction is a mysterious dimension of pain management, and some evidence for this was presented in Chapter 1. Patient satisfaction is not directly related to pain score reduction, timeliness of analgesia or opioid usage but to human factors such as caring and touch. Acupuncture is an analgesic modality intimately associated with these factors. There is no doubt that patient satisfaction is crucial to ED performance because it influences the doctor-patient therapeutic relationship, compliance with treatment and the risk of complaints and litigation. Patient satisfaction is somewhat connected to the effectiveness of acupuncture because those willing to use it and who expect to benefit from it are more likely to have reductions in pain scores (see Chapter 7, Section 5.4).

4.1.2 What was done that was different?

Besides asking participants about their willingness to use non-pharmacological methods, the survey extracted information about patient attitudes to standard analgesics. For acupuncture to become a first- or second-line analgesic option in some scenarios and displace opioids or NSAIDs, it is important to understand the patients’ perspective on these analgesics before doing so.

While it does not rank highly in the hierarchy of evidence, this questionnaire adds to the body of evidence about secondary outcomes gathered from RCTs and observational studies presented in
Chapter 2. In Australia, there is sufficient interest in opioid alternatives, including non-pharmacological methods such as acupuncture, to submit our paper to *Emergency Medicine Australasia*. Much of the original acupuncture research was carried out in Melbourne, Australia. Respected researchers such as David Taylor frequently publish studies on pain management and patient satisfaction and expected this research to be well received.⁵
SHORT REPORT

Patient attitudes towards analgesia and their openness to non-pharmacological methods such as acupuncture in the emergency department

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Abstract

Objective: To investigate patient attitudes to analgesia, opioids and non-pharmacological analgesia, including acupuncture, in the ED.

Methods: ED patients with pain were surveyed regarding: pain scores, satisfaction, addiction concern, non-pharmacological methods of pain relief and acupuncture. Data were analysed using logistic regression.

Results: Of 196 adult patients, 52.8% were 'very satisfied' with analgesia. Most patients (84.7%) would accept non-pharmacological methods including acupuncture (68.9%) and 78.6% were not concerned about addiction. Satisfaction was associated with male gender, and 'adequate analgesia' but not with opioids.

Conclusion: Most patients were generally satisfied with ED analgesia and were open to non-pharmacological analgesia including acupuncture.

Key words: acupuncture, emergency medicine, pain management.

Introduction

There are increasing government and prescriber concerns regarding adverse effects of opioids. Current ED practices may contribute to these concerns by introducing and dispensing take-home supplies. Some doubt exists whether opioids improve patient satisfaction in the ED. There is increased interest in the use of acupuncture analgesia in the ED. However, a paucity of research exists on patient perspectives in the ED on non-pharmacological methods such as acupuncture, the short-term adverse effects of opioids and the long-term concerns regarding addiction.

Aims

The aims of this survey were to investigate patient perceptions of their usual analgesic care (UAC), including pharmacological and non-pharmacological modalities, and their willingness to use non-pharmacological methods such as acupuncture in conjunction with UAC.

Methods

After receiving ethics approval as a low-risk human research project (St John of God HREC reference 1107), we performed a prospective survey using a convenience sample of adult patients presenting to our private ED over a 9 month period. Inclusion criteria were presenting to the ED with acute pain, assigned Australian triage scale categories 3–5 and indicating a numerical pain rating scale (NPRS) ≥4/10 (where 0 = no pain and 10 = worst pain). Patients were interviewed approximately 1 h (range up to 3 h) after analgesia was first offered. The questionnaire (Appendix S1) surveyed analgesia taken within 4 h of ED attendance, pharmacological analgesia administered in ED, pain scores and patient attitudes towards their pain management. Likert scales were used to document patient satisfaction, willingness to receive non-pharmacological analgesia and acupuncture as an adjunct to UAC, concern regarding addiction to UAC given in ED and if patients reported an adverse event to their analgesia – their willingness to receive this medication again.

Data analysis

‘Adequate analgesia’ was defined as NPRS decreased by ≥2 from the triage NPRS and to a level of <4. Six-point Likert scales were collapsed to binary responses with no ≤3 and yes ≥4. For example, 'general
satisfaction’ was defined as ≥4/6. To allow comparison with other studies, those who were ‘very satisfied’ (6/6) were also compared to those who scored ≤5. Stata (14.1 StataCorp™, College Station, TX, USA), was used to conduct univariable logistic regression to assess associations between binary outcomes and potential predictors. Multivariable models included predictors with P-values ≤0.1 on univariable analysis. A P-value <0.05 was considered significant.

Results

Key results including responses to questionnaire and logistic regression outcomes are reported in Tables 1 and 2, respectively. Of 196 adult patients who completed the survey (six documented refusals), 52.8% were ‘very satisfied’ with their analgesia. General satisfaction was significantly associated with male gender (multivariable odds ratio [OR] = 8.44). Achieving ‘adequate analgesia’ was significantly associated with being ‘very satisfied’ (multivariable OR = 3.92), but not with receipt of opioid analgesia. Most patients (84.7% rating ≥4/6 on Likert scale) would accept non-pharmacological

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Median score (IQR)</th>
<th>Percentage ≥4/6 on Likert scale (95% binomial exact confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity of pain on ED presentation, NPRS (n = 196)</td>
<td>7 (6, 8)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Severity of pain 1 h after analgesia was offered, NPRS (n = 193)</td>
<td>4 (3, 6)</td>
<td></td>
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<tr>
<td>Time from triage assessment to first dose of pharmacological analgesia (min) (n = 168)†</td>
<td>45 (26, 79)</td>
<td></td>
</tr>
<tr>
<td>Time from pharmacological analgesia to administration (min) (n = 116)§</td>
<td>8 (3.8, 14.3)</td>
<td></td>
</tr>
<tr>
<td>Satisfaction out of 6 Likert scale (n = 195)</td>
<td>6 (5, 6)</td>
<td>93.3% (89.5–96.8%)</td>
</tr>
<tr>
<td>Patients’ openness to non-pharmacological methods of analgesia as an adjunct to their pain management – rating out of 6 Likert scale (n = 196)</td>
<td>5 (4, 6)</td>
<td>84.7% (78.9–89.4%)</td>
</tr>
<tr>
<td>Patients’ willingness to use acupuncture in addition to pharmacological analgesia – rating out of 6 Likert scale (n = 195)</td>
<td>4 (3, 5)</td>
<td>68.9% (61.9–75.3%)</td>
</tr>
<tr>
<td>Patient’s concern regarding addiction to the pharmacological analgesia given in ED – rating out of 6 Likert scale (n = 196)</td>
<td>1 (1, 3)</td>
<td>21.4% (15.9–27.8%)</td>
</tr>
<tr>
<td>Of patients who reported adverse effects to their pharmacological analgesia (n = 39/196 = 19.9%, confidence interval 14.5–26.2%) rating out of 6 Likert scale the likelihood they would avoid this medication in the future</td>
<td>4 (2, 4)</td>
<td>51.2% (34.8–67.6%) (of the 39 that had reported side-effects)</td>
</tr>
</tbody>
</table>

†Categories for the Likert scales: 1 = ‘very’ unsatisfied/unagreeable/unconcerned/unlikely; 2 = ‘un’-satisfied etc.; 3 = ‘slightly’ unsatisfied etc.; 4 = ‘slightly’ satisfied etc.; 5 = ‘satisfied’ etc.; 6 = ‘very’ satisfied etc. §Sixteen documented refusals of offered analgesia. †In 52 cases doctor order time not noted. ¶88.2% gave a yes response before providing Likert range quoted here. IQR, interquartile range; NPRS, numerical pain rating scale.
<table>
<thead>
<tr>
<th></th>
<th>Satisfied (≥4/6 Likert)</th>
<th>Very satisfied</th>
<th>Patients taking opioids ≥4/24 prior to ED</th>
<th>Patients receiving opioids in ED</th>
<th>Patients willing to use non-pharmacological methods</th>
<th>Patients willing to use acupuncture</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (%)</td>
<td>183 (93.9%)</td>
<td>103 (52.8%)</td>
<td>48 (24.5%)</td>
<td>113 (57.7%)</td>
<td>166 (84.7%)</td>
<td>135 (68.9%)</td>
</tr>
<tr>
<td>Very satisfied</td>
<td>N/A</td>
<td>N/A</td>
<td>0.90 (0.48–1.74)</td>
<td>1.07 (0.60–1.89)</td>
<td>1.84 (0.83–4.07)</td>
<td>1.02 (0.56–1.87)</td>
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<tr>
<td>(reference = not very</td>
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<td>satisfied)</td>
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<tr>
<td>Age 18–29 years</td>
<td>1.00 (0.58–1.60)</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td>0.54 (0.09–2.27)</td>
<td>1.52 (0.33–4.32)</td>
</tr>
<tr>
<td>Age 30–49 years</td>
<td>3.11 (0.58–16.80)</td>
<td>4.26 (1.20–15.02)</td>
<td>2.42 (0.63–9.32)</td>
<td>1.57 (0.57–4.34)</td>
<td>0.46 (0.09–2.27)</td>
<td>1.52 (0.33–4.32)</td>
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<tr>
<td>Age ≥50 years</td>
<td>3.03 (0.69–13.20)</td>
<td>4.67 (1.40–15.48)</td>
<td>2.00 (0.55–7.28)</td>
<td>3.96 (1.48–10.58)</td>
<td>0.61 (0.13–2.87)</td>
<td>1.37 (0.52–3.59)</td>
</tr>
<tr>
<td>Gender</td>
<td>8.44 (1.05–67.44)</td>
<td>1.47 (0.83–2.59)</td>
<td>0.52 (0.26–1.02)</td>
<td>0.87 (0.49–1.54)</td>
<td>0.40 (0.18–0.90)</td>
<td>0.57 (0.31–1.04)</td>
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<td>(reference = female)</td>
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<tr>
<td>Adverse effects</td>
<td>0.47 (0.13–1.66)</td>
<td>0.81 (0.40–1.64)</td>
<td>1.68 (0.78–3.60)</td>
<td>1.86 (0.88–3.93)</td>
<td>0.99 (0.38–2.62)</td>
<td>1.65 (0.73–3.73)</td>
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<td>(reference = nil)</td>
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<tr>
<td>Concern for addiction</td>
<td>1.35 (0.28–6.44)</td>
<td>1.73 (0.85–3.52)</td>
<td>0.65 (0.28–1.52)</td>
<td>0.43 (0.21–0.89)</td>
<td>2.76 (0.80–9.60)</td>
<td>1.58 (0.72–3.48)</td>
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<td>to pharmacological</td>
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<td>analgesia administered</td>
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<td>in ED (≥4/6)</td>
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<tr>
<td>(reference = no concern)</td>
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<tr>
<td>Achieved ‘adequate</td>
<td>6.76 (0.84–54.12)</td>
<td>3.92 (2.06–7.45)</td>
<td>1.36 (0.70–2.62)</td>
<td>0.87 (0.49–1.57)</td>
<td>0.70 (0.32–1.54)</td>
<td>1.00 (0.54–1.86)</td>
</tr>
<tr>
<td>analgesia’</td>
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<td>(reference = not achieved)</td>
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</table>
| †Note where values associated with P-values <0.05 are marked in bold. ‘Adequate analgesia’, triage pain score reduced by ≥2 and to a level <4; CI, 95% confidence interval; OR, odds ratio from univariable or multivariable logistic regression (latter marked ‘adjusted’).
methods of analgesia including acupuncture (68.9%) as an adjunct to their ED pain management. Overall 78.6% were unconcerned about addiction to the pharmacological analgesia received in ED; of those who received an opioid 84.1% were unconcerned. A significant minority (19.9%) had patient reported UAC adverse effects. Increasing age was associated with being ‘very satisfied’ with ED pain management and females were significantly more willing to use non-pharmacological analgesia. Patients who were concerned about addiction to the medications received in ED were less likely to have received opioids, while older patients were more likely to have received opioids.

Discussion

We found similar results to the TARGET study for percentages of patients ‘very satisfied’ with UAC and the association with ‘adequate analgesia’. In addition, our study showed an association between general satisfaction and being male but not with administration of opioids. The lack of improved satisfaction with opioids is consistent with the study by Bhakta et al. There was a high degree of willingness of patients in our study to try non-pharmacological methods of analgesia including acupuncture, particularly for females, which is consistent with other studies. In recent trials, non-pharmacological methods such as acupuncture, achieved high patient satisfaction. The reasons for willingness to use non-pharmacological methods may be because of a desire for holistic care and to avoid UAC adverse effects including addiction. Our survey showed a significant incidence of UAC adverse effects, but a minority were concerned about addiction.

There is only a theoretical risk, as opposed to ED discharge prescription of opioids where there is a documented risk, that brief exposure to intra-departmental opioids could trigger ongoing misuse, hence the trend to ‘opioid free’ or ‘opioid light’ EDs. Further investigation is required to evaluate this risk and whether the low concern by patients is justified. In recent acute pain management guidelines, such as for low back pain, non-pharmacological therapies are increasingly encouraged, and the use of opioids discouraged. The aims of these recent guidelines have been to reduce accidental overdose deaths from opioids (particularly middle-aged males) and addiction. It is reassuring that most of the surveyed patients, and in particular females, would be open to this change in direction.

Conclusion

Most patients were ‘generally satisfied’ with analgesia in the ED and willing to accept non-pharmacological methods of pain relief, including acupuncture. The further introduction and evaluation of acupuncture as a non-pharmacological analgesic alternative in ED from the patients’ perspective is justified.

Limitations

There are several limitations to this study creating possible bias. The questionnaire was not formally validated and was administered 1–3 h after UAC was offered, therefore patient perceptions may not be reflective of the entire ED presentation. Our methodology utilised a convenience sample with recruitment limited by researcher availability. The sample size may be underpowered for some outcomes and predictor variables while analysis was post hoc rather than preassigned.

Acknowledgements

ALJ is a PhD candidate and received support from the University of Notre Dame Australia, Fremantle, the Australian Government Research Training Programme Scholarship and St John of God Murdoch Hospital.

Author contributions

ALJ, ESA, IRR, EJV and MKB designed the study, while ALJ, ESA, IRR and EJV carried out data collection and all (ALJ, ESA, IRR, EJV, MKB and DAH) assisted with analysis. All authors contributed to review and revision of the manuscript, and all take responsibility for the final version. This study was carried out at St John of God Murdoch Hospital.

Competing interests

None declared.

References


Supporting information

Additional supporting information may be found in the online version of this article at the publisher’s website.

Appendix S1. Questionnaire used for this study.

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4.2 Afterword

Supplementary materials for the publication presented in this chapter can be found in Chapter 4 Appendix, Section A.

4.2.1 What went well?

4.2.1.1 Methodology

A quality questionnaire has content validity, i.e., representing the theoretical construct and reliability between survey personnel and repeat surveys. The research team experts assessed the content validity of the questionnaire. An established measurement tool was used to cover aspects of the ED pain journey, from pre-attendance analgesia to the end of the first hour. It was likely reliable given the sample size and the consistent results between various survey personnel (see Chapter 7 Appendix, Section C).

4.2.1.2 Findings

The strength and reliability of the survey was demonstrated by the consistency of findings with similar research (see Chapter 7 Appendix, Section C). Survey findings show that the clear majority of patients were willing to use acupuncture, which is consistent with the findings of other surveys, including those based in public EDs. The comments section of the survey provided useful information, with some quotes provided on the first page of this chapter. Frequent reasons for rejecting acupuncture included a phobia of needles, prior experience of acupuncture being ineffective and the condition being too painful. Although these qualitative comments were outside the standard Likert responses, they provide some in-depth insights into ED acupuncture.

Consistent with the literature and expected was the lack of association between patient satisfaction and opioid use. Interestingly, and again consistent with the literature, women were more interested in non-pharmacological methods such as acupuncture. It may be coincidental, but males, particularly the middle-aged group, prefer pharmacological analgesia and are more frequently the victims of accidental opioid death. Further, logistic regression analysis showed an inverse relationship between concern about opioid addiction and the likelihood of receiving opioids. Although associations were found post hoc, this survey generated a theoretical narrative with which to understand the complexities of pain management in our community. This narrative may then be subjected to more rigorous research for validation.
Based on the results of the survey, the three conditions chosen for the upcoming RCT were abdominal pain, limb trauma pain and low back pain, all of which are commonly seen in the ED. There is also evidence for acupuncture’s analgesic efficacy for these conditions based on RCTs and observational studies presented in Chapter 2.

4.2.2 What was unexpected or disappointing?

4.2.2.1 Methodology

Ideally, a pilot study would have been conducted prior to the survey to test content and construct validity (questionnaire tool consistently measures what it purports to measure). Although we did not use kappa statistics to measure reliability, we used logistic regression to test for differences between survey participants, as mentioned above (see Chapter 7 Appendix, Section C).

4.2.2.2 Findings

The survey only covered pre-attendance analgesia and analgesia administered within the first hour of ED admission. However, ED analgesia continues to be administered following the first hour and post discharge; thus, future surveys could research this time frame. In their study on ED acupuncture, Cohen et al. found that patient satisfaction with acupuncture improved on second-day follow-up (see Chapter 7 Appendix, Section E ref. no. 51). This reason for this is that retrospective reflections on pain management—once the patient is out of pain and away from the hectic ED environment—may differ. These retrospective perspectives may also apply to the adverse effects of analgesia. In our survey, the 20% incidence of adverse effects was unexpectedly high, with half of these patients stating that they would not have their administered analgesia in the future. However, this result could change once adverse symptoms have passed.

The high rate of opioid administration in the ED was disappointing. This high rate was consistent by comparison with similar surveys (see Chapter 7 Appendix, Section C). The research findings on the hazards of take-home opioid prescription appear to have been incorporated into our department's mindset, with almost zero opioid prescriptions supplied and a small take-home pack provided instead. However, at the time of the survey, the study by Veal et al. had not yet been released (see Chapters 1 ref. no. 8). This study showed that 5.6% of opioid-naive patients that had received oxycodone administered while in the ED persisted with opioid use following discharge.
Another surprising result was the low patient concern about opioid addiction compared with patients in the US (see Chapter 7 Appendix, Section C). This may be attributable to lower concerns about addiction in Australia, opioid addiction being less publicised or a higher concern about take-home prescriptions. As stated above, patients with little concern about opioid addiction are more likely to receive opioids. Thus, to some extent, patients receive the analgesics they want, highlighting the importance of patient attitudes towards analgesia. If there is a change in practice, patients will need to have the same concerns as those of providers (i.e. therapeutic alignment).
Chapter 5: Lessons Learned in Teaching Battlefield (Ear) Acupuncture to Emergency Medicine Clinicians

‘The national conference acupuncture course was fantastic’.
‘The course was both concise and well presented’.
‘Great introduction, with useful tools given. Will definitely start using acupuncture again’.
‘I believe this acupuncture work/research is one way forward to addressing the opioid epidemic problem’.

—Sample of comments from emergency clinicians attending the acupuncture workshops

<table>
<thead>
<tr>
<th>What is already known on the topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Half-day battlefield acupuncture (BFA) courses are popular in the US. To date, likely over 7,000 non-acupuncturist providers have been trained in BFA. Medical candidates deemed competent receive a letter recommending they be credentialed for BFA and given clinical privileges at their hospitals.</td>
</tr>
<tr>
<td>• Physiotherapists in Australia require a minimum of 16 hours of training to practise body or ear acupuncture techniques. It is uncertain what the minimum training for ED clinicians should be.</td>
</tr>
<tr>
<td>• Prior studies have shown that extended acupuncture training does not improve analgesic outcomes.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What this research adds</th>
</tr>
</thead>
<tbody>
<tr>
<td>• BFA is teachable in a short-course format to emergency clinicians.</td>
</tr>
<tr>
<td>• Appropriate BFA teaching methods for emergency department (ED) doctors and nurses should cater to the unique case mix and challenging environment.</td>
</tr>
<tr>
<td>• Administrative barriers to clinicians administering BFA or body acupuncture in Australia and other countries include the undefined minimum training standards and lack of formal credentials for acupuncture in the ED.</td>
</tr>
<tr>
<td>• Further administrative support from emergency medicine and acupuncture colleges is required to provide minimum training standards and promote ED acupuncture courses.</td>
</tr>
</tbody>
</table>
5.1 Foreword

5.1.1 What is already known or knowledge gaps that require elaboration

The aim of Chapter 5 is to provide information about the training outcomes outlined in Chapter 1. The question posed in Chapter 1 was, ‘How much basic training do ED clinicians (doctors, nurse practitioners, physician assistants and nurses) need to be competent and safe?’ Alternatively, qualified acupuncturists may be employed as pain management assistants. Both have advantages and disadvantages, and applicability may depend on the size of the ED.

To date, the teaching of ED acupuncture in Australia is minimal. Two workshops have been presented at annual national emergency medicine conferences. Only a small number of emergency physicians practise ED acupuncture in Australia, the majority of whom have received training at AMAC, with the remainder receiving training abroad. While BFA courses are popular in the US, the number of clinicians performing BFA in EDs is unknown. It is also unknown how many emergency physicians practise traditional or body acupuncture. However, several emergency physician researchers in the US, including Lindsay Fox, Shui-Lin Tsai, John Burns and Jonathon Glauser, are currently promoting the use of BFA and body acupuncture.

Minimum training standards for ED acupuncture remain ill defined. While medical professional attendees to BFA courses are given a letter of competency and recommendation for accreditation, it is unknown how much supervision these candidates require following the course. This chapter explores these issues.

Given the vast range and acuteness of presentations seen in the ED at all hours, demands exist for multiskilled clinicians being immediately available. Having multiskilled emergency physicians is preferable to relying on continual access to a range of hospital specialists. The challenging process of incorporating specialist skills such as anaesthesia and ultrasound has been a feature of the evolution of emergency medicine. The introduction of these skills initially involved interdisciplinary disputes and discussions about minimum training and competency standards. I envisage ED acupuncture will follow a similar path.

5.1.2 What was done that was different?

Chapters 2–7 provide evidence about the various outcomes stated in Chapter 1 to justify the introduction of acupuncture into the ED. For ED acupuncture to ultimately become embedded in the ED analgesic armamentarium, several processes will need to happen to ensure its long-
term success. This process may be compared to the well-known ‘chain of survival’ for cardiac arrest (see Figure 5.0). Chapter 4 focused on the second link in the chain—patients’ willingness to use and satisfaction with ED acupuncture. Chapter 5 provides information on the final three links in the chain—provider satisfaction, teaching and governance (see Figure 5.0)—as part of the chain of processes required for the successful incorporation of acupuncture into ED SAC.

![Figure 5.0: Chain of processes needed to embed acupuncture in the emergency department analgesic armamentarium.](image)

While much of the evidence presented in this thesis is based on high-quality evidence, there is still a place for expert opinion, which serves the purpose of linking the art of medicine with evidence-based practice (discussed further in Chapter 7). Chapter 5 mostly offers expert opinion on training outcomes. There is a place for advice from an experienced teacher, emergency physician and acupuncturist such as me. I was certified as a specialist emergency physician in 1987 and a specialist acupuncturist in 1995. I learned the BFA technique from Joseph Helms in 2012 and received further training from Colonel Richard Niemtzow, the inventor of BFA. I have used acupuncture techniques both in the ED and outpatient settings, along with teaching of emergency medicine, for most of my medical career. The publication presented in this chapter also sourced information from the ED acupuncture post-course questionnaires and external literature.
Lessons Learned in Teaching Battlefield (Ear) Acupuncture to Emergency Medicine Clinicians

Andrew L. Jan, MBBS, FACEM, BA, FAMAC, MPhil

ABSTRACT

Background: Acupuncture, in general, is being proclaimed as an alternative analgesic amid the opioid crisis, and along with this, within emergency departments (EDs) there is a specific interest in a form of ear acupuncture called Battlefield Acupuncture (BFA). It is expected that BFA will be used more widely in emergency medicine as it is easy to learn and can be applied both promptly and easily. Teaching programs will be required to sustain this increased demand and upskill emergency clinicians in this skill.

Objectives: This article provides experiences and recommendations, based on faculty experiences from teaching BFA in Australia to ED clinicians combined with formal participant feedback.

Main Points: BFA courses were adjusted to suit ED doctors and nurses, along with their unique case mix and associated challenging environment. The content of the BFA courses included evidence, pain indications, contraindications, application, safety, mechanism of action, and how to negotiate barriers of credentialing. Workshops used the latest and most effective teaching methods that encompassed problem-based learning, infotainment, simulation, “four stage skills teaching,” and “teaching on the run.”

Conclusion: It is hoped that the experiences gained, and lessons learned in educating this new frontier of BFA to emergency clinicians will assist others in teaching BFA and its related techniques as a viable analgesic alternative in emergency medicine.

Keywords: teaching, auriculotherapy, battlefield acupuncture, emergency medicine, ear acupuncture, pain management

BACKGROUND

Acupuncture, in general, is being proclaimed as an alternative analgesic amid the opioid crisis. With the current increased provider and consumer interest in the use of all forms of acupuncture within the emergency department (ED), it is expected that acupuncture will be used more widely in emergency medicine.

Different approaches for acupuncture are required compared with outpatient or perioperative acupuncture, as ED patients have varied acutely painful conditions, and the environment is chaotic and busy. To date, formal training requirements and governance to perform any form of acupuncture in ED are ill-defined. Teaching in emergency medicine has advanced considerably over the years with the introduction of such new methods as problem-based learning, infotainment, simulation, “four stage skills teaching,” and “teaching on the run.”

Battlefield Acupuncture (BFA) is the most likely form of acupuncture to gain traction in the ED as it is standardized, easily learnt, readily applied, can be used for a wide range of painful conditions, and has been subject to many randomized clinical trials (RCTs) (Table 2). BFA is a form of ear acupuncture invented in 2001 by United States Airforce Colonel Richard Nientzow for rapid non-pharmacological analgesia by medical and allied health professionals.

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To gain traction of BFA in the emergency setting, education in BFA for emergency clinicians needs to adopt these recent education advancements, negotiate administrative hurdles, and adapt teaching to suit the ED clinicians, case mix, and environment.

OBJECTIVES

This article will provide an overview of ED-based BFA training, based on faculty experiences from teaching BFA workshops, combined with formal student (participant) feedback. It will assemble experiences, ideas, and recommendations on teaching BFA by looking at: "who was taught"; "how BFA was taught"; "what was taught"; "who taught"; the "take-home manual" and "using feedback."

MAIN POINTS

Who Was Taught?

The audience for our workshops included predominantly emergency physicians (EPs), but also ED nurse practitioners and ED nurses. This article, although focusing on teaching EPs BFA, will also include some discussion concerning nurse practitioners and nurses and collectively refer to them as "emergency clinicians." The insightful educator understands the personality, the needs and interests of these candidates, and adopts a teaching style accordingly.15,16

What Are the Characteristics of Emergency Clinicians That Need to Be Accommodated in Teaching? EPs, whether it be through career selection or by necessity, enjoy making a diagnosis and completing management in the first ED visit. Furthermore, there is often the profusely satisfying reward of making a diagnosis, the utilization of hands-on intervention and rapid symptom improvement in a limited time frame.17 This vocational contentment applies to such interventions as joint relocation, repair of lacerations, and relief of symptoms such as dyspnea or pain. EPs do vary among themselves in risk taking with modalities or procedures.18 They are more radical and open to new modalities compared with other specialties, and the majority are willing to challenge old stagnant paradigms, with the proviso that there is grounding in evidence.19 Many begin with a strong sense of social justice,20 and this is reinforced by emergency staff (such as prehospital workers) working at the coal face having to manage patients’ acute medical and mental crises caused by their surrounding societal circumstances. EPs like to feel that their practice is not influenced by the pecuniary forces of pharma and industry.21,22 However, according to expert opinion and evidence, this is unlikely to be true.21,23 There are many subtle ways that both prescribing habits and referrals for procedures are swayed.

BFA, although initially intended for frontline military usage with its rapid and standardized approach, might suit the EP mind-set. This mind-set should resonate with this modality as it suits their risk profile as acupuncture has minimal risk of adverse events and is justified ethically by a growing body of evidence. It is a hands-on practical skill with a potential immediate intervention/symptom relief modality. BFA is a new modality amidst a current pharmaceutical and interventionist-based medical fraternity, although having its roots in the Chinese healing arts of yesteryear.24 This modality potentially offers a refreshing and rewarding new paradigm, with a hands-on skill that stands outside the current influences of industry and pharma.

Nurse practitioners hold that space somewhere between a doctor and a nurse. They have developed the cognition that includes differential diagnoses and a skill set that includes ED procedures. Indeed, as a group, they also have an active social conscience,25 and those in our specific ED are deeply concerned with opioid overprescribing and have had some training in acupuncture. In all, they are ideal candidates to learn both body and ear acupuncture.

ED nurses have the mind-set to keep the department moving and often enjoy a closer relationship to the patient compared with the treating doctor. They perform necessary skills such as intravenous lines, urinary catheters, and defibrillation. The skill and application of BFA are ideal for them as it can be applied at triage, has one prescription that fits all, and is easy to learn.

How BFA Was Taught

An effective teacher in BFA for informed EPs must be both up-to-date and well versed in the evidence-based paradigm. The teaching of evidence and what it must cover is discussed in a subsequent section. The current standing of BFA is presented in our previous reviews.2,13

However, the BFA teacher can also present some of the limitations of our current evidence-based paradigm. Some examples include utilizing therapies when trials have shown a nonstatistically significant result, excluding long-term outcomes such as quality of life and using the supposed placebo effect by incorporating "the art of medicine" into their practice.

There are RCTs that show a nonstatistical difference for the effectiveness of acupuncture as stand-alone or as an adjunct (for some examples see Table 2). Young et al. argue that for modalities such as acupuncture, which has a low adverse event rate and cost, then one should consider incorporating these therapies even if trials show a nonstatistically significant difference.26 These authors believe that the burden of proof should lie with the expensive harming treatments and not with the cheaper nonharming
modalities. Furthermore, many RCTs have outcomes that are short term and exclude long-term quality measures. The natural progression from a successful general acupuncture treatment is for the patient to move on to other healing modalities within the Taoist framework, such as meditation, Tai Chi, Chi Kung, and its associated philosophies. Patients requiring opioid analgesia after an acutely painful problem, such as an injury or post-operative, are significant and constitute 27% of those becoming chronic users. Whereas body or ear acupuncture patients are more likely to move on to other nonpharmacological techniques that empower them as a whole person and may improve well-being for years.

Eps may be skeptical about an aspect of acupuncture known as "therapeutic touch." This therapeutic touch can be described as belonging to the "art of medicine," with such methods as "compassion," "soft words," and the "holding of hands." Acupuncture, in general, incorporates therapeutic touch and a positive verbal exchange as key elements in the acupuncturist-patient interaction. BFA, although being a specific form of acupuncture, is likely to utilize this "art of medicine" with its substantial evidence base. Eps may regard therapeutic touch as part of the placebo effect and, therefore, stands outside evidence-based medicine. For some, it may be just "too touchy-feely" (Haphephobia). These misconceptions can be argued against and even supported by evidence-based medicine.

First, incorporating this "art of medicine" into emergency medicine practice is likely to reduce malpractice claims and improve patient satisfaction. Second, there is some evidence that this "therapeutic touch" is an effective analgesic. The teacher presents this, is a challenge, as doctors get caught up in their biases and prejudices. To date, it has been raised in various ways, mostly dependent on the audience. There were times when this "art of medicine" was made a serious issue, whereas at other times a quick reference was presented in a humorous tone.

Methods. The author and faculty delivered blended BFA courses (online and face-to-face) to Eps at a national conference, clinicians in his ED (both within and external to a BFA clinical trial), and physiotherapists. A mixture of teaching techniques was used oriented to specific outcome measures that included multimedia presentations, including prerecorded videos, problem-based learning, simulation, Peyton’s 4-stage method, infotainment and “teaching on the run.”

Precourse learning was provided primarily through prerecorded videos of lectures and skills along with assigned prereading. Topics covered in our prerecorded videos included: “Overview of application, suitability and case selection of ED BFA”; “Current evidence supporting ED ear acupuncture”; “How to perform BFA”; “Ear Acupuncture mechanisms”; and “Safety of BFA.” Included in the precourse package were videos by the inventor Dr. Richard Nientzow on, “Opening the packaging, removing an applicator and demonstration of the size of the needle” and “Application of the BFA points in sequence on one ear.” Also included were videos that we made ourselves on, “The application of BFA and Duoderm tapes” and “The safe removal of the needles in the ED environment.”

We provided key articles that included our systematic ear review, but would recommend for future courses for EP participants to include Dr. Richard Nientzow’s original BFA article, along with all BFA trials to date as listed in Table 2. The advantages of the online precourse learning were flexibility and time saved for the participants. The intentions were to enable the more rapid progression of the cognitive and skills load required for mandatory competencies in the face-to-face session. Complex new skills require multiple exposures for skill acquisition and could be attributed to latent learning or explained as digestion and integration of new material between sessions. The student could clarify questions that arose during the precourse materials through various platforms (e.g., web browsing) or by contacting the faculty. These online materials were also used for postworkshop reference and confirmation of specific skills and knowledge.

Simulation was especially crucial for participants using ear needles for the first time. The BFA sequence and anatomical point locations are shown in Figure 1. In this study, we provided model silicone ears that helped teach the dexterity required in using the Aguinile Semi-Permanent (ASP—Sedateele, Igny, France) ear needles (Figs. 2 and 3). Silicone ears can be obtained cheaply in bulk from Chinese distributors through an online marketplace company such as Alibaba.com. The ears with needles in situ also provided an aide-memoir for point location and a tool to assist informed consent for future patients.

“Peyton’s four-stage method” of teaching is frequently utilized in ED teaching and is heavily promoted in Advanced Life Support, and Advanced Trauma Life Support courses. This method can be adapted to acupuncture teaching, where “the silent run through” is shown directly or on prerecorded videos. Then in hands-on sessions, the instructor talked the candidate through, students then talked each other through, and then began self-practice.

“Infotainment” is teaching with humor, competitions, multimedia, and music. This technique was used in teaching a couple of the aspects within the course, including the contraindications for BFA (Table 3). We intend to increase and recommend to others this modern teaching technique in future courses to gain maximum traction and remain aligned to other Free Open Access Medical education (FOAM) materials.

“Teaching on the run” was a useful modality when any of the ED faculty were present in the department. With actual patients, the teacher called upon candidates to further reinforce learnt skills concerned with BFA indications, safety, and application.
**FIG. 1.** Sequence and point location for the 10 points of Battlefield Acupuncture for left and right ears (used with permission). Point locations are in order of application: Cingulate (1,2), Thalamus (3,4), Omega 2 (5,6), Shen Men (7,8), and Point Zero (9,10). In clinical practice, pain score checks are performed after needle insertion with pauses (walking, raising arms, or deep breaths), and application is ceased when pain reduction is achieved or if the patient requests.

“Problem-Based Learning” is paramount as teaching and research must be connected to the real world, that is, linked to real clinical analgesia problems that currently do not have ideal outcomes. In this study, problem-based learning methods were applied to the utilization of BFA. Cases presented in Table 1 were put to the class for discussion before BFA was recommended as an analgesic option.

There is both body and ear acupuncture research in emergency medicine that does not apply to analgesic problems encountered in the participants’ local ED case mix. Analgesic problems will vary according to local patient demographics and illness prevalence. For example, there was a recent trial on using body acupuncture to treat renal colic, which showed noninferiority to morphine. In our suburban Australian case mix, nonsteroidal anti-inflammatory drugs and opioids are used successfully to treat renal colic without apparent short or long-term adverse effects. Therefore, it does not make much sense to an Australian EP to recommend any form of acupuncture for renal colic. However, for a different location and case mix, where renal colic may be a guise for opioid seeking or recurrent use, then it may be appropriate to consider BFA or body acupuncture as an analgesic alternative. Using the same argument for other trials on different painful conditions, treating limb fractures or sprains, is illogical from this perspective as these conditions are at low risk of ongoing opioid use. After splinting or strapping, the pain should be controlled. In contrast, if the patient and practitioner were in the wilderness or on the front line in combat, then a prescription for BFA would be highly appropriate.

**FIG. 2.** Take-home life-size silicone ears were used for the initial practice of Battlefield Acupuncture. These ears not only provided suitable simulation but also were an aide-memoir for point location and a useful tool to assist in obtaining patient consent.
What Was Taught—The Curriculum

Objectives and Outcomes. The BFA course aimed to provide the essential areas of evidence, safety, mechanisms, application, and needle use. We expected that emergency clinicians be competent to practice BFA after completion of the course. Although body acupuncture has been taught on some of the courses, BFA was given priority as it is easy to learn, was designed to treat all pain types, and has been studied in many RCTs for acute pain in the ED and perioperative environment (Table 2).

Table 1. Showing Six Examples of Problematic Presentations, Where Standard Analgesia Care Has Risks in Management, and Where Battlefield Acupuncture Could Have a Role

<table>
<thead>
<tr>
<th>Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>A middle-aged man presents with low back pain and has some</td>
</tr>
<tr>
<td>yellow flags picked up by an astute clinician using the “STArt Back” screening tool. Paracetamol and anti-inflammatorities had no effect! This man has a risk of opioid ongoing adverse effects, including overdose and death.</td>
</tr>
<tr>
<td>A patient with chronic pain presents with an acute exacerbation and</td>
</tr>
<tr>
<td>wanting opioids.</td>
</tr>
<tr>
<td>A middle-aged woman represents with a headache that has already</td>
</tr>
<tr>
<td>been thoroughly investigated, and standard analgesia care has failed!</td>
</tr>
<tr>
<td>An elderly patient presents with osteoarthritis of the knee or hip</td>
</tr>
<tr>
<td>with pain and difficulty walking.</td>
</tr>
<tr>
<td>An elderly person presents with fully investigated spinal pain secondary</td>
</tr>
<tr>
<td>to degenerative disease.</td>
</tr>
<tr>
<td>A middle-aged patient presents with prior multiple shoulder steroid</td>
</tr>
<tr>
<td>injections for subacromial bursitis, supraspinatus tendinitis, or</td>
</tr>
<tr>
<td>adhesive capsulitis.</td>
</tr>
</tbody>
</table>

Understanding the Evidence. Teaching the evidence supporting BFA use is the one cornerstone that will ultimately gain BFA’s traction in the ED. The teaching should not only include the actual evidence but also how to interpret it. The evidence presented needs to apply to real-world problems that the specific audience of EPs and nurses face. In teaching evidence, 3 study designs and meta-analyses need to be explained. Other aspects can include the study setting, the Cochrane quality assessment tool, and secondary outcomes such as opioid reduction, adverse events, or patient satisfaction.

The first form of evidence is to examine a study design where acupuncture as the modality under question, is compared with placebo. A potential alternative efficacious modality needs analgesic effectiveness above sham. This evidence can be applied to a clinical situation where a patient has a high risk of adverse effects to standard analgesia care (SAC) and justifies the use of acupuncture as an alternative analgesic. One is replacing an established therapy with an evidence-based alternative, for example, with the use of ear acupuncture for migraines as shown by Allais et al.9 The ear point used in this migraine trial corresponds to the Thalamus point used in the BFA sequence (Fig. 1).

The second study design is acupuncture versus SAC. This type of evidence reassures the practitioner that acupuncture is noninferior and can also justify its clinical use as an alternative to SAC. The only ear trial of ear acupuncture versus SAC to date was for biliary colic.10 In this study, they used the sole acupoint “Erzhong,” which corresponds to Point Zero in the BFA prescription (Fig. 1).

The third situation or study design is using acupuncture as an adjunct. Here one can administer simple analgesia alongside acupuncture, such as by Goertz et al. for mixed pain types and show an improvement above SAC.11 This evidence may be the most sought-after evidence for future acupuncture trials as it anticipates that utilizing analgesia through different modalities is additive in terms of effectiveness and that opioids sparing occurs. This anticipated opioid sparing has been shown to occur in perioperative acupuncture studies but not in ED studies to date.24,26 Table 2 highlights aspects of the BFA studies to date. All except 1 trial showed a mean pain score reduction on day 1; however, this should be interpreted with caution as it was not the predefined primary outcome. The predefined primary outcome for pain score reduction was not statistically significant in 3 of the 9 studies. It is imperative in teaching BFA to emergency clinicians that current evidence is presented succinctly and objectively.

Needle Handling. Acupuncture needle handling was in alignment with current ED aseptic methods and included the “five moments of hygiene” and the aseptic no-touch technique.26 With the ASP gold needles, the applicator ensures that the needlepoint and shaft are not touched (Fig. 3). Isopropyl alcohol wipes were recommended for the use of semipermanent ear needles.26

FIG. 3. The ASP gold needle applicator and needle with a ruler in centimeters with 1-mm subdivisions. ASP, Aiguille Semi-Permanent.
### Table 2. Showing Battlefield Acupuncture Randomized Controlled Trials to Date

<table>
<thead>
<tr>
<th>First author, year and ref.</th>
<th>Study type</th>
<th>Location</th>
<th>Acute pain type</th>
<th>No. of participants (enrolled)</th>
<th>Overall study pain score improvement result</th>
<th>Pain score reduction at 24 hours or less compared with control</th>
<th>Secondary outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goertz, 2006&lt;sup&gt;44&lt;/sup&gt;</td>
<td>Adjunct</td>
<td>ED</td>
<td>Mixed</td>
<td>100</td>
<td>SS</td>
<td>Benefit <em>P</em> &lt; 0.05</td>
<td>Opioid use NSS</td>
</tr>
<tr>
<td>Moss, 2015&lt;sup&gt;36&lt;/sup&gt;</td>
<td>Adjunct</td>
<td>ED</td>
<td>Sore throat</td>
<td>56</td>
<td>SS</td>
<td>Benefit <em>P</em> &lt; 0.05</td>
<td>Less NSAIDs</td>
</tr>
<tr>
<td>Fox, 2016&lt;sup&gt;67&lt;/sup&gt;</td>
<td>Adjunct</td>
<td>ED</td>
<td>Low back pain</td>
<td>30</td>
<td>SS</td>
<td>Benefit <em>P</em> &lt; 0.05</td>
<td>Opioid use NSS</td>
</tr>
<tr>
<td>Crawford, 2019&lt;sup&gt;48&lt;/sup&gt;</td>
<td>Adjunct</td>
<td>PO</td>
<td>Lower limb</td>
<td>233</td>
<td>NSS</td>
<td>Benefit NSS</td>
<td>Opioid use NSS, Less NSAIDs</td>
</tr>
<tr>
<td>Plunkett, 2018&lt;sup&gt;50&lt;/sup&gt;</td>
<td>Adjunct</td>
<td>PO</td>
<td>Tonsillecctomy</td>
<td>95</td>
<td>NSS</td>
<td>Benefit NSS</td>
<td>Opioid use NSS</td>
</tr>
<tr>
<td>Kim, 2019&lt;sup&gt;50&lt;/sup&gt;</td>
<td>Adjunct</td>
<td>PO</td>
<td>Postpartum</td>
<td>70</td>
<td>NSS</td>
<td>Benefit NSS</td>
<td>Satisfaction NSS</td>
</tr>
<tr>
<td>Ndubisi, 2019&lt;sup&gt;51&lt;/sup&gt;</td>
<td>Adjunct</td>
<td>PO</td>
<td>Abortion</td>
<td>153</td>
<td>SS</td>
<td>Benefit <em>P</em> &lt; 0.05</td>
<td>Less anxiety</td>
</tr>
<tr>
<td>Collinsonworth, 2019&lt;sup&gt;52&lt;/sup&gt;</td>
<td>Adjunct</td>
<td>PO</td>
<td>Shoulder</td>
<td>41</td>
<td>SS</td>
<td>No benefit NSS</td>
<td>Opioid use NSS</td>
</tr>
<tr>
<td>Shah, 2019&lt;sup&gt;53&lt;/sup&gt;</td>
<td>Adjunct</td>
<td>PO</td>
<td>Tonsillecctomy</td>
<td>134</td>
<td>SS</td>
<td>Benefit <em>P</em> &lt; 0.05</td>
<td>Opioid use NSS</td>
</tr>
</tbody>
</table>

All trials used BFA as an adjunctive analgesic technique to standard analgesia care. Note that Goertz et al.<sup>44</sup> only used 2 of the 5 BFA points (Cingulate and Thalamus bilaterally), whereas Ndubisi et al.<sup>51</sup> replaced Omega 2 with Centre C ear acupuncture points. BFA, Battlefield Acupuncture; ED, emergency department; NSAIDs, nonsteroidal anti-inflammatory drugs; NSS, not statistically significant; PC, primary care; PO, perioperative; SS, statistically significant.

**Safety.** In teaching BFA, we remained mindful of the chaotic ED environment. This environment theoretically increases the risk of acupuncture adverse events, although they are uncommon. Although theoretically standard, a formal checklist for contraindications is crucial in the ED environment such as counting and documenting numbers of needles, the securing of needles with tapes, being prepared for fainting, and allowing patients to have access to a call button. The tapes supplied by Sedatelec are inadequate for the ED environment. They are poorly adhesive and do not prevent needle fall-out/blood exposure. In the ED environment, 2 other suitable tapes include cut 1-cm square Duo-DERM extra-thin (Convatec, Flintshire, United Kingdom) or Fixomull (BSN Medical, Charlotte, NC). The contraindications, both absolute and relative, were taught with the following mnemonic: “FABOH PIN” (Table 3) using entertaining video files.

In these early days of the utilization of acupuncture by ED staff, all participants are potential future advertisements and champions of the modality. Any complications caused by these potential champions could jeopardize this modality’s introduction as it attempts to gain a foothold in potentially skeptical EDs. Therefore, we added more emphasis on safety precautions and contraindications (Tables 3 and 4). Safety recommendations are aligned with current standards on other procedural skills performed in the ED, and hence hand hygiene, aseptic technique, and sharp disposal were easily taught. This case of learning provides further support to the argument supporting EDs requiring less training than other healthcare workers.

**Mechanisms of Acupuncture Analgesia.** Some researchers debunk acupuncture because it has no unified defined mechanism of action.<sup>25</sup> Likewise, for participants to “make sense” of this novel analgesic modality, they repeatedly asked the question, “how does acupuncture (including ear) work?” We frequently had to spend extra time to address the mind-set of the attendee on this point. To fully

### Table 3. Summary of Relative and Absolute Contraindications for Battlefield Acupuncture Using the Mnemonic “FABOH PIN”

<table>
<thead>
<tr>
<th>Contra-indications mnemonic for BFA: “FABOH PIN”</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>F. Fainting to needles</td>
<td>Take a fainting history, ask the patient to tell the practitioner if they feel sick or are going to faint, preferably perform acupuncture sitting on a trolley.</td>
</tr>
<tr>
<td>A. Allergy to tapes or gold</td>
<td>Avoid BFA for patients with a bleeding predisposition, on novel anticoagulants, or warfarin.</td>
</tr>
<tr>
<td>B. Bleeding predisposition (relative)</td>
<td>Patient already on opioids or who have chronic pain may get less effective pain relief.</td>
</tr>
<tr>
<td>O. Already on opioids</td>
<td>Risk of perichondritis seeding abnormal heart valve. Hearing aid interferes with application.</td>
</tr>
<tr>
<td>H. Heart valves prosthesis/ hearing aid</td>
<td>Little research on the safety of BFA in pregnancy.</td>
</tr>
<tr>
<td>P. Pregnancy</td>
<td>Predisposes to perichondritis and/or sepsis.</td>
</tr>
<tr>
<td>I. Infection at the needle insertion site, blood infection, or immune suppression</td>
<td>BFA may cause anxiety, fainting, or a stress response.</td>
</tr>
<tr>
<td>N. Needle phobia</td>
<td>BFA may cause anxiety, fainting, or a stress response.</td>
</tr>
</tbody>
</table>
TEACHING BATTLEFIELD ACUPUNCTURE IN ED

Table 4. Adverse Effects of Battlefield Acupuncture and How to Avoid Them

<table>
<thead>
<tr>
<th>Possible adverse effect</th>
<th>Prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needlestick injury</td>
<td>Don’t rush technique, don’t place finger directly behind acupuncture point on the ear, tape (DaoDERM or Fixomull) securely. Don’t perform over carpet, do a count, retrieve dropped needles with a magnet or vacuum cleaner.</td>
</tr>
<tr>
<td>Fainting</td>
<td>Take fainting history, warn of symptoms, apply acupuncture with the patient on a trolley.</td>
</tr>
<tr>
<td>Bleeding/body fluid exposure</td>
<td>Avoid those patients on novel anticoagulants or warfarin. If removing in ED or stopping bleeding—wear gloves.</td>
</tr>
<tr>
<td>Infection</td>
<td>Use isopropyl alcohol wipe with all patients, avoid those with poor hygiene, immune suppression, or local ear infection.</td>
</tr>
</tbody>
</table>

accept BFA, some needed to know of its likely precise mechanism! However, at times we encouraged them to be pragmatic, and agree that it is more critical to ask whether it is effective and whether patients accept it.

There are multiple and varied well-researched mechanisms of analgesia in acupuncture in general. These various mechanisms can range from the local release of mediators such as adenosine, bradykinins, prostanoids, “cord inhibition via the gate control model,” descending inhibitory control (endorphins, gaba amnibutyric acid, and acetylcholine); and central mechanisms that include alteration of the pain matrix, glial cells, and neurotransmitters. Since Dr. Richard Nienitzow invented the Battlefield prescription and its sequencing in 2001, BFA has stood the test of time, with clinical usage and a surge of clinical trials in recent times (Table 2). This BFA prescription included masterpoints from the research of Paul Nogier in the latter part of the 20th century. The ear, although likely achieving its mode of action through the aforementioned general mechanisms, also has ear-specific explanations. The Thalamus and Cingulate gyrus are parts of the brain matrix that are activated by body acupuncture in functional MRI studies. The Thalamus and Cingulate ear points have been demonstrated to affect analgesia when used alone, and are part of Nogier’s somatotropic representation of the cerebral homunculus on the ear. Nogier postulated that Omega 2 influences the mesodermal tissues of the body. Shen Men (spirit gate) is a traditional Chinese ear point, and its name suggests its mechanism. As previously mentioned, Point Zero (Chinese point Erzhong) was used in a study as the sole analgesic point in biliary colic. Furthermore, Point Zero is the center point of Nogier’s fetal homunculus, corresponds to the umbilicus, and is both innervated by and theoretically influenced by the vagus nerve.

Negotiate Administration Requirements. A primary goal of the course was to assist the candidate in identifying a pathway from learning to clinical practice with competence. This section required significant elaboration and was repeatedly questioned by candidates. Acupuncture in general and BFA are novel techniques that are encapsulated in controversy, territorial disputes, and ill-defined training requirements. This controversy applies to Australia, the United States, and many countries around the world.

In Australia, the Medical College of Acupuncture (AMAC) in alignment with the World Health Organization (WHO), recommends a minimum of 200 hours of training before a medical practitioner is deemed competent to perform any form of acupuncture (the first part certicate). At this stage, there are no minimum training standards within the Australian College of Emergency Medicine. Theoretically, all medical practitioners can perform body or ear acupuncture (or “dry needling”) with no training requirement and receive an Australian government Medicare rebate. However, a medical practitioner could be considered irresponsible if an adverse event occurred secondary to acupuncture if performing acupuncture without attending a recognized (currently no standard) basic course that included sufficient training on acupuncture safety. Both the medical board and medical insurers would be critical of a doctor carrying out procedures for which they are untrained.

Physiotherapists in Australia require 16 hours as minimum training before Western acupuncture, or dry needling can be practised. EPs have more advanced skills and knowledge of potential complications with needling than physiotherapists. It is the author’s opinion that EPs would require fewer hours in training to be competent in BFA or body acupuncture for common pain presentations than stipulated by these authoritative bodies. This is especially so for BFA, which should be regarded as being a stand-alone technique with separate credentialing and should not be placed under the umbrella of body acupuncture training requirements. Having such long training requirements (200 hours) would be an obstruction to the timely uptake of acupuncture as an analgesic alternative in the current opioid crisis. Currently, there are no clearly stated minimal training requirements for emergency doctors to practice any form of acupuncture in the ED. Post-BFA course, we recommended that participants obtain local approval from the ED Director and accreditation from the hospital credentialing committee. We will recommend that a Specialist Interest Group within the Australian College for Emergency Medicine be established to recommend minimum training standards.

In the United States, credentialing for physicians practicing acupuncture varies from state to state, with some allowing acupuncture within their existing scope of practice, and is presuming of the individual that they have had appropriate training and competency to offer safe treatment. Other states are recommending a minimum of 200 hours as recommended by WHO. In the BFA 4-hour courses run by the United States military, candidates deemed
Who Taught

Potential teachers on our Australian courses included EPs with formal general acupuncture qualifications, general (family medicine) practitioners from the examination faculty of the AMAC, and Traditional Chinese Medicine (TCM) practitioners. EPs understood the case mix and what problems of analgesia could be solved. Furthermore, they knew how to adjust body and ear acupuncture techniques to the ED environment while understanding the mind-set of the participants. We envisaged full-time general (family medicine) practitioner teachers from the examination faculty of the medical acupuncture college and full-time TCM practitioners would have precise point selection, location, and needle techniques. The TCM practitioner faculty we used had excellent knowledge on the Chinese cosmological theories but unfortunately had some biases against the biomedical model, which was noted in the formal feedback.

Take-Home Manual

A take-home manual was provided to allow further study, reinforcement of lecture content, and ready access to the BFA prescription, point location, and safety issues. It was provided in a pdf format and designed to be accessed on emergency staff’s mobile phones while on shift.

Using Feedback

Feedback was an essential component of the curriculum for such a novel modality attempting to gain traction with a new audience and for teaching methods that are attempting to match current benchmarks. It was agreed among the faculty that in establishing this new modality, the educators and the providers would be kept fully informed of each other’s challenges and successes. This feedback was the foundation on which the new modality would be laid. Participant feedback was all very positive, with an average rating for the BFA course being 5.6/6 on a Likert scale. As mentioned previously, requests were made for more lecture time on the theory of BFA’s mechanism for analgesia. Attendees enjoyed learning BFA mainly because of the ease of initial practice with the simulation silicone ears and felt the overall training time was adequate (Fig. 2). This feedback was compared with the 8-hour body acupuncture course where most participants felt that more practical training on needle insertion, meridians, and point location was required.

The author would recommend questions asked in our recent systematic ear review,19 and the BFA trials (Table 2) for future feedback from participants. This feedback ideally would be asked 6 weeks postcourse. Suggested questions to include are as follows: whether they perceived peer and patient acceptance; was opioid use reduced; whether it was time-consuming; was it too costly; and which pain types that they found it to be effective? During these 6 weeks, there is an opportunity for quality reassurance of the trainee on both patient selection and point location. This process could be executed face-to-face if the BFA instructor and trainees are collocated or if not, through digital photographs of needle placement with a brief synopsis of the patients’ presentations. Feedback from other experienced BFA instructors is that this is required for the first 10–20 patients.

CONCLUSION

BFA is accumulating evidence as an adjunctive analgesic technique in the ED. There is increased patient demand, along with provider interest in this nonpharmacological modality. Teaching BFA needs to be adjusted to suit ED doctors and nurses, along with their unique case mix and associated challenging environment. Just as crucial as teaching BFA skills, were teaching participants how to negotiate barriers of undefined minimum training standards and credentialing for staff administering BFA in the ED. The BFA course content also included understanding evidence, needle handling, safety, and mechanism of analgesia while utilizing the best faculty with the most effective teaching methods. We hope that our lessons learned in teaching BFA to emergency clinicians will assist others in the education of this ear acupuncture technique as a viable analgesic alternative in emergency medicine.

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REFERENCES


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5.2 Afterword

5.2.1 What went well?

5.2.1.1 Methodology

A hybrid framework was used for the article, which was largely based on a lessons-learned approach, as reflected in the title, and includes a partial narrative review of BFA. Unlike RCTs and systematic reviews, there are no standardised tools by which to assess such a paper. However, assessing it against the lessons learned framework used in industry, it successfully communicates how to teach clinical knowledge (i.e. indications, acupuncture points and adverse effects), skills and safety aspects. Like any educational resource, it needed to be both simple and engaging. Thus, to be simple, the paper focuses on only one form of ED acupuncture and is engaging through its style of prose and use of tables and figures, including entertaining mnemonics.

5.2.1.2 Findings

The publication provided a forum to share my opinions on provider satisfaction (the ED clinician practising acupuncture), teaching and governance links described in the foreword. These links are essential for ED acupuncture to become established in SAC.

There is the potential for provider satisfaction or emergency physician acceptance of the modality. ED acupuncture is a novel hands-on modality that can offer rapid symptom relief. This publication provides an excellent opportunity to cross-pollinate current emergency medicine teaching methods with the discipline of acupuncture. It offers a useful forum through which to share ideas, initiate a narrative around ED acupuncture and create a foundation upon which evidence can be superimposed. Acupuncture regulations are poorly defined in Australia. The Australian Health Practitioner Regulation Agency has circumnavigated this problematic issue by protecting the title of ‘acupuncturist’. Only those trained in TCM or who have successfully completed AMAC Course Part 1 (a minimum of 200 hours) can use the title. In the US, acupuncture requirements vary from state to state. Some states accept acupuncture as part of medical practice, while others require a further 200 hours of training (see Chapter 7). The preferred scenario for ED acupuncture would be that BFA remain separate from the usual acupuncture regulations.
This publication also provides the opportunity to present existing evidence for the efficacy of BFA for acute pain. In six of the nine studies, the use of BFA as an adjunctive analgesic led to a primary outcome pain score reduction. According to Trinh et al., the cut-off for accepting evidence as being consistent is to have at least 75% concordance between studies (see Chapter 1 ref. no. 83). None of the nine studies showed a reduction in opioid usage. Given the number of BFA RCTs to date, I eagerly awaited the upcoming meta-analysis on the use of BFA for acute pain by Yang et al. (see Chapter 7 Appendix, Section B ref. no. 26). Unfortunately, the authors could include only three of the nine RCTs in their meta-analysis, two of which included gross errors in data extraction and one of which used a 1-month time frame. Consequently, no useful information on BFA was obtained from Yang’s systematic review and meta-analysis (see the letter to the editor in Chapter 5 Appendix, Section D).

Evidence on the training outcome was collated from post-course feedback surveys, which provided support for the teachability of BFA in a half-day session and expert opinion guidance on post-course BFA supervision. In our RCT (presented in Chapter 6), ED clinicians were taught how to deliver BFA in the same time frame.

5.2.2 What was unexpected or disappointing?

5.2.2.1 Methodology

This publication initially covered the teaching of body acupuncture, which was ultimately removed for simplicity because the editors and reviewers believed that it made the paper confusing. This opinion may have been partly based on the failure to deliver enough body acupuncture courses to gather sufficient experience or data. Hence, the evidence for the training outcome was based on expert opinion and qualitative feedback only, which sits at Levels IV and V on the hierarchy of evidence (see Chapter 1). While the study presented in this chapter provides some information, more reliable studies are available. Witt et al. (see Chapter 7) combined four RCTs, generating an overall sample of 10,000 patients, to measure the effect of physician training on pain outcomes. Sensitivity analyses showed that basic training (< 200 hours) was not inferior to more extended training (> 200 hours) in terms of pain outcomes. Future research could consist of an RCT with two arms—physicians with basic training and qualified registered acupuncturists with more than 200 hours of training—to compare their effects on pain reduction and safety as a secondary outcome (see Chapter 7).
5.2.2.2 Findings

While it appears that BFA is teachable in a basic format, the question of training for body acupuncture remains largely unanswered. Participant feedback suggests that more than 1 day (4 hours online and 4 hours face to face) is required to learn body acupuncture. The minimum body acupuncture training standard of 16 hours for physiotherapists provides a starting point for ongoing discussions. Physiotherapists avoid the title ‘acupuncturist’, offering ‘dry needling’ instead. While unanswered questions may be disappointing, they are important to define future research.
Chapter 6: Battlefield Acupuncture Added no Benefit as an Adjunct Analgesic in Emergency Department for Abdominal, Low Back or Limb Trauma Pain

Offering patients effective nonpharmacological options for pain relief should be a priority. Battlefield acupuncture (BFA) has the potential to help patients, given both the high prevalence of patients with chronic pain not related to cancer and competing medical comorbidity.

—Daniel Federman, Professor of General Medicine, 2017

What is already known on the topic

- Our previous meta-analysis on all forms of acupuncture and BFA showed a lack of studies and limited evidence for acupuncture as an adjunct to standard analgesia care (SAC).
- A recent large study by Cohen et al. showed no statistical superiority for body acupuncture as an adjunct to SAC in the emergency department (ED).
- The majority (68%) of patients are willing to be treated with acupuncture in the ED.
- To date, there are nine trials on postoperative and ED BFA. Two-thirds of these show the effectiveness of acupuncture as an adjunct.

What this research adds

- While BFA improved pain scores compared with SAC alone, BFA as an adjunct to routine analgesia for abdominal, low back or limb trauma pain in the first 2 hours failed to show a statistically significant benefit.
- BFA was not associated with reduced opioid administration or improved patient satisfaction in the given time frame.
- Given the mixed results from this and other published trials, BFA needs more research before firm recommendations can be made on its use.

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6.1 Foreword

6.1.1 What is already known or knowledge gaps that require elaboration

The systematic review presented in Chapter 2 provides strong evidence for the effectiveness of all forms of acupuncture as a standalone analgesic, with ear acupuncture performing better than body acupuncture. However, there is limited evidence for both forms of acupuncture as an adjunct (see Chapters 2 and 3). A recent large study by Cohen et al. found no improved analgesia with body acupuncture as an adjunct to SAC in the ED. Given that BFA is both easy to learn and has applicability to the ED setting, this form of acupuncture is of particular interest. Further, given the uncertainty about the effectiveness of acupuncture as an adjunct, we conducted the trial presented in this chapter.

6.1.2 What was done that was different?

This study was set in a private ED that was trial naive. Given the lack of funding, the trial was run solely on goodwill; thus, the design needed to be ethical and acceptable to clinical staff and patients. The use of acupuncture as an adjunctive analgesic fulfilled these criteria. Our prior survey showed that patients were likely to be cooperative and satisfied (see Chapter 4). Initially, we considered running a pilot study. However, given the numbers needed to power the trial, the expected consent rate and confidence in the protocol, we proceeded directly to the RCT. Rather than using qualified and registered acupuncturists, we wished to test whether non-acupuncturists could achieve the expected results. All ED clinicians (including nurses, nurse practitioners and medical staff with varied experience) were given 2 hours of face-to-face and 2 hours of online training.

At the time of the trial, the climate of open-access emergency medical education had led to scepticism about the analgesic effects of acupuncture, with much criticism of the methods used in ED acupuncture trials. Therefore, to avoid similar criticisms, our RCT needed better blinding, a sophisticated sham and a fixed acupuncture prescription (see the preregistered protocol in Chapter 6 Appendix, Section A). Rather than only blinding the assessors, we also blinded the treating clinicians and nurses. We achieved this by covering the ear needles with tape and an opaque central mark. The sham design generated an innovative and credible pseudo-intervention (see Chapter 3, Section 2.1.2). We used an accepted acupuncture delivery device—an off-the-shelf piezoelectric acupuncture tool (Pulsar Plus, Helio Medical Supplies, San Jose, California). It was anticipated prior to the study that participants would be likely to interpret this
device as a genuine intervention. The device produced both a clicking sound and a flash of light, adding to its suitability as a sham intervention. However, its suitability as a sham was ensured by discharging it close to but not directly onto the ear. The handling of the ear would be the same as if ear needles were inserted. This sham design was a first, and we anticipate that it will be used in future acupuncture trials. Finally, we wanted to ensure no bias in the intervention arm. In previous trials on BFA, patients have been walked following the insertion of needles to assess whether pain scores have reduced to an acceptable level, and needles continue to be inserted until the pain score drops significantly. However, this flexible acupuncture procedure enables investigators to pay additional attention to participants in the intervention arm, which could be a significant source of bias (see Chapter 7 Appendix, Section E).
Battlefield acupuncture added no benefit as an adjunct analgesic in emergency department for abdominal, low back or limb trauma pain

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Abstract

Objective: To ascertain whether ear acupuncture (modified Battlefield technique) as an adjunct (Adj-BFA) to standard analgesia care (SAC) significantly reduces pain scores compared with sham acupuncture (Adj-Sham) or SAC alone, when delivered by medical and nursing practitioners in an ED.

Methods: A randomised controlled trial using a convenience sample of 90 patients attending an ED with acute abdominal, limb trauma or low back pain were allocated to three treatment arms: Adj-BFA, Adj-Sham and SAC. The primary outcome of change in pain scores out-of-10 (NPRS-10) from triage were assessed immediately after intervention and at 1 and 2 h post-intervention. Secondary outcomes were the percentage of patients reporting ‘adequate analgesia’ or ≥30% reduction in pain score, analgesic medication use (in morphine equivalent dose [milligrammes]), analgesics and needle costs (Australian dollars), adverse effects and patient satisfaction (Likert scale).

Results: There was no significant difference in pain scores (P = 0.582) or secondary outcomes measures between Adj-BFA, Adj-Sham and SAC.

Conclusion: The present study on 90 patients did not show a significant difference in analgesia outcomes in the first 2 h using Adj-BFA for acute pain in the ED, and there were no significant differences for secondary outcomes between treatment arms. Given the mixed results of recent BFA trials, further research using the original BFA technique on different painful conditions, as either stand-alone or as-adjunct to non-opioid analgesia are needed before BFA can be recommended as a technique for acute pain management in the ED.

Keywords: acupuncture, acupuncture therapy, acute pain, battlefield acupuncture, emergency department.

Introduction

Pain is the most frequent presenting complaint to EDs, and correspondingly, there is an emerging interest in alternative analgesic techniques such as acupuncture in managing acute pain in this environment. This interest is in response to the rising burden of deaths, disability and rehabilitation costs associated with opioid use. Acupuncture has good evidence supporting its application in a variety of conditions including chronic pain and perioperative analgesia, while evidence is accumulating for the use of acupuncture as an analgesic alternative for the ED.

In our previous meta-analysis on all forms of acupuncture (including ear), it was superior to sham and non-inferior to standard analgesia care (SAC) for pain relief in the ED, but with limited evidence for it as an adjunct. We performed a further specific meta-analysis on ED ear
acupuncture which showed reduced pain scores, but with the limited number of studies we recommended further research. Our initial postulate for this research was that acupuncture would not replace SAC, but as an adjunct might improve the overall pain experience and reduce opioid requirements. Studies included in the meta-analysis and more recent randomised clinical trials (RCTs) have been criticised for lacking sham,7–10 assessor blinding,6,9,10 and post hoc alteration of trial outcomes from initial trial registration.9

The hectic environment of the ED together with a requirement for rapid administration of analgesia by usual ED workers, may not be conducive to acupuncture treatments compared to the outpatient or perioperative setting.11 Despite this, from the patients’ perspective, we showed the majority (68%) of patients are willing to be treated with acupuncture in the ED.12 To date, the emergency medicine community remains undecided on the exact role of ED acupuncture; however, there is an agreement that further quality investigation is required.13

In the current study, we tested whether Battlefield (ear) acupuncture (BFA), when delivered by usual medical and nursing staff, would reduce pain scores post-intervention and at 1 and 2 h. BFA is a form of ear acupuncture which is standardised, quickly learnt and applied, and allows body access for other procedures.6 Since its inception, BFA has been extensively used by non-acupuncturists while being subject to multiple studies.6 Unlike body acupuncture that uses traditional filiform needles, BFA uses small semi-permanent needles that can remain in situ up to 3 days (Fig. 51). Secondary outcomes were: the percentage of patients who achieved ‘adequate analgesia’14 or ≥30% reduction in pain score; analgesic medication dose requirements (measured in milligrammes morphine equivalent dose); pharmaceutical costs; adverse effects and patient satisfaction.

Methods

Design, setting and participants

The present study was a prospective, single-blind, RCT comparing pain scores up to 2-h post-intervention between SAC; sham acupuncture as an adjunct to SAC (Adj-Sham) and BFA as an adjunct to SAC (Adj-BFA) for three painful conditions. Ethics approval was obtained from St John of God Health Care Human Research Ethics Committee (reference 1426), and the trial was registered with www.anzctr.org.au and assigned Universal Trial Number U1111-1218-5037.

The trial recruited a convenience sample based on triage nurse and investigator availability performed in the ED of an urban S07-bed private hospital in Perth, Western Australia, that sees approximately 20 000 patients with a 38% admission rate. The triage nurse or investigator identified eligible patients aged 18–80 years with a numeric pain rating scale out-of-10 (NPRS-10) ≥4 and Australasian Triage Scale (ATS) ≥3 for three acute conditions: abdominal pain, low back pain (not trauma) and limb trauma pain. Exclusion criteria were: difficulty with English language or comprehension; immediate medical intervention required; pregnancy; chronic pain (>6 weeks); chest pain; immune deficiency; on anticoagulants (except aspirin); artificial heart valve; permanent pacemaker; needle phobia; allergy to gold or taps; known bloodborne pathogens; recent ear infection or trauma; and deafness/use of hearing aids.

Interventions

Participants consented post-triage, and SAC was ordered at the discretion of the medical investigator or ED doctor and was not otherwise dictated by the trial protocol. All analgesic modalities employed were typical of those widely used in Australian EDs. Examples of SAC used included: paracetamol, non-steroidal anti-inflammatory drugs, opioids (oxycodeone, tapentadol and buprenorphine), antacids, splinting, ice and heat packs. Then within each pain type (abdominal, limb trauma or low back) participants were randomly allocated to one of the three treatment interventions (Fig. 1). Block randomisation was by Stata software (14.2; StataCorp, College Station, TX, USA) and presented in sealed opaque envelopes. Investigators and data analysts remained blinded to allocation until analyses were completed. Trial interventions were performed by 10 usual ED health workers who each had 4 h of BFA training.

Adj-BFA subjects received 10 Aiguille semi-Permanent (ASP) gold needles (Sedatelec, Igrigny, France) according to the BFA protocol, that is needles placed in both ears at the ear points: cingular gyrus, thalamus, omega-2, then men and point zero (Fig. 51).13 To allow sham trial requirements, we modified the BFA protocol as initially described,13 and removed pausing, physical movements (e.g. walking) and pain score analyses between points.

Patients allocated to Adj-Sham were informed that they would receive ‘painless electric ear acupuncture’. The piezoelectric sham device (Pulsar Plus; Helio Medical Supplies, San Jose, CA, USA) was activated with both the same sequence and hand technique as if placing a BFA needle but not directly onto the skin. Patients allocated to the SAC group had tapes applied and then usual analgesia care.

All participants had Duo-DERM extra-thin (Convatec, Flintshire, UK) 10 mm cut tapes with an obscuring black mark applied to the 10 points to blind nurse assessors, other investigators and treating physicians. Immediately following the allocated intervention and application of tapes, patients were given the initially prescribed SAC. Participants were asked not to inform treating staff of the technique they received.

Measures

Pain scores were measured at rest using a verbal NPRS-10. The triage NPRS-10 was confirmed by the trial investigator. At time zero (T0), a NPRS-10 was taken immediately
post-trial arm intervention by a blinded nurse, who then administered the initial prescribed SAC. Blinded nurse assessors repeated NPRS-10 at 1 h (T1-NPRS-10) and 2 h (T2-NPRS-10) along with a 6-point Likert satisfaction questionnaire and an open question regarding adverse effects. Soon after the 2-h time point, an investigator removed needles and ended data collection. Any data queries from either the data collection sheets or patient drug charts were resolved within 2 days. The primary outcome measure was the mean change in NPRS-10 at rest from triage at three time points, that is immediately after intervention and at 1 and 2 h post-intervention for the three treatment arms. Secondary outcomes were: percentage of each arm reporting ‘adequate analgesia’ (defined as a decrease in NPRS-10 from triage of ≥2, with a final pain score of <4); with a total of 90 were required. The mean difference and SD were based on estimates from prior studies and our previous meta-analyses.²,³

For the primary outcome of a mean NPRS-10 pain score change from triage, linear mixed models were used and included treatment group, time and the interaction as fixed effects, and a random intercept for the participant to account for the correlation within each person. Patients not able to tolerate the placement of all the needles or withdrew post allocation were included in an intention-to-treat analysis. The same model was refitted to include sex, age, ‘any analgesia’ and opioids prior, in separate models to investigate the potential for confounding by these variables. The final model was assessed visually for compliance with the assumptions of linearity, homoscedasticity and normality of residuals. Sensitivity analyses were performed to explore the impact of those participants who did not complete their treatment allocation or may have been excluded in retrospect as fitting exclusion criteria, by eliminating these participants in two separate models and comparing these findings to the final model.

For secondary outcomes, we performed logistic regression analyses of dichotomous outcomes: ‘adequate analgesia’ achieved (yes/no), ≥30% NPRS-10 pain score reduction (yes/no), Likert satisfaction rating less than ‘very-satisfied’ (yes/no), side effects (yes/no) and linear regression on morphine dose equivalent and costs including treatment group as the independent variable. These models were also subjected to sensitivity analyses as described above. All analyses were conducted using Stata, and \( P < 0.05 \) was considered significant.

**Data analysis**

Data were presented as means, standard deviations (SD) and frequencies/percentages for baseline characteristics. Group differences at baseline were not compared for statistical significance as recommended by current CONSORT guidelines.\(^{16}\) The trial was 80% powered to detect a pain score difference of 1.8/10 (SD = 2.5) at a 0.05 significance level using the independent Student’s t-test, where 30 participants per group

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**Results**

**Participant characteristics**

A total of 90 patients with three painful conditions were enrolled and randomised between 18 January and 27 August 2019. The numbers of participants, including explanations for enrolment, intervention allocation, follow-up and data analysis are shown on the CONSORT diagram (Fig. 1).\(^{16}\) The baseline
characteristics are shown in Figure 2 and Table S1.

Three participants did not complete the Adj-BFA intervention. In one patient, the pain resolved post consent, and two patients found the needling too painful. There were three subjects with potential retrospective exclusions with final diagnoses of chronic pain (Adj-BFA), Crohn’s disease on immunomodulators (Adj-BFA) and limb ischaemia (SAC).

Investigator characteristics

The trial intervention for the 89 participants was performed by nurses ($n = 30$ patients), specialist trainees ($n = 25$), emergency physicians ($n = 19$), nurse practitioners ($n = 13$) and family medicine practitioners ($n = 2$).

Primary outcome

The mean pain scores are shown in Figure 3 and Table S2. There were lower pain scores in the Adj-BFA group; however, this was not statistically significant. Linear regression showed no interaction of treatment allocation with pain scores over time ($P = 0.582, \chi^2 = 4.711$, degrees of freedom [df] = 6), and nor was there any effect of treatment allocation overall ($P = 0.761, \chi^2 = 0.55$, df = 2). However, time including administration of SAC for all groups itself, was a predictor of pain reduction ($P = 0.000, \chi^2 = 304.04$, df = 3; Table S3).

Adjustments for sex, any analgesia or opioids prior, and pain type, did not alter these results (Table S3). Likewise, sensitivity analyses using the same model for the three incomplete Adj-BFA treatments, and three potential retrospective protocol violations did not alter results.

Secondary outcomes

The secondary outcomes of achievement of adequate analgesia and 30% NPRS-10 reduction with their logistic regression analyses are shown in Table 1. The remainder of the secondary outcomes is depicted in Figure 2. Baseline characteristics of treatment groups: age (decades with mean all groups = 5.15, standard deviation [SD] = 1.4), Australasian triage score (mean all groups = 3.8, SD = 0.38), triage NPRS-10 (mean all groups = 6.4, SD = 1.6), sex (female count total all groups = 61%), ‘any analgesia prior’ (total all groups = 37.6%) and opioids prior (total all groups = 15.6%). Note y-axis is unitless and is interpreted according to variables stated on the x-axis. For non-parametric data (sex, ‘any analgesia prior’ or opioids prior), the maximum score is 30 per group. SDs are shown for parametric data (see Table S1 for exact SDs).

Figure 3. Mean NPRS-10 pain scores and standard deviation bars for study time points: triage, immediate post-intervention, 1 and 2 h. Exact standard deviations and confidence intervals are provided in Table S2.

Figure 4. There was no evidence using linear regression analysis for morphine dose equivalent ($P = 0.563, \chi^2 = 1.15$, df = 2) or pharmaceutical costs ($P = 0.277, \chi^2 = 2.57$, df = 2) differing between groups. Similarly, there was no evidence for difference using logistic regression analysis for adverse effects (yes/no: $P = 0.348, \chi^2 = 2.11$, df = 2).
and Likert satisfaction (≤56/6 ≤6; $P = 0.395$, $\chi^2 = 1.86$, df = 2). Thus, evidence for a difference between treatment groups was not observed for any secondary outcome. An exploratory sensitivity analyses for incomplete treatments, potential exclusions, and pain type, using the same regression models were performed which did not alter these results (Table S4).

All adverse effects reported were minor. Opioids were administered in the ED to 63% (n = 19) in the SAC arm, 50% (n = 15) in the Adj-Sham, and 60% in the Adj-BFA (n = 18) with a trial average of 56.7% (n = 52). The mean duration of application time for BFA was 7.8 min (SD = 2.88 min, median = 7 min, interquartile range 5–10 min).

**Discussion**

Both our 2017 meta-analysis and more recent ED acupuncture studies have supported acupuncture as a likely effective analgesic in the ED. The present study had contrary findings, showing no statistically significant difference in mean pain scores at time points up to 2 h between Adj-BFA, Adj-Sham or SAC alone for the three chosen conditions. The contrary result holds considerable authority overall for ED acupuncture studies, as our trial was arguably the most methodologically rigorous to date. It was designed to address criticisms of previous RCTs regarding issues such as the use of sham,7–10 assessor blinding,6,9,10 and no alteration to outcomes at trial registration.7 There have also been three perioperative analgesia Adj-BFA RCTs which are aligned with the present study’s negative primary outcome result.26–28

This finding was somewhat unexpected given the number of positive results from prior meta-analyses,1,6 and recent BFA RCTs on post-operative pain.23–25 There are potential explanations for the absence of a significant analgesic effect. One reason may be because the study was of BFA as an adjunct, and standard analgesia including opioids is appreciably effective such that the analgesic effect of the adjunct was masked.

Furthermore, the original BFA technique1,15 was modified to suit our ED trial sham requirements better. In this trial, 10 needles were inserted consecutively with no pauses or NPRS-10 checks in-between needle insertions. In three recent studies, where the formal technique was performed, all were positive suggesting that efficacy may be associated with this original technique.15,24,26

While the present study did not show differences within the first 2 h post-trial intervention between the three study arms concerning morphine dose equivalent usage, pharmaceutical costs, adverse effects and patient dissatisfaction, it was not adequately powered to do so. No adjacent to SAC ED acupuncture study to date, including ours, has shown reduced opioid use either administered within the ED, the number of take-home scripts or post-discharge usage.6,8,18,19 To make an economic argument to support acupuncture, one would need to offset the extra costs of needles and labour time against the avoided costs of the opioid burden. In the six other relevant ED acupuncture studies,6,8,18 where the pertinent indicator of patient satisfaction was measured, there was an improvement in satisfaction, which is in contrast to our research. Interestingly, Cohen et al. found that satisfaction with acupuncture was not better when measured in the ED but improved at 48 h post-discharge compared with SAC.18

There was no significant difference between groups in both incidence and severity of side effects with all being minor. Pain with needleing was considered a minor side effect, but in two of the trial participants, it was enough for them to withdraw from completing the acupuncture protocol. Pain with needleing can discourage some patients,12 and could be interpreted as a weakness of the modality. The absence of significant adverse effects is consistent with other BFA trials and is a recognised feature of this modality.5

**Future direction**

Ultimately, to decide on the role of ED acupuncture, further studies are needed which adhere to the highest standards of study design. These
studies will need to select appropriate conditions and measures while using the best technique and model. Our study with a sample size of 90 was adequately powered to detect a pain score difference of 1.8 (SD of 2.5), a larger study might detect a smaller clinical or statistical difference. To most fully evaluate BFA, it is arguably necessary to use the initially described BFA technique, but this creates challenges in sham design.

Currently, patients are demanding non-pharmacological analgesic methods, while clinicians are seeking opioid alternatives. Trial models could address this real-world demand by using acupuncture as a stand-alone as per Cohen et al. or as an adjunct to simple non-opioid SAC, reserving opioids for rescue analgesia. From an ED and opioid use perspective, further studies should choose painful conditions that are at risk of recurrent opioid use. These include conditions that are leading global causes of disability, such as spinal pain, headache and osteoarthritis of the major joints. Future trials might also consider outcomes on pain, satisfaction and opioid use post-discharge.

Conclusion

This RCT did not show a significant difference in analgesia outcomes using Adj-BFA for three acutely painful conditions in the first 2 h post-trial intervention. Likewise, secondary outcomes did not show an improvement in cost, adverse effects, patient satisfaction or opioid use. Given the mixed results of recent BFA trials to date, further research should focus on the highest standards of study design, might employ the original BFA technique, study varied ED conditions, and use BFA as both stand-alone and adjunct to non-opioid analgesia.

Acknowledgements

We wish to thank Richard Nienzte of his mentorship and Paula Davis, Natasa Raj-Azlan, Matthew Howl, April L. Krejting, Stephen Dunjey, Ankur Kumar, Georgia Larcombe, Brigitte Heitz and lan Lyttle for their assistance as co-investigators. The RCT was carried out at St John of God Murdoch Hospital in Perth, Australia. This research did not receive any specific grant from funding agencies; however, we wish to acknowledge general support from St John of God Murdoch Hospital, and as a PhD candidate, the University of Notre Dame Australia with an Australian Government Research Training Program Scholarship.

Author contributions

Conceptualisation and methodology: AJJ, IRR, FJV, ESA, LKPS, DAH, MKB. Data curation: AJJ, ESA. Formal analysis and validation: AJJ, DAH. Investigation/Data collection (see Acknowledgements): MVW, PD, NRJ, MH, ALK, SD, AK, GL, BH, IL. Original draft and Visualisation: AJJ. Review and editing: AJJ, IRR, FJV, ESA, LKPS, MVW. Supervision: IRR, FJV. Project administration: AJJ.

Competing interests

None declared.

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**Data availability statement**

Individual participant data will be available that underlie the results reported in this article, after deidentification (text, tables, figures and appendices) beginning nine months and ending 36 months following article publication; and for investigators whose proposal use of the data has been approved by an independent review committee identified for individual participant data meta-analysis. The study protocol is accessible through www.anzctr.org.au. Reference: Taichman DB, Sahni P, Pinborg A, et al. Data sharing statements for clinical trials: a requirement of the International Committee of Medical Journal Editors. JAMA 2017; 317: 2491-2.

**References**


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Supporting information

Additional supporting information may be found in the online version of this article at the publisher’s web site:

Figure S1. Sequence, point location, applicator and needle(s) for the five points of Battlefield acupuncture applied to the right and left ears. Point locations are in the following sequence: cingulate (1 R&L), thalamus (2 R&L), omega 2 (3 R&L), shen men (4 R&L) and point zero (5 R&L). In this trial, all 10 acupuncture points were used without pauses or pain score checks between needling. The ASP gold needle (Sedatelec, Irgny, France) and applicator were used in the study. The ruler is in centimetres with one-millimetre divisions (see close-up).

Table S1. Baseline characteristics comparing treatment groups with age (years), Australasian triage score (range 1–5), NPRS-10, sex (female count), ‘any analgesia prior’ and opioids prior (yes/no). Standard deviations (SD) are shown for parametric data and percentages (%) for non-parametric data.

Table S2. Mean NPRS-10 pain scores, standard deviations (SD), 95% confidence intervals (CI) for study time points: triage, immediate post-intervention, 1 and 2 h.

Table S3. Adjusted mean pain score with 95% confidence intervals (CI), $\chi^2$, P values and degrees of freedom (df) for the baseline characteristics of age, sex, ‘any analgesia prior’, opioids prior and pain type along with sensitivity analyses for incomplete treatments and potential retrospective exclusions.

Table S4. $P$ values, $\chi^2$ and degrees of freedom (df) for sensitivity analyses performed with either linear or logistic regression for secondary outcomes adjusted for: those who did not complete treatments; were potential exclusions; and pain type.

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6.2 Afterword

Supplementary publication material for this chapter can be found in Chapter 6 Appendix, Section A.

6.2.1 What went well?

6.2.1.1 Methodology

There were no significant deviations from the protocol, unexpected adverse events or patient complaints. However, some staff members complained about the extra work when the ED was overloaded. Given the typical high demands on ED staff, it would have been ideal to have secured funding for dedicated staff to administer the trial. The presence of the principal investigator was essential to encourage staff participation.

6.2.1.2 Findings

Although there was a mean pain score improvement for acupuncture as an adjunct compared with SAC alone, this was not statistically significant. Despite not showing significant improvement in ED acupuncture's secondary outcomes, further data was obtained to contribute to the final analysis of outcomes in Chapter 7.

6.2.2 What was unexpected or disappointing?

6.2.2.1 Methodology

As discussed in the Chapter 7 Appendix, Section E, we could have improved the trial design by using simple analgesia (either paracetamol or NSAIDS alone or in combination) for pain and opioids for pain rescue. Conditions associated with a higher risk of opioid dependence may have been better to study than the painful conditions chosen. Taking follow-up measures post discharge would also have provided much-needed information on pain reduction, satisfaction and opioid usage.

6.2.2.2 Findings

This RCT showed no statistically significant benefit for BFA as an adjunctive analgesic in the first 2 hours of ED attendance. Cohen et al. found the same result, as mentioned in the foreword.¹⁸ These results generate further uncertainty about the efficacy of BFA as an adjunct.
Chapter 2 and its corresponding appendix described studies that were not included in the meta-analysis but showed the adjunctive analgesic benefit of acupuncture. Chapters 3 and 5 provide indirect support for the effectiveness of ear acupuncture in postoperative adjunctive analgesia. These studies offer encouragement for further research on this analgesic category. The release of a meta-analysis on BFA by Yang et al. in December 2020 was highly anticipated (see Chapter 7 Appendix, Section B ref. no. 26). However, as discussed in Chapter 5, it only included three of a possible seven studies on acute pain, and there were significant errors in the meta-analysis. Unfortunately, the systematic review did not add any vital information to the current body of research on the topic.

Chapter 1 stressed the importance of the effectiveness of acupuncture as an adjunctive analgesic given that patients commonly need further pain management following failed initial analgesia. The acceptance of ED acupuncture would be more likely if it showed benefit in the primary analgesic outcomes.

The SAC prescribing patterns in our ED were somewhat disappointing. Results of both the 2017 survey and 2019 trial showed a similar percentage of opioids being administered (58% and 57%, respectively). However, there was one significant change. The survey showed that atypical opioids (predominantly tramadol) constituted approximately 3% of administered opioids, while the trial showed that atypical opioids (predominantly tapentadol) constituted 21% of administered opioids. It is likely that the opioid crisis and restrictions on codeine use had resulted in oxycodone and codeine being replaced with atypical opioids. In this intervening period, I was hoping for opioid alternatives to make their way into SAC as has occurred in USA EDs.

There was also no statistically significant difference in our secondary outcomes of patient satisfaction, opioid-sparing ability and adverse effects of acupuncture, although the study was not sufficiently powered to ascertain these. As discussed in Chapter 1, the strength of findings on secondary outcomes may range from being merely hypothesis generating to being comparable to Level III or IV evidence with caveats. This strength depends on how close the primary outcome is to the secondary outcome in terms of incidence or effect and whether it is adequately powered. This is discussed further in the next chapter, where evidence on the secondary outcomes is collated and synthesised. However, briefly, our trial is only one of many. Whether for primary or secondary outcomes, the assessment of findings depends on consistency with those other studies and their research quality. The opioid-sparing ability of acupuncture will need to be tested as a primary outcome measure, and larger samples are needed to verify any
significant adverse effects of acupuncture. The interpretation of minor adverse effects is contentious. In TCM, the minor pain associated with needling (de qi) is considered part of the essential therapeutic mechanism (see Chapter 7). However, as mentioned in the publication presented in this chapter, others may perceive this as a reason to avoid the modality.
Chapter 7: Discussion and Conclusion: The Role of Acupuncture as an Analgesic in the Emergency Department

I will remember that there is an art to medicine as well as science, and that warmth, sympathy and understanding might outweigh the surgeon’s knife or the chemist’s drug.

—The Hippocratic Oath (a modern translation)**


What is already known on the topic

- Level I evidence exists for acupuncture as a standalone analgesic.
- Battlefield (ear) acupuncture appears applicable to the ED environment but adds no benefit as an adjunct to standard analgesia care.
- Most patients are willing to use and satisfied with acupuncture as an analgesic.
- Battlefield acupuncture requires 4 hours of training, but the duration of training necessary for emergency clinicians to practise body acupuncture remains uncertain.

What this research adds

- Acupuncture can play a role when the risk of adverse effects from standard analgesia care is high. Examples include patients at risk of opioid reuse and adverse effects from non-steroidal anti-inflammatory drugs (NSAIDs) or invasive procedures.
- A knowledge gap exists with respect to the use of acupuncture as an adjunct to simple analgesia (either paracetamol or NSAIDS alone or in combination).
7.1 Outline

This chapter begins with a recap of the background and methodology described in Chapter 1. In that chapter I shared my personal rationale for undertaking this thesis regarding the merging of two seemingly distinct paradigms. Here, I provide examples collected during this thesis journey of where these two paradigms merge. Next, I sum up what was done, beginning with general themes that run through all publications before discussing individual publications from the perspectives of novel findings or those with potential impact. Next, the findings from the preceding chapters and relevant external literature are collated and synthesised. The findings for each outcome are presented under the following subheadings: ‘My research’, ‘External literature’, Synthesis’, ‘GRADE’ and ‘Future research’. The discussion begins with a final evaluation of the outcomes and subsequently includes aspects of how findings impact, integrate and embed themselves into current knowledge. I then make recommendations for clinical practice and future research. The chapter ends with a conclusion of the entire thesis. Figure 7.1 depicts a summary of the chapter.

**Note:** ED: emergency department; BFA: battlefield acupuncture; SAC: standard analgesia care; NSAIDs: non-steroidal anti-inflammatory drugs.
7.2 Summary of Background and Methodology

The research questions posed in Chapter 1 pertain to the role of acupuncture as an analgesic in the ED, its potential indications and how it should be applied. The impetus to ask whether acupuncture would be useful in the ED was provided in the first and subsequent chapters. Briefly, pain is poorly managed in the ED, often unrecognised, undertreated, or subject to delayed treatment. Emergency medicine has contributed to the opioid crisis through the excessive administration and prescription of opioids. A surprising and substantial number of ED pain presentations are exacerbations of chronic pain or recurrent painful conditions. Acupuncture is frequently used in the community, especially for these aforementioned painful conditions, but not in the ED.

The methodology used in this thesis was outlined in Chapter 1 (see Figure 7.2) and is reiterated here for the reader’s convenience. This thesis encompasses a broad topic with a vast amount of information from multiple sources of varying quality. Therefore, a robust framework was needed to arrange the findings in such a way that the research questions may be answered. The framework needs to describe outcomes in terms of a theoretical gold standard (or ideal) analgesic to compare the effect of acupuncture with SAC or a specific analgesic. Further, given that findings may be of varying quality, directness and consistency, a transparent process for assessing the strength of findings was required. The assessment of outcomes was based on both my research and the external literature. Key uncertainties that remain after this information-gathering process are perceived as opportunities for further investigation. The arrangement of outcomes into a hierarchy of high to low importance is also essential given that the criteria for analgesic use in the ED may be different from those in other health sectors, times and populations. The GRADE approach was chosen as a tool to grade the strength of findings and rank the importance of each outcome.¹

It is beyond this thesis's scope to provide detailed evidence on other analgesics using the GRADE approach. Chapter 1 provided some evidence of the potential weaknesses of SAC (particularly opioids and NSAIDs). More detailed research is likely needed for readers, clinicians and policymakers for specific analgesics of concern. However, it is recommended that the framework
be utilised to compare a particular analgesic with acupuncture.

![Problems with Standard Analgesia Care](image)

Problems SAC matched to acupuncture outcomes
1st outcome: analgesic standard or is it as effective as acupuncture? 2nd outcome: patient satisfaction, adverse effects, opioid sparing, administration time, cost, training time & applicability

<table>
<thead>
<tr>
<th>Analgesia</th>
<th>Adverse effects</th>
<th>Satisfaction</th>
<th>Opioid sparing</th>
<th>Time</th>
<th>Training</th>
<th>Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>My research</td>
<td>Systematic reviews and meta-analyses, patient questionnaires &amp; surveys, teaching ED acupuncture experience with feedback &amp; randomized clinical trial</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>External literature</td>
<td>Recent ED acupuncture studies, outpatient &amp; peri-operative systematic reviews, observational studies, guidelines</td>
<td></td>
<td></td>
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<tr>
<td>GRADE</td>
<td>Approach to the arrangement of outcomes, assessing quality of evidence and comparison to SAC</td>
<td></td>
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</table>

**Clinical Recommendations**
- Acupuncture can be used when concerns about analgesic side effects are high, e.g., patients at risk of opioid misuse (opioid risk personalities), exacerbations of chronic musculoskeletal pain, chronic pain conditions, non-catastrophic recurrent headaches, NSAIDs, adverse effects, risks of steroid injections or other procedures. Usage is influenced by severity of pain and patient choice.

**Future direction**
Acupuncture trials as adjunct with simple analgesia, opioid sparing as primary outcome Special interest groups in the relevant colleges.

**Figure 7.2:** Methodology used in this thesis.

Note: As mentioned in Chapter 1, weaknesses in standard analgesia care (SAC) were matched against the ideal analgesic, becoming the outcomes of acupuncture investigation. The investigation included both my original research and a literature review. The findings were then appraised using the GRADE approach, collated for each outcome, and compared with the ideal analgesic or a specific analgesic used in the ED. GRADE: Grading of Recommendations, Assessment, Development and Evaluation; NSAIDs: non-steroidal anti-inflammatory drugs.

### 7.3 Personal Rationale and Reflections from This Thesis

In Chapter 1 it was stated that some experts believe that acupuncture should not be assessed using EBM methods because it is a holistic paradigm. The central paradigm of Western medicine is based on scientific reductionism and contrary to that of acupuncture. However, following Kuhn’s theory of scientific revolutions, creating this dialectic and subjecting acupuncture to EBM will develop new insights for both paradigms. My rationale for undertaking this thesis is to promote the merging of Chinese and Western medicine/EBM paradigms with a focus on pain. Table 7.1 summarises my reflections on the differences between the two paradigms and where they merge.
<table>
<thead>
<tr>
<th>EBM - the core of Western Medicine</th>
<th>Chinese Medicine</th>
<th>Reflections on CM versus WM on acute pain while carrying out research on this PhD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>History</strong></td>
<td>EBM treats patients the same for a given disease or condition.</td>
<td>Condition determined by prior ancestors, the alignment of elements and planets at the time of birth (pre-natal chi), and thereafter, the degree of rejuvenation or exhaustion of postnatal chi, influenced by intervening pathogenic forces. The ED pain crisis is one moment in an unfolding story.</td>
</tr>
<tr>
<td><strong>Body</strong></td>
<td>Body is made up of parts - pain results from a malfunctioning part.</td>
<td>Body works as an integrated whole - each part influences the other.</td>
</tr>
<tr>
<td><strong>Spirit</strong></td>
<td>Spirituality is less emphasised and difficult to measure but still subject to research.</td>
<td>Strength of the spirit determines prognosis.</td>
</tr>
<tr>
<td><strong>Community</strong></td>
<td>Pain due to a diseased part, altered neurotransmitters, curable by procedures and pharmaceuticals.</td>
<td>The cause of pain crises is in part due to a disharmony of the environment, family, ancestors and community. Respected masters, sages and healers lead community.</td>
</tr>
</tbody>
</table>

| Practitioner and treatment |
|-----------------------------|-------------------------------------------------|----------------------------------------------------------------------------------|
| **Competency** | Therapeutic success is primarily based on EBM modality but may recognise factors such as length of training and qualifications. | The practitioner’s ability to have therapeutic success is based just as much on the level of the provider's spiritual attainment, compassion and intention as skill in acupuncture. The provider will transmit chi with right intention to restore balance or open meridians through therapeutic touch. | Both patients and medical colleagues recognise that the ideal physician has both skill and “bedside manner”. Bedside manner is akin to therapeutic touch. |
| **Goal** | EBM focuses mostly on short-term outcomes such as pain reduction as these are logistically easier to measure. | Positive intervention could positively alter a life trajectory. The primary goal is to assist the patient to find ‘the way’. The goal may not necessarily to become immediately pain free but to make a realisation that pain (suffering) and happiness are two features of life (yin and yang). | EBM includes long term goals and quality of life measures. A growing group of WM doctors question the EBM paradigm and advocate narrative medicine as a better model for conditions such as ongoing pain. |
| **Prescription** | Therapy is based on managing the painful part or specific neuroreceptors/transmitters. Prescription modality choices based on hierarchy of evidence. | For a Western diagnosis, choice of needle placement varies according to spirit, organ and elemental imbalance; pain location, and avasion of pathogenic factors. | WM recognises that EBM is not the sole determinant of treatment and that a patient’s wishes and culture are important components of “shared decision making.” Acupuncture initiation is more likely to have both repeat acupuncture and be educated on healthier ways of being. Opioid initiation leads to re-use. WM encourages a consumer like dependence. |
| **Follow up** | Use of pharmaceuticals or procedure changes view of these procedures and dependence on medical intervention. Failure implies progress to bigger doses or a more invasive modality. | By introducing a modality such as acupuncture, patients are more likely to reuse and cultivate mind and body through other CM related therapies e.g. Tai Chi, meditation, Chi Kung, Feng Shui, diet & herbs. | Both systems accommodate successful practitioners by amassing collections of stories to create a reputation. WM does better on collecting objective outcome results. |
| **Assessment of success** | Pain reduction, quality, functional and satisfaction outcomes. | Patient and practitioner satisfaction. | |

This table highlights the author’s impressions on the differences between the two paradigms. As foretold in the introduction, I have mentioned examples of where these two paradigms have shown signs of gaining common ground or remain disparate.
It appears that Western medicine is more than simply EBM and includes the art of medicine. Western medicine's art— the intuitive wisdom, empathy to suffering and power of touch— may be considered its heart and soul and assist in recognition of evidence that has face validity but is incorrect. Regius Professor of Medicine Sir David Weatherall argues that the art of medicine gives doctors the autonomy and ‘authority to act independently of both the wishes of the patient and the preponderance of medical evidence’. The foundation of the art of medicine goes back to the Hippocratic Oath, as cited on the first page of this chapter. EBM may be the intellectual foundation or primary tool of Western medicine, but it is not all that should be used when making decisions about patients.

Is there a weakness in EBM or Western medicine that has contributed to the current opioid crisis? Some researchers have postulated that a major factor contributing to the opioid epidemic was a low-quality retrospective audit of hospitalised opioid-naive patients exposed to opioids, which showed an identifiable low addiction rate. Along with other weak evidence, this audit convinced many of the safety of opioids. Medicine as a business took advantage of this information. Had Western medicine retained its wisdom and authority, this audit may have been recognised as low-quality evidence and misaligned with the ethics and art of the profession.

Therefore, my final reflection after completing this PhD thesis is that Western medicine is more than just EBM. The art of medicine is its heart and soul and overlaps with many TCM principles. EBM represents the powerful intellect of Western medicine. Perhaps TCM could adopt the tools of EBM to be more measured in assessing its myriad therapies. This movement is underway, with Chinese and international bodies developing a core set of outcomes for Chinese medicine therapies. Either way, Kuhn was likely correct—I now see both paradigms in a different light.

7.4 What Was Done

This section summarises what was done to answer the research questions and is primarily centred around the publications. A chronological list of the publications and associated tasks is provided in Figure 7.3. Rather than present a formal summary, I have emphasised approaches that were novel or a first. I also make recommendations where methods may have implications for future researchers. Essential points are taken from the forewords and afterwords of each chapter and the methodology aspects from the discussion on strengths and weakness in Chapter 7 Appendix.
### PhD Proposal: What is the role of acupuncture in the ED?

Formulate list of issues in current analgesia care in the ED that acupuncture might address.

Arrange outcomes to investigate in this thesis that will address these issues.

1st outcome: Analgesic effectiveness, 2nd outcomes: satisfaction, adverse effects, administration time, cost, training time & applicability.

<table>
<thead>
<tr>
<th>2016</th>
<th>A systematic review and meta-analysis on acupuncture for analgesia in ED</th>
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<tbody>
<tr>
<td></td>
<td>Used 7 data bases, PRISMA &amp; STRICTA guidelines, all languages, all forms of acupuncture, for typical ED presentations with acutely painful conditions.</td>
</tr>
<tr>
<td></td>
<td>Acupuncture is an effective analgesic and equivalent to SAC but had limited evidence as adjunct. Acupuncture has a low adverse effect rate, is low cost, &amp; administration time &lt; 10 minutes, uncertain if opioid sparing.</td>
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<table>
<thead>
<tr>
<th>2017</th>
<th>A systematic review and meta-analysis on ear acupuncture for analgesia in ED</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Used 7 data bases, using PRISMA, STRICTA guidelines, all languages, for typical ED presentations with acutely painful conditions.</td>
</tr>
<tr>
<td></td>
<td>Ear acupuncture has limited evidence of superiority above controls. Low adverse effects, low cost, applicable to ED environment and easy to learn. Uncertain if opioid sparing.</td>
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<table>
<thead>
<tr>
<th>2017</th>
<th>Patient survey</th>
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<tbody>
<tr>
<td></td>
<td>A survey of current ED pain management and patient questionnaire on pain scores, satisfaction, adverse effects, non-pharmacological analgesia, acupuncture and addiction concerns on 196 patients within an hour post initial analgesia.</td>
</tr>
<tr>
<td></td>
<td>70% of patients willing to use acupuncture, 20% of patients had adverse effects to SAC</td>
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<table>
<thead>
<tr>
<th>2018</th>
<th>ED acupuncture courses</th>
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<tbody>
<tr>
<td></td>
<td>ED acupuncture courses on body acupuncture and BFA delivered to ED clinicians (ACEM &amp; and trial investigators) and physiotherapists.</td>
</tr>
<tr>
<td></td>
<td>Body acupuncture requires a minimum of 16 hours while BFA 4 hours of training.</td>
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<table>
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<tr>
<th>2019</th>
<th>RCT: Battlefield (ear) acupuncture (BFA) as an adjunct to SAC</th>
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<tr>
<td></td>
<td>This RCT recruited 90 patients with abdominal, low back or limb trauma pain and allocated to either ‘BFA &amp; SAC’, ‘sham &amp; SAC’ or ‘SAC alone’ with measures taken in first 2 hours.</td>
</tr>
<tr>
<td></td>
<td>Trial revealed no statistical benefit of BFA as an adjunct over sham or SAC. Secondary outcomes showed no differences between arms in adverse events, opioid use and patient satisfaction.</td>
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</table>

<table>
<thead>
<tr>
<th>2020</th>
<th>Further literature review</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Recent ED acupuncture studies, recent BFA postoperative analgesia, systematic reviews on acupuncture in the outpatient and postoperative setting, RCTs and large observational studies.</td>
</tr>
<tr>
<td></td>
<td>Acupuncture likely effective in acute exacerbations of degenerative musculoskeletal pain, radiculopathy and migraines. Acupuncture has a very low adverse event rate and mortality.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2020</th>
<th>PhD thesis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Synthesising and collation of own research and external literature above.</td>
</tr>
<tr>
<td></td>
<td>Acupuncture is most likely to lie in situations where the expected adverse effects of SAC outweigh the benefits, e.g., opioids at risk of re-use (at risk personality, painful non-catastrophic conditions as headache, spinal pain, major joint osteoarthritis), NSAIDs in renal/gastrointestinal disease, interventions in patients with multiple co-morbidities.</td>
</tr>
</tbody>
</table>

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**Figure 7.3. What was done to answer the research questions.**

Note: The year of completion is shown in the arrows on the left and publication dates on the right. Peer-reviewed publications are indicated by shaded boxes. Each box includes a brief description of the main findings. ED: emergency department; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-analyses; STRICTA: Standards for Reporting Interventions in Clinical Trials of Acupuncture; SAC: standard analgesia care; RCT: randomised controlled trial; NSAIDs: non-steroidal anti-inflammatory drugs; ACEM: Australasian College of Emergency Medicine; BFA: battlefield acupuncture; EMA: *Emergency Medicine Australasia*; MA: *Medical Acupuncture.*
7.4.1 Overall aspects

This thesis has gone beyond my initial ideas. In many respects, I became a conduit for information and concepts. The success of this thesis has arisen from the selection of an excellent team of supervisors and publication co-authors. Thus, this thesis is the result of a fusion of ideas from pain medicine, emergency medicine, acupuncture and biostatistics. Ideas also came from conference presentations, which helped immensely in the crystallisation of ideas and design of graphics for PowerPoint slides. Further, conference delegates were crucial in the exchange of ideas and providing feedback on the interpretation of research relevant to this thesis. Similarly, teaching in workshops facilitated with the clarification and simplification of concepts (see Chapter 5 Appendix). The exchange of ideas also took place during my publicity of the work (see Chapters 1, 3 and 6 appendices). Letters to the editor encouraged dialogue with other authors of ED acupuncture studies (see Chapters 2 and 5 appendices). Finally, patient feedback and clinical experiences with ED acupuncture techniques on patients outside the trial setting helped inform the research ideas.

Although there have been many publications on ED acupuncture, this is the first PhD thesis. Some have argued that such an undertaking would be risky given the size of the topic.\(^33\) Despite the well-documented inherent dangers of tackling such a large-scale PhD topic, I wanted this thesis to have a clinical impact on my two areas of expertise—emergency medicine and acupuncture. I hope that the framework (i.e. the ideal analgesic–based outcomes and GRADE approach) has offset the risks of investigating such a broad topic.

To make this thesis accessible to a broader audience, I chose a novel approach for the presentation of this PhD, including a *British Medical Journal* first-page style, with ‘what is already known’ and ‘what this research adds’, and tables and graphics that cater to a varied readership. I have also stepped outside the usual by including my personal reasons and philosophy for undertaking a PhD. While this is not directly related to the research question, it is important momentarily to see beyond the EBM paradigm and view this research from a broader philosophical perspective. The downside, however, is being distracted by another set of ideas.
7.4.2 Individual publications

7.4.2.1 Does acupuncture have a role in providing analgesia in the emergency setting? A systematic review and meta-analysis

Published in *Emergency Medicine Australasia* in September 2017, this was the first systematic review on ED acupuncture (of four) to have a meaningful outcome. Its success was likely based on various factors. First, experts on various subjects were selected for the research team, and the research question was focused solely on analgesia. Second, the inclusion criteria were broadened to include trials on clinical conditions typically treated but not necessarily conducted in an ED. Acute care EDs vary worldwide, and some do not involve a detailed workup before patients are referred to specialty areas. Types of cases may also overlap with those in other health sectors such as general practice. As discussed in the appendices to Chapters 5 and 7, I recommend future researchers to use tools such as AMSTAR or PRISMA prior to submitting a formal prepublication protocol to avoid the minor deficiencies of this study.

7.4.2.2 Does ear acupuncture have a role for pain relief in the emergency setting? A systematic review and meta-analysis

Published in *Medical Acupuncture* in October 2017, this was the first systematic review specifically on ear acupuncture in the ED. It was undertaken despite the few known studies and the likelihood of inconclusive outcomes. A postulate from the previous systematic review on all forms of acupuncture was that ear acupuncture would be ideal in the ED environment. Despite the lack of high-quality evidence to support its extensive use, it has become popular in the US, creating some tension. Consequently, the publication became a high-impact article (see Chapter 3 Appendix, Section C).

7.4.2.3 Patient attitudes towards analgesia and their openness to non-pharmacological methods such as acupuncture in the emergency department

Published in *Emergency Medicine Australasia* in November 2018, this study was the first patient survey specifically on ED acupuncture and provided valuable information, despite its overt weaknesses such as the survey being unvalidated and outcomes being assessed post hoc. It emphasised what was already known about the determinants of patient satisfaction but offered this knowledge to the modality of acupuncture. Understanding the effectiveness of acupuncture
in the ED is not sufficient—it is also essential to determine whether patients would be willing to use acupuncture and identify the problems they perceive with SAC.

This research primed the mindsets of ED staff. Given that the department was trial naive, it provided a step beyond an ED simply aspiring to provide a high-quality service. I highly recommend to future researchers to perform such research before beginning a formal RCT.

7.4.2.4 Lessons learned in teaching battlefield (ear) acupuncture to emergency medicine clinicians

Published in Medical Acupuncture in October 2020, this was the first publication on teaching BFA in the emergency setting. In comparison, there are many publications on the BFA technique and its effectiveness. The acupuncture movement cannot gain a hold through these publications alone; therefore, the time was right to promote the teaching of BFA. It was imperative to teach ED acupuncture in a way in which emergency clinicians were familiar. This publication was largely based on an ED acupuncture workshop delivered at a national conference in Australia. While this was the second ED acupuncture workshop at an Australian emergency medicine conference, it was the first to be run by emergency physician acupuncturists. While much of the information provided in this thesis on training would be classified as low-ranking evidence, it was enough to start a discussion about whether basic training is sufficient for ED clinicians to perform acupuncture.

7.4.2.5 Battlefield acupuncture added no benefit as an adjunct analgesic in emergency department for abdominal, low back or limb trauma pain

This study was published as an advance online publication in Emergency Medicine Australasia in September 2020. Much of what was done well in this trial addressed the criticisms about ED acupuncture arising from emergency medicine open-access education forums. This involved careful consideration about the ideal sham, acupuncture prescription and blinding of individuals involved in the research and ensuring the rigid adherence to the preregistered protocol. Achieving these objectives has raised the standard of ED acupuncture research for future researchers and will have a substantial impact on upcoming ED acupuncture research.

The sham device used is particularly noteworthy and makes a substantial contribution to acupuncture research. Informal feedback from the investigators was that most patients perceived
the sham (piezoelectric device) as real. I would recommend future trials to consider using this novel sham technique.

While there were no significant quality omissions in our trial, I would recommend that researchers subject their protocols to the Consolidated Standards of Reporting Trials (CONSORT), Scottish Intercollegiate Guidelines Network (SIGN), Cochrane Risk of Bias 2 (RoB 2) or the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) checklists.

7.5 Findings and Outcome Determinations

As outlined in Section 7.2, this thesis draws on multiple lines of evidence, including my original research and the external literature, to obtain the most accurate interpretation of outcomes. All research, including my own, has strengths and weaknesses (see Chapter 7 Appendix).

The synthesis of disparate information is a complicated process but can be made easier using the GRADE approach (see Chapter 1). High-quality studies using large samples and whose findings are consistent with those of other studies are ranked highly, while low-quality studies with indirect and inconsistent findings are ranked low. The evaluation of an analgesic's performance may be facilitated by ranking the various outcomes by importance and comparing them against a gold standard (ideal) analgesic or another analgesic modality.

Each study outcome is briefly defined and discussed below under the following subheadings:

- My research: presents the findings from my original research and systematic reviews and the level of evidence according to the NHMRC hierarchy. Notable strengths or weaknesses are discussed (more details on strengths and weaknesses are provided in Chapter 7 Appendix).
- External literature: presents the findings from the literature, the level of evidence and strengths or weaknesses. This section is further subdivided into ED studies, postoperative studies and outpatient studies.
- Synthesis: provides an overall conclusion for the outcome.
- GRADE: includes confidence in the outcome determination and ranking of the outcome in terms of its importance.
- Future research.
There is also a brief paragraph on acute versus moderate pain under standalone analgesia.

7.5.1 Primary outcome: Acupuncture as a standalone analgesic

This outcome relates to acupuncture being used as the sole analgesic rather than in combination with a pharmacologic analgesic. Its efficacy as an analgesic may be assessed by comparing it with sham acupuncture or SAC.

7.5.1.1 My research

The first meta-analysis on all forms of acupuncture showed that standalone acupuncture was superior to sham acupuncture and equipotent to SAC for low back pain, migraine, renal colic, limb trauma and biliary colic.

7.5.1.2 External literature

- Emergency department studies: Two recent RCTs on ED acupuncture show that acupuncture is not inferior to SAC,\textsuperscript{43,44} Unfortunately, no sham intervention was used in either study. The RCT on renal colic found acupuncture to have a rapid onset of analgesia but had some issues with quality (see Chapter 7 Appendix, Section E).\textsuperscript{44}
- Outpatient studies: There is further supportive evidence, albeit indirect, for the effectiveness of acupuncture in acute and chronic degenerative spinal pain (cervical and lumbar), large joint osteoarthritis, migraine and non-catastrophic chronic headache. This supportive evidence was obtained from systematic reviews and meta-analyses on acupuncture in the outpatient setting and is summarised in Table 7.2. The weakness of this evidence arises from the variable quality of studies, which include those on chronic pain and using multiple treatments. However, as mentioned in Chapter 1, approximately 40% of pain presentations are exacerbations of chronic or recurrent painful conditions.

7.5.1.3 Synthesis

Acupuncture is effective as a standalone analgesic.
Table 7.2: Systematic Reviews on Acupuncture for Acute and Chronic Painful Conditions

<table>
<thead>
<tr>
<th>Condition</th>
<th>Outpatient acupuncture systematic reviews with quality of evidence</th>
<th>ED acupuncture RCT: first author and year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck pain</td>
<td>Trinh 2016 (chronic).(^{49}) High and low quality RCTs</td>
<td>Amos 2012.(^{50})</td>
</tr>
<tr>
<td>Low back pain with radiculopathy (sciatica)</td>
<td>Ji 2015 (acute and chronic).(^ {57}) High and low quality RCTs</td>
<td>Nil</td>
</tr>
<tr>
<td>Major joint osteoarthritis (e.g. hip, knee, shoulder)</td>
<td>Zhang 2017 - knee (chronic),(^ {58}) Manheimer 2018 hip (chronic) - uncertain,(^ {59}) Rubio 2017, Yang 2018 - Shoulder (chronic).(^ {61}) High and low quality RCTs</td>
<td>Nil</td>
</tr>
</tbody>
</table>

Note: Acupuncture outpatient systematic review evidence for acute and chronic painful conditions frequently seen in the ED. RCT: randomised clinical trial; ED: emergency department. Orange = mixed quality; Underlined = results not in favour of acupuncture. Corresponding RCTs on ED acupuncture for the same condition are provided in the right-hand column.

7.5.1.4 **GRADE**

- **Confidence in the outcome determination:** The evidence for this outcome is based on my own meta-analysis as well as recent RCTs and systematic reviews on outpatients. There is confidence in this assessment, and future studies are unlikely to alter this determination.
- **Ranking of importance:** Along with adjunctive analgesia and adverse effects, standalone analgesia ranks highly. However, adverse effects are ranked the highest in importance because pain relief should not take priority over causing harm. The current opioid crisis emphasises this point. Even if the numeric pain rating scale out of 10 (NPRS-10) score
maintains its status as the fifth vital sign, it should be ranked behind the other vital signs.\textsuperscript{45} Two decades ago, emergency doctors paid more attention to airway, breathing and circulation than to pain relief.\textsuperscript{46} Further, pain scores have been criticised for being the sole indicator of analgesic choice, and there are calls for a multimodal assessment of pain (MAP).\textsuperscript{47,48}

7.5.1.5 Moderate versus severe pain

This section warrants a discussion of whether acupuncture is effective for severe pain. Most trials have been based on an NPRS-10 score of greater than 4 (moderate to severe pain). However, severely distressed patients are typically excluded from clinical acupuncture trials. Clinicians intuitively use an unvalidated MAP that quantifies the severity of pain and the need for strong opioids. This MAP includes patient history (of chronic pain, previous opioid use and personality type), patient behaviour, likely pathology and autonomic and vital signs.\textsuperscript{67} Therefore, while acupuncture may be used in patients with high pain scores, if the MAP signifies severe pain with likely serious pathology, acupuncture should be deferred. A MAP assessment in the ED would be an interesting field of research to address this issue.\textsuperscript{48}

7.5.1.6 Future research

Future studies on whether body acupuncture, ear acupuncture or a combination of both is more effective are warranted. Ear acupuncture is simpler to learn, may be applied during triage and allows the co-application of other ED procedures with needles in situ. A MAP may be more useful for determining analgesic administration than pain scores alone. An ED-specific MAP tool could be devised, validated and used to limit the use of acupuncture to pain of mild to moderate severity. Future acupuncture studies could include postintervention questions on patient perceptions of whether or not they were allocated to the sham control group. This feedback could provide information on the authenticity of the sham device or procedure such as the piezoelectric device used in our RCT.

7.5.2 Primary outcome: Acupuncture as an adjunct

This outcome refers to acupuncture being used alongside SAC (or components thereof) to provide additional pain relief.
7.5.2.1 My research

Both systematic reviews and meta-analyses showed limited evidence for acupuncture as an adjunctive analgesic. Two RCTs on BFA (for sore throat and mixed pain, respectively) were included in the meta-analyses.\textsuperscript{35,68} RCTs that were not included in the meta-analyses but showed the benefit of body acupuncture as an adjunctive analgesic included studies on fractured ribs, back pain and migraine.\textsuperscript{50,66,69} Our RCT on BFA did not establish a statistically significant benefit for BFA over SAC. In this category of acupuncture as an adjunct, all studies represented in the meta-analysis were on BFA. This result may not be representative of the effectiveness of body acupuncture as an adjunctive analgesic.

7.5.2.2 External literature

- ED studies: The RCT conducted by Cohen et al.\textsuperscript{43} showed no superiority of acupuncture as an adjunctive analgesic over SAC alone.
- Postoperative analgesia: Unlike the ED RCTs, Level I evidence from systematic reviews and meta-analyses supports the effectiveness of body acupuncture as an adjunctive analgesic.\textsuperscript{70} Murakami et al. also conducted a systematic review and meta-analysis of RCTs on ear acupuncture for early pain relief, which showed benefit but only included three RCTs (two ED studies and one postoperative).\textsuperscript{71} Since then, there have been three studies supporting the efficacy of BFA as an adjunctive analgesic.\textsuperscript{72–74} Unfortunately, a more recent systematic review and meta-analysis of BFA studies in both the ED and postoperative period by Yang et al.\textsuperscript{75} contained significant flaws; thus, any conclusions are doubtful (see letter to the editor in Chapter 5 Appendix).

7.5.2.3 Synthesis

The evidence for the effectiveness of acupuncture as an adjunct in the ED setting is less convincing, but Level I evidence from a systematic review of postoperative body and ear acupuncture is indirectly supportive. Further research is likely to influence this determination.

7.5.2.4 GRADE

- Confidence in the outcome determination: There is some uncertainty with respect to this outcome. Findings from RCTs in the ED setting are inconsistent—four show a statistically significant benefit of acupuncture as an adjunct, while two do not. Cochrane researchers recommend that more than 75% consistency between RCTs is required to
have confidence in results.\textsuperscript{49} Level 1 evidence in the postoperative setting provides encouragement for further research.

- Ranking: This outcome is ranked of equal importance to acupuncture as a standalone analgesic. In the ED, patients are frequently treated following the failure of simple analgesia. Therefore, the effectiveness of adjunctive analgesia is of high importance.

7.5.2.5 Future research

Future studies could validate the use of acupuncture as an adjunct to paracetamol in patients at risk of adverse effects from NSAIDs. My RCT showed no benefit of acupuncture over SAC that included a majority of patients administered opioids. However, acupuncture as an adjunct to paracetamol and NSAIDs may be useful in the case of failed simple analgesia when opioids need to be avoided (e.g. in patients at risk of recurrent use). Future research could also evaluate whether acupuncture is effective as an adjunct to typical and atypical opioids. Although this in part may be a repeat of our RCT, the researcher would need to aim for a lower mean pain score difference of 1.3 and a larger sample size.

7.5.3 Adverse effects

The adverse effects outcome is divided into mortality and significant and minor adverse effects. Significant adverse effects require treatment, whereas minor adverse effects are transient.

7.5.3.1 Mortality

7.5.3.1.1 My research

There were no deaths in the studies included in the systematic reviews nor in our RCT on BFA. However, none of the RCTs included in the systematic reviews were sufficiently powered to determine this secondary outcome.

7.5.3.1.2 External literature

- Observational study: To date, the most reliable approximation of acupuncture mortality is from a prospective observational study by Weidenhammer et al.\textsuperscript{76} on approximately half a million patients who had an average of eight acupuncture treatments along with usual analgesia care. There were no deaths in this study. Given that there were approximately eight acupuncture treatments for each participant with nearly half a million patients, it could be argued that the death rate $[1/(8 \times 454,920)]$ is less than one
in three million treatments. Case reports of deaths caused by acupuncture are reported in the literature. One paper reported on 65 deaths from case reports from 1965 to 2010.\textsuperscript{77} Using the approximate figure of 900 million treatments per year worldwide,\textsuperscript{78} this would imply a mortality rate of approximately one per billion treatments.

7.5.3.1.3 Synthesis

Acupuncture has a very low death rate.

7.5.3.1.4 GRADE

- Confidence in the outcome determination: The evidence for this outcome is based on an observational study, which is generally considered fair quality. However, I have upgraded my confidence in the results of this study because of the large sample size.
- Ranking: As discussed above, adverse effects, including mortality, is ranked the highest in importance because pain relief should not take priority over potential harm.

7.5.3.1.5 Future research

Given the confidence in this result for this outcome and the large sample size in the observational study by Weidenhammer et al.,\textsuperscript{76} further research is unlikely to alter this result.

7.5.3.2 Significant adverse effects

Significant adverse effects are defined as those that require treatment.

7.5.3.2.1 My research

Both systematic reviews included adverse effects of acupuncture as a secondary outcome. The first systematic review (on all forms of acupuncture) reported a 1% incidence of adverse effects (three needle breakages and four fainting incidents), which is consistent with the global literature (0.02–2.0%).\textsuperscript{79} The relative risk of adverse effects for acupuncture versus SAC was less than 0.1. In our RCT on BFA, no significant adverse effects occurred.

7.5.3.2.2 External literature

- Observational study: Again, the study most sufficiently powered to evaluate the incidence of significant adverse effects was that by Weidenhammer et al.,\textsuperscript{76} who found per treatment course (an average of eight acupuncture sessions) a 0.4% incidence of
fainting and a one in 295,000 incidence of severe adverse reactions (e.g. pneumothoraces, hypotension and asthma).

7.5.3.2.3 Synthesis

Acupuncture has a low significant adverse effect rate.

7.5.3.2.4 GRADE

- Confidence in the outcome determination: Given the consistency of findings from multiple sources, including the large observational study (graded as relatively high-tier evidence), there is confidence in this result.
- Ranking: As above for mortality.

7.5.3.2.5 Future research

The sample size required to adequately power a study to measure adverse effects as a primary outcome would be very large. It would be challenging to improve on the results of the large prospective observational study by Weidenhammer et al.76

7.5.3.3 Minor adverse effects

Minor adverse effects include mild and local manifestations such as pain on needle insertion, minor bleeding or bruising following needle removal, transient skin reactions and temporary alterations in mental and emotional states.80 The difficulty lies in whether these reactions should be deemed therapeutic (de qi) or adverse.81,82 De qi, translated from Chinese, means the arrival of qi. This issue reflects the challenge of using the Western scientific paradigm to assess the Chinese holistic approach.81,82 Inconsistent reporting makes quantification difficult, while open-ended questions yield lower response rates than structured questionnaires.82

7.5.3.3.1 My research

The first systematic review on all forms of acupuncture revealed a 2.4% incidence of minor side effects. Survey comments on reasons for not wanting acupuncture included minor effects such as pain arising from needling.83 In our RCT, two participants did not complete the protocol because of the pain from inserting the ear needles.56 While designated as a minor effect, discomfort from or fear of needles may be seen as a disadvantage of the modality. However,
paradoxically in TCM, these minor symptoms could be considered a manifestation of a successful therapeutic intervention.

7.5.3.3.2 External literature

- Outpatient study: An RCT based on an open-ended questionnaire specifically measured the mild adverse effects of acupuncture as a primary outcome, finding an incidence of 3.5% above placebo (NNH = 29).82

7.5.3.3.3 Synthesis

Acupuncture commonly causes minor adverse effects.

7.5.3.3.4 GRADE

- Confidence in the outcome determination: This result was consistent across my research (systematic reviews, survey and RCT) and with an external RCT on minor adverse effects as a primary outcome. Therefore, this finding is likely to be valid, and further research is unlikely to alter it.
- Ranking: While minor adverse effects may deter some patients, it is regarded as being of low importance.

7.5.3.3.5 Future research

Low-level laser acupuncture is painless and may be an option for patients unwilling to use acupuncture because of fear or the pain of needling. An ED study on the effectiveness of low-level laser acupuncture is warranted. Further, a qualitative study on patient experiences with acupuncture in the ED setting would provide useful insights into the nature of de qi and the mechanism of acupuncture analgesia.29,84

7.5.4 Patient satisfaction

Patient satisfaction is typically a secondary outcome, measured using Likert satisfaction or agreeability scores. Likert ratings ask patients to rate their pain management or willingness to use or reuse acupuncture.
7.5.4.1 My research

The systematic review showed that in all RCTs on ED acupuncture, patient satisfaction improved. In the observational study, around two-thirds of patients would be willing to use acupuncture again. In the patient survey, the majority were willing to use acupuncture. In our RCT, there was no difference in satisfaction rating between treatment arms.

7.5.4.2 External literature

- ED studies: A large study by Cohen et al.\textsuperscript{43} showed an improvement in satisfaction post discharge. A recent observational study shows the majority of patients were willing to use acupuncture.\textsuperscript{85}

7.5.4.3 Synthesis

Acupuncture is a patient-satisfying analgesic modality.

7.5.4.4 GRADE

- Confidence in the outcome determination: Apart from our BFA RCT, all ED studies on acupuncture where satisfaction was measured ($n = 11$) found that satisfaction improved with acupuncture; however, these were all secondary outcomes.\textsuperscript{43,79} Despite these being secondary outcome measures, there is confidence in acupuncture as a patient-satisfying therapy given the consistency in results. It is unlikely that future studies will alter this determination.

- Ranking: Patient satisfaction is an essential component of pain management and requires a separate outcome measure because pain score reduction does not necessarily correlate with patient satisfaction.\textsuperscript{86,87} Further, pain and its associated suffering is a subjective experience, and while a medical understanding of the disease process is essential, each patient has a unique phenomenological experience.\textsuperscript{88} Another reason to rank patient satisfaction more highly include is that it is a physician’s legal duty to relieve pain and suffering.\textsuperscript{89} Improved satisfaction warrants specific attention, leading to improved patient compliance and reduced litigation.\textsuperscript{90} On the negative side, patient satisfaction surveys contribute to excessive opioid prescribing. Therefore, the medical profession should not prioritise this outcome because it may not be in patients’ long-term interests.\textsuperscript{20} Therefore, satisfaction is ranked as important but below pain score reduction.
7.5.4.5 Future research

All studies to date have included patient satisfaction as a secondary outcome. The ideal method to ascertain patient satisfaction would be an RCT with satisfaction as the primary outcome measure. A Likert scale or specific pain management satisfaction questionnaire adapted to the ED could be utilised to provide more detailed information.\textsuperscript{91,92}

7.5.5 Opioid-sparing ability

From the emergency medicine perspective, opioid-sparing ability would include the reduction of ED administration of opioids, take-home supplies and opioid use post discharge.

7.5.5.1 My research

Four studies included in the systematic review measured overall analgesic use (not specifically opioids), with two showing a reduction. Our BFA RCT found no reduction in opioid use.

7.5.5.2 External literature

- ED study: In a recent pilot ED BFA study, no intradepartmental reduction in opioid administration occurred.\textsuperscript{55}
- Postoperative studies: Opioid reduction has been shown as a primary outcome in Level I studies on both body and ear acupuncture.\textsuperscript{70,71} In all BFA studies to date \((n = 9)\), opioid reduction has not been demonstrated\textsuperscript{93} (see Table 5.2).

7.5.5.3 Synthesis

It is uncertain whether acupuncture reduces opioid use in the ED, take-home prescriptions or post-discharge home use.

7.5.5.4 GRADE

- Confidence in the outcome determination: Given the lack of studies overall and the fact that most existing studies have measured the reduction of all analgesics, it is uncertain whether acupuncture is opioid sparing in the ED environment. There is Level I evidence for the opioid-sparing ability of ear and body acupuncture in the postoperative setting.
- Ranking: As mentioned in Chapter 1, opioids are associated with increased mortality, adverse effects, abuse and dependence. ED administration and take-home prescriptions
increase recurrent use. The harm caused by the excessive and injudicious use of opioids is now well accepted in the field of pain medicine; hence, this outcome is ranked as important.

7.5.5.5 Future research

Is acupuncture an opioid-reducing strategy? To date, two RCTs have shown this not to be so, but these were based on opioid reduction as a secondary outcome only. Therefore, to accurately measure this outcome, opioid sparing would need to be the primary outcome. The best models are postoperative acupuncture trials, the majority of which have used a patient-controlled analgesia pump that provides rescue boluses of opioids as required.94-96 Ideally, the study would be sufficiently powered (including anticipated dropout rate) to be able to measure a 30% reduction in opioid use and use a strict algorithm in which opioids are administered according to a designated pain score (i.e. NPRS-10 > 4).

7.5.6 Administration time

Administration time is the time taken to administer acupuncture and includes patient preparation and needle insertion.

7.5.6.1 My research

The systematic reviews and BFA RCT all determined that body or ear acupuncture takes less than 10 minutes to apply.

7.5.6.2 External literature

There are no studies beyond those included in our systematic reviews on the administration time of acupuncture.

7.5.6.3 Synthesis

Application time is significant, especially compared with the time taken to administer oral or parenteral analgesia.

7.5.6.4 GRADE

- Confidence in the outcome determination: The evidence is based on consistent secondary outcome results and is likely to be valid.
• Ranking: Application time can be demanding on clinicians’ time. This may be partially compensated by the nursing time involved in opioid documentation and post-opioid observations. Even though 10 minutes may appear to be minimal, in busy EDs this may be viewed as a disadvantage of this modality. This outcome is given a low ranking.

7.5.6.5 Future research

Could the employment of a dedicated full-time acupuncturist in the ED save time for ED clinical staff and improve length of stay and numbers of patients seen in the ED? A pre- and postintervention study design would be best suited to answer this question.

7.5.7 Costings

This outcome refers to the direct costs of needles as consumables. If there were a reduction in analgesic usage, this would be deducted from the cost.

7.5.7.1 My research

The systematic reviews and BFA RCT found that BFA needles cost up to A$6.50 per patient, with filiform needles being less expensive. The BFA RCT showed that the wholesale price of standard pharmaceutical analgesics was a little over A$1.00 per patient.

7.5.7.2 External literature

There are no studies on the costs of acupuncture beyond those included in our systematic reviews.

7.5.7.3 Synthesis

Acupuncture consumables are low in cost but do not produce a cost saving in relation to standard analgesics. As mentioned above, reduction of analgesia in the ED as a result of acupuncture has mixed results to date. Indeed, if acupuncture became more widely used, the cost of needles would become cheaper if purchased at wholesale prices.

7.5.7.4 GRADE

• Confidence in the outcome determination: There were consistent costing results among the RCTs included in the systematic reviews; therefore, there is confidence in this assessment.
• Ranking: Costs are a factor in deciding on therapeutic modalities at the department, hospital, community and national levels. However, this outcome is of limited utility (see ‘Future research’ below) and is given a low ranking.

7.5.7.5 Future research

The costing outcome should be more complicated than provided here. If acupuncture eventually leads to a reduction in opioid use, then savings in community costs (e.g. rehabilitation, health care and legal costs) may be possible.97,98 A cost–benefit analysis could also be calculated based on the proposed study for the administration time outcome above. A full-time acupuncturist (A$60,000) earns about half the salary of an emergency physician (A$120,000).99 Therefore, if there are time and cost savings, a business case could be made to employ acupuncturists in the ED.

7.5.8 Training requirements

Can ED physicians, nurses, nurse practitioners and physician assistants be trained in the effective and safe use of basic acupuncture? Training may be an obstacle if emergency physicians require extensive training in acupuncture. Alternatively, EDs could employ qualified acupuncturists. For this secondary outcome, the level of training needed to practise acupuncture in the ED was investigated.

7.5.8.1 My research

The systematic reviews showed that registered acupuncturists performed body acupuncture but BFA was delivered by non-acupuncturists, as occurred in our BFA RCT. I successfully taught BFA to emergency clinicians in 4 hours, while at least an 8-hour course is required to teach body acupuncture.

7.5.8.2 External literature

In 2015–2016, over 1,300 BFA course attendees (mostly non-acupuncturists) were taught BFA. To date, attendees are likely to be over four times this number.100,101 In Australia, physiotherapists require a minimum of 16 hours training before they can use acupuncture techniques.102,103 Witt et al.104 showed that practitioners with less than 200 hours of training in body acupuncture were no more effective than those with over 200 hours of training.
7.5.8.3 Synthesis

BFA competency can be achieved in 4 hours. The ideal duration and form of post-course supervision are yet to be determined, but general skill retention principles should apply. The minimum training needed for emergency clinicians to perform body acupuncture remains uncertain.

7.5.8.4 GRADE

- Confidence in the outcome determination: There is confidence that the BFA technique can be learned in 4 hours. This assessment is based on trials using non-acupuncturists, the popularity of courses in the US and my teaching experience. The training requirements for body acupuncture remain uncertain, and further research will likely influence this assessment.

- Ranking: While the delivery of acupuncture in the ED is an important question, it is given a lower ranking. The outcomes on the efficacy of acupuncture as an adjunct and its opioid-sparing ability need to take priority because they will be more likely to influence the use of acupuncture.

7.5.8.5 Future research

Do ED clinicians perform ED acupuncture as effectively and safely as qualified acupuncturists? To answer this question, an RCT is needed in which providers are randomised to two groups (i.e. basically trained and formally trained acupuncturists) and the study is sufficiently powered to measure pain reduction, patient satisfaction and adverse effects (particularly minor). A shorter duration of training would suit smaller EDs, which are unlikely to have a sufficient number of cases to justify employing a registered acupuncturist. Minimum training standards to practise acupuncture in the ED could be decided by a panel of experts, such as a specialist interest formed by the college of emergency medicine with assistance from the medical acupuncture college.
Table 7.3: Acupuncture Infographic: Primary and Secondary Outcomes of Research on the Role of Acupuncture in the ED

<table>
<thead>
<tr>
<th>Outcomes for evaluating ED acupuncture</th>
<th>Level of evidence (primary or secondary outcome)</th>
<th>Strength of determination</th>
<th>Compared with the Ideal analgesic</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse effects</td>
<td>Large prospective UOBS for mortality and significant AE, secondary outcomes for minor adverse effects</td>
<td>Confident</td>
<td>Acupuncture has low mortality, low significant adverse effects, but common minor side effects</td>
<td>High importance</td>
</tr>
<tr>
<td>Pain reduction (stand-alone)</td>
<td>SR • MA primary outcome</td>
<td>Confident</td>
<td>Acupuncture has analgesic potency as a stand-alone</td>
<td></td>
</tr>
<tr>
<td>Pain reduction (adjunct)</td>
<td>Limited evidence SR • MA primary outcome, Mixed results from RCTs</td>
<td>Uncertain</td>
<td>Uncertain whether acupuncture adds analgesia above SAC</td>
<td></td>
</tr>
<tr>
<td>Satisfaction</td>
<td>SR secondary outcome</td>
<td>Confident</td>
<td>Acupuncture is a patient satisfying modality</td>
<td>Important</td>
</tr>
<tr>
<td>Opioid sparing</td>
<td>SR secondary outcome</td>
<td>Uncertain</td>
<td>Uncertain whether acupuncture is opioid sparing</td>
<td></td>
</tr>
<tr>
<td>Administration time</td>
<td>SR secondary outcome</td>
<td>Confident</td>
<td>Acupuncture is time consuming, takes &lt; 10 minutes to administer</td>
<td></td>
</tr>
<tr>
<td>Cost</td>
<td>SR secondary outcome</td>
<td>Confident</td>
<td>Acupuncture is low cost but ear needles more costly than SAC</td>
<td>Low importance</td>
</tr>
<tr>
<td>Training requirements</td>
<td>SR secondary outcome, Expert opinion</td>
<td>Uncertain</td>
<td>BFA easy to learn, uncertain with body acupuncture</td>
<td></td>
</tr>
</tbody>
</table>

This infographic reveals the decision-making process of this thesis to ascertain the role of acupuncture in the ED. It orders the evidence, confidence of the determination, and relation to the ideal analgesic for primary and secondary outcomes. These outcomes are then ranked in importance for evaluating an analgesic in today’s current environment. ED: emergency department; UOBS: uncontrolled observational study; AE: adverse effects; SR: systematic review; MA: meta-analysis; RCT: randomised controlled trial; BFA: battlefield acupuncture; SAC: standard analgesia care. Green = good quality evidence, confidence in results or ideal analgesic qualities; orange = uncertain; red = expert opinion, low confidence in results or not an ideal analgesic.

7.6 Discussion

This section provides the final evaluation of findings and subsequently discusses them in relation to the global literature by answering the following questions: Which of the findings are already embedded in the literature? Which findings are likely to have a substantial impact and become embedded in the literature? How do these findings integrate with current knowledge? How does it change things in the short term? How may acupuncture fit into the ED analgesic armamentarium? What does the future hold?

7.6.1 Final evaluation of the outcomes on emergency department acupuncture

As foretold in Chapter 1, the infographic —Table 7.3 is populated with my research findings and the extant literature. The evaluation process involved grading the evidence and revealing the
confidence of the final assessment of the outcome. These outcomes are then compared to the ideal analgesic and ranked in importance to pain management priorities in the ED.

Acupuncture has an almost negligible rate of both mortality and significant adverse effects. It can cause minor adverse symptoms, which, paradoxically, are considered by traditional acupuncturists essential mechanisms of its therapeutic effect. It is effective as a standalone analgesic but has uncertain effectiveness as an adjunctive analgesic. This uncertain effectiveness is concerning given the considerable number of patients requiring further pain relief following failed oral analgesia. Conditions showing successful pain reduction include recurrent painful musculoskeletal conditions, spinal pain, migraines and renal colic. Acupuncture is associated with patient satisfaction and willingness to use it, although a small number of patients may refuse acupuncture because of its minor adverse symptoms or ineffectiveness in the past.

At this stage, unlike in the postoperative setting, acupuncture has not been shown to be opioid sparing in the ED. Unfortunately, acupuncture does take time to administer, which may not be suitable in a busy ED. Acupuncture needles are low in cost relative to the overall running costs of an ED but are not currently cheaper than the wholesale price of analgesics. While some forms of acupuncture such as BFA are easily learned, it remains unknown whether basic training on body acupuncture for ED clinicians, similar to that for physiotherapists, would be effective and safe.

These findings address the research questions presented in this thesis. Clinicians and policymakers can compare these ED acupuncture characteristics with ED analgesics to evaluate acupuncture's potential clinical usage. Figure 7.4 provides a visual comparison of ED acupuncture outcomes versus the ideal analgesic and opioids. As mentioned previously, a detailed analysis of opioid or NSAID characteristics is beyond the scope of this thesis, and clinicians and policymakers may need to engage in further research to substantiate this summary.

7.6.2 Which of the findings are already embedded in the literature?

Both of the systematic reviews have influenced recent scientific publications. The findings from our review on all forms of acupuncture have been cited in *Acute Pain Management: Scientific Evidence*, a Consortium Pain Task Force white paper, a review on advances in acupuncture analgesia and two narrative reviews on ED acupuncture for emergency physicians and nurse practitioners, respectively. Table 7.4 shows the outcomes that have been cited in other papers.
Our systematic review on ear acupuncture has been labelled as high impact by the journal because of the high number of downloads (see Chapter 3 Appendix, Section C). It has been cited in *Acute Pain Management: Scientific Evidence*, a review on the adverse effects of ear acupuncture, a systematic review on BFA and numerous trials as background information to support reasons for carrying out the trial (see Chapter 7 Appendix). The aforementioned systematic review of BFA by Yang et al. noted the uncertain effectiveness of ear acupuncture as an adjunctive analgesic.

---

**Figure 7.4: Acupuncture analgesia compared with the ideal analgesic and opioids.**

Figure showing the performance of acupuncture analgesia against the ideal analgesic and opioids. An infographic comparing the ideal analgesic with SAC is shown in Figure 1.4. The same process could be applied to other analgesics in the ED armamentarium (e.g. non-steroidal anti-inflammatory drugs). ED: emergency department; SAC: standard analgesia care; BFA: battlefield acupuncture. Green = ideal; orange = uncertain; red = poor performance; white print = primary outcomes for this thesis.
Table 7.4: Systematic Review Findings in the Global Literature

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Acute pain management: scientific evidence (Zheng et al.)</th>
<th>USA Consortium Pain Task Force White Paper (Tick et al.)</th>
<th>Acupuncture in the Emergency management of painful conditions (Glauser et al.)</th>
<th>Complementary therapies for acute pain management (Jackson et al.)</th>
<th>Advances in analgesia (Qiao et al.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low adverse effects—significant and minor</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Effective as a Stand-alone analgesia</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Uncertain whether effective as an adjunct</td>
<td></td>
<td></td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient satisfying modality</td>
<td></td>
<td></td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uncertain opioid sparing and analgesia</td>
<td></td>
<td></td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Administration time is small but significant</td>
<td></td>
<td></td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low cost</td>
<td></td>
<td></td>
<td>☑</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training requirements</td>
<td>Created a new category on ED acute pain and trauma non-pharmacological analgesia. Quoted as Level 1 evidence</td>
<td>Quotes points and conditions where efficacious</td>
<td>Quotes conditions where efficacious and clinical indications</td>
<td>Applicable to the ED setting and conditions where efficacious</td>
<td></td>
</tr>
</tbody>
</table>

Table showing outcome findings from Chapter 2 that are embedded in world literature. The five reviews are cited by the first author.

7.6.3 Which findings are likely to have a substantial impact and become embedded in the literature?

7.6.3.1 Analgesia as an adjunct

The ineffectiveness of acupuncture as an adjunct to SAC (including opioids) in two recent RCTs (including ours) was unexpected. As previously discussed, the effectiveness of this outcome is important given the rate of failed initial analgesia following triage or ED administration. However, positive results from acupuncture studies in the postoperative and outpatient settings provide encouragement for further research.76,96

7.6.3.2 Patient satisfaction

This thesis generated new knowledge about patient willingness to receive acupuncture as an analgesic in the ED and reinforced the lack of patient satisfaction with opioids. This result has implications for administrators, who seek patient satisfaction to improve hospital reputation, therapeutic alignment and compliance with take-home instructions and reduce complaints and litigation.86,90,111

7.6.3.3 Training

This thesis has found that BFA is acceptable as a standalone analgesic modality and teachable in a half-day course. This may lead to controversy because some countries, states and institutions (including the World Health Organization) have recommended a minimum of 200 hours acupuncture training for doctors.112
7.6.4 How do these findings relate to and integrate with current knowledge?

Acupuncture as a standalone or adjunct analgesic is an evidence-based modality that has been accepted into the fields of chronic and postoperative pain relief. It seems natural that acupuncture will eventually be used in the ED setting, and it is surprising that its uptake has been limited to ED trials. It is anticipated that with this body of evidence on acupuncture and the enthusiasm for alternative analgesics, interest in and use of acupuncture will gather momentum.

This knowledge will help to meet the demand from researchers, providers, administrators and the public for opioid alternatives. There are growing demands for alternatives to opioids analgesia as well as opioid-free and opioid-lite EDs. This thesis adds another modality to the opioid alternative list from which researchers and clinicians can choose.

The short- and long-term adverse effects of SAC, the growing number of chronic pain patients and the failure to relieve pain are driving changing perspectives in chronic pain management. Some researchers argue that patients expect an easy solution for their pain using drugs or procedures. This behaviour is promoted by medicine as a business, resulting in the disempowerment and disrespect of patients. It makes intuitive sense that non-pharmacological methods are more likely to result in a healthier mind, body and lifestyle, with consequent improvements in long-term quality of life. This thesis has highlighted the high percentage of patients with chronic pain or ongoing recurrent painful conditions attending EDs. Patients presenting with pain to EDs should be treated with the same care as those presenting to pain clinics rather than being processed quickly with the short-term goals of pain reduction.

Patients presenting with pain to the ED pain are experiencing a moment of crisis. Introducing opioids at that point increases the risk of those patients reusing opioids. In contrast, a positive non-pharmacological intervention such as acupuncture is more likely to lead to the future use of such an intervention.

This knowledge offers a new approach to ED pain presentations and may be integrated with the ethics, values and foundation of the Western medical paradigm. There are times when EBM is incorrect, and it is in these times that the art of medicine or ethics should guide us to make better decisions.
7.7 Recommended Clinical Indications

7.7.1 How does it change things? Where might acupuncture fit into the ED analgesic armamentarium?

This thesis makes recommendations regarding the clinical indications for ED acupuncture and when to change the current approach to SAC. In the current SAC approach, patients who fail to respond to simple analgesia (e.g. paracetamol and ibuprofen) and those presenting with severe pain are typically administered opioids. However, a subset of these patients are at risk of recurrent opioid use or early adverse effects and should be considered for acupuncture (see Figure 7.5).

Many patients at risk of recurrent opioid use are those with non-catastrophic pain such as spinal pain (with or without radiculopathy), degenerative large joint disease and recurrent headaches. There is evidence for the efficacy of acupuncture for these conditions in both the ED and outpatient settings. As mentioned in Chapter 1, it is surprisingly common for patients with an exacerbation of chronic pain or recurrent painful conditions to present to the ED. The risk of recurrent opioid use is also determined by a patient’s psychological profile. Screening patients in ED with an opioid risk tool could assist in detecting these patients. Some patients are also at a higher risk of early adverse effects from all types of opioids.

Both separate and included in the groups above are those patients with a risk of early adverse effects. This scenario occurs when the clinician predicts adverse effects to NSAIDs, steroid injections or other procedures. There are a small group of patients that suffer from early adverse effects to all available opioids.

A proviso to these recommendations is that patients in genuine severe pain should still be treated with opioids. However, a proportion of patients with high pain scores (NPRS-10 ≥ 7) may not be assessed via MAP to be in severe pain. It is for these patients that ED acupuncture (either ear or body acupuncture) may be chosen, subject to provider competency (see Figure 7.5).

Finally, some patients refuse standard analgesia but are open to acupuncture as first-line treatment.
Note: Acupuncture may be used when concerns about adverse effects of analgesia are high. Usage is influenced by pain severity and patient choice. Following a multimodal assessment of pain (rather than pain score alone), acupuncture should be used for patients with mild to moderate pain.

### 7.7.2 When not to use emergency department acupuncture

Opioids are indicated for most patients presenting to the ED in acute severe pain (as assessed using MAP rather than NPRS-10 alone). However, prior to dispensing opioids, patients should be screened with an opioid risk assessment tool, have a low likelihood of recurrence of the painful condition and no prior adverse reactions to opioids. Opioids are the mainstay treatment for fractures, dislocations and acute abdominal pain. Acupuncture should only be used for patients who are willing because its efficacy is associated with an expectation of benefit. Acupuncture should not be administered by inadequately trained providers or in unsuitable circumstances (e.g. lack of time, no accessible nurse call system or patient supervision).

#### 7.7.2.1 Acupuncture—a reminder for better analgesic prescribing!

There may be times when a practitioner does not have acupuncture skills or disagrees with the evidence on ED acupuncture presented in this thesis. However, the mere suggestion of acupuncture as an alternative may encourage ED clinicians to make more considered analgesic choices. Alternatives to opioids, including physiotherapy, lifestyle recommendations, fewer
prescriptions or even suggesting that patients mindfully tolerate their pain, are more desirable for at-risk patients.

7.8 Future Directions

7.8.1 What does the future hold? Where do we go with this information?

Identifying knowledge gaps, which inform research questions for future studies, is as crucial as the data presented on acupuncture characteristics.

7.8.1.1 Future research summary

Research questions for suggested future studies have already been mentioned in some detail under the relevant outcomes. This section summarises the key proposed studies.

Ear acupuncture appears well suited to the ED environment and is easily taught. Ascertaining its effectiveness compared with body acupuncture is warranted. There are potential inherent biases in selecting patients for acupuncture trials, as the process of consent excludes a distressed patient or those that are deemed to require urgent medical attention. Yet, patients with high pain scores still enter trials. Perhaps an objective provider assessment of pain severity might have given a lower score than the patient’s subjective evaluation for these patients. One method for ascertaining severe pain is MAP. Such a tool could be further investigated in the ED environment to assess whether it correlates with analgesic type and use. In our BFA RCT, the majority of patients received opioids, and acupuncture showed no benefit as an adjunct. Therefore, the next step would be to ascertain the effectiveness of acupuncture as an adjunct to simple analgesia (e.g. paracetamol, NSAIDs). For patients that refuse acupuncture because of the pain involved, low-level laser therapy may be an option. The opioid-sparing ability of acupuncture is a crucial question, and the two trials that have tested this as a secondary outcome showed no reduction in opioid use. Therefore, the opioid-sparing ability of acupuncture should be tested as a primary outcome. Given that acupuncture takes time to administer, the employment of a lower-salaried acupuncturist in the ED could make economic sense while improving throughput.

7.8.2 Future emergency department acupuncturists

The introduction of acupuncture to the ED setting may be achieved either by the employment of a qualified registered acupuncturist or by training ED clinicians in basic acupuncture. While large departments may be able to rationalise the former, small to medium-sized EDs have lower
attendances and varied presentations. Consequently, a full-time acupuncturist may have too much downtime. These EDs rely on clinicians with a wide range of skills to handle the large variety of presentations. Therefore, the findings of this thesis will have little clinical impact if ED clinicians are not trained in basic acupuncture. Researchers and colleges of medical acupuncture and emergency medicine will need to decide on minimum acupuncture training standards. BFA is already established as a modality that requires half a day of training. The World Health Organization and medical acupuncture colleges mandate a minimum of 200 hours training for physicians to perform general (body) acupuncture and assume the title of acupuncturist. However, as we have seen with general practitioners, physiotherapists, chiropractors and osteopaths, acupuncture techniques appear effective with only basic training. Demanding lengthy formal training would be an impediment to the progress of a potential beneficial modality.

7.9 Conclusion

This thesis asked one central question: Is there a role for acupuncture in the ED? The answer is yes, but only in certain circumstances.

Acupuncture in the ED would be regarded by many as novel. With few trained ED clinicians, the immediate blanket incorporation of acupuncture into the ED analgesic armamentarium would be both impractical and premature. Therefore, at the current level of knowledge, acupuncture use may be considered and rationalised only if the adverse risks of SAC outweigh the benefits.

This situation occurs much more frequently than expected. Medical and allied health providers outside the ED typically envisage ED pain presentations as acute injuries or initial presentations of painful conditions. The high proportion of chronic pain exacerbations, recurrent painful conditions or patients at risk of opioid reuse presenting to the ED is surprising. Short- and long-term adverse effects of both opioids and NSAIDs are common.

ED clinicians are aware of the hazards of opioids. Despite this, many have not changed their practices or have merely replaced oxycodone with atypical opioids rather than reconsidering the entire pain management approach. It is beyond the scope of this thesis to investigate the rate of adverse effects and profile of atypical opioids. However, significant dependence and mortality occur and are yet to be definitively determined.125
The following patients would likely benefit from acupuncture analgesia and suffer less harm in the short and long term: those at risk of opioid dependence; those suffering exacerbations of chronic musculoskeletal pain, spinal pain (with or without radiculopathy) or non-catastrophic recurrent headaches; and those at risk of adverse effects of NSAIDs, steroid injections or other procedures. Acupuncture use would be influenced by the severity of pain and patient choice.

At this stage, acupuncture should be reserved for mild to moderate pain as deemed by the medical provider using a MAP rather than subjective pain scores alone, which are somewhat unreliable. ED acupuncture research to date is likely to have an inherent bias towards patients with moderate rather than severe pain. For those in genuine severe pain, especially those with their first pain presentation, it would be inappropriate to displace opioids.

There are still knowledge gaps with regard to ED acupuncture. Given that recent high-quality studies, including my own, have shown that acupuncture adds no benefit when used as an adjunct to opioids, fellow researchers are requested to investigate acupuncture as an adjunct to simple analgesia (i.e. paracetamol and/or NSAIDs). The opioid-sparing ability of acupuncture has only been measured as a secondary outcome in two studies; thus, the findings are likely to be inaccurate. Given the high-quality evidence showing the opioid-sparing ability of acupuncture in postoperative pain, opioid sparing in the ED setting should be tested as a primary outcome to allow the acupuncture movement to progress and hopefully help address the opioid crisis.

Given the low numbers of emergency clinicians with even basic acupuncture skills, the incorporation of acupuncture into the ED analgesic armamentarium is likely to be minimal. Therefore, this thesis recommends a special interest group be formed at ACEM with support from AMAC to promote ED acupuncture courses and establish minimum training standards. Similar organisations in countries outside Australia could do the same. To expect ED clinicians to become fully trained acupuncturists is likely to impede the widespread uptake of this analgesic modality.
Chapter 7 References


87. Kelly A-M. Patient satisfaction with pain management does not correlate with initial or discharge VAS pain score, verbal pain rating at discharge, or change in VAS score in the emergency department. *J. Emerg. Med.* 2000; 19(2): 113–6. doi.org/10.1016/S0736-4679(00)00219-5


Appendix to Front matter – Section A

Co-author permissions to include publications and agreed contributions
Dear Co-authors: Professor Eric Visser Professor Ian Rogers, Emogene Aldridge, Professor Max Bulsara, Associate Professor/Colonel Richard Nienstow, Associate Professor Lorna Suen, Dr Dana Hince and Dr Michael Woosey

I am preparing the final thesis. Can I have your permission to include the following co-authored papers in my thesis? At this stage, we are planning to add the published journal pdf versions in thesis for the examiners. Then after that, we are undecided whether to have a one year’s embargo with the latter before posting the thesis on-line or present our submitted articles in word without a year’s embargo. You might let me know your thoughts on either alternative, but either way, I still need your permission.

5. Jan AL, Aldridge ES, Rogers IR, Visser EJ, Bulsara MK, Hince D. Patient attitudes to standard analgesia care and their openness to non-pharmacological methods such as acupuncture in the ED. Emergency Medicine Australasia. 2019; 31: 475-8

Andrew Jan
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MBBS FACEM BA FAMAC MPhil
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E. drandrewjan@gmail.com
Appendix 3
Hi Richard,

I'm just tidying up the appendix - this email may have been misinterpreted. Is it OK to include from your perspective our co-authored papers listed?

Andrew

Hi Andrew,

I definitely would place the published articles in your dissertation as they represent outstanding accomplishment that you have earned and substantiates the value of your work! Wonderful!

I got busy with the journal. PTSD is moving forward and IRB approved, and have to prepare for the low vision retinal degeneration application.

We should chat sometime.

Richard

Richard C. Niemtzow, MD, Ph.D., MPH
Assistant Professor
Final pdf and details of conference

Emogene Aldridge <emogene.> To: Andrew Jan <drandrewjan@gmail.com>
Sun, Jan 10, 2021 at 12:14 PM

Hi Andrew,

I've attached the final PDF here.

This is my resume entry for this presentation.
Aldridge ES, Jan AL, Rogers IR, Visser E, Bulsara M. Is there a point? The role of acupuncture for acute pain in the emergency department: A systematic review and meta-analysis. Presented at the 33rd Annual Scientific Meeting of the Australasian College for Emergency Medicine 2016.

Don't mind you including it at all.

Kind regards,
Emogene

From: Andrew Jan <drandrewjan@gmail.com>
Sent: Saturday, 9 January 2021 3:56 PM
To: Emogene Aldridge <emogene.> Subject: Final pdf and details of conference

[Quoted text hidden]

Attachments:

ACEM POSTER.pdf 2834K
Appendix

Appendix 6
Appendix to Chapter 2 - Section A

Supplementary material for the publication:

Appendix Figure 1 Showing relative risk of adverse events for acupuncture versus standard analgesia care.
Appendix Figure 2 Forest plot of acupuncture versus sham with calculated weighted mean difference for pain score difference.
Appendix Figure 3 Forest plot of acupuncture versus standard analgesia care with calculated weighted mean difference for pain score difference.
**Appendix Figure 4** Forest plot of acupuncture as adjunct versus standard analgesia care with calculated weighted mean difference for pain score difference.
### Appendix to Chapter 2 Supplementary Table 1

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute pain</td>
<td>“The physiologic response and experience to noxious stimuli that can become pathologic, is normally sudden in onset, time limited, and motivates behaviors to avoid actual or potential tissue injuries”.61 Acute pain management occurs in a variety of patient care settings e.g. prehospital, emergency department, and perioperative environments.61 In all settings patients may suffer from acute and chronic pain simultaneously.</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>“Acupuncture includes traditional body needling, moxibustion, electric acupuncture (electro-acupuncture), laser acupuncture (photo-acupuncture), microsystem acupuncture such as ear (auricular), face, hand and scalp acupuncture, and acupressure (the application of pressure at selected sites)”.62 Modern modification of this system have been developed and include: Japanese, Korean, Wrist-Ankle and Western (uses evidence based medicine).</td>
</tr>
<tr>
<td>Sham acupuncture</td>
<td>The insertion of needles into wrong points or non-points, superficial needling or non-skin penetration with all being in violation of traditional acupuncture theories.53</td>
</tr>
<tr>
<td>Sham acupuncture trial (sham)</td>
<td>Comparing acupuncture alone against sham acupuncture alone.</td>
</tr>
<tr>
<td>Standard analgesia care (SAC) trial</td>
<td>Using the standard of pain care designated by the local institution, researcher or guidelines as the comparator against acupuncture.</td>
</tr>
<tr>
<td>Acupuncture adjuvant analgesia (AdjA) trial</td>
<td>A trial where SAC is combined with acupuncture versus either SAC alone.</td>
</tr>
<tr>
<td>Author (year)</td>
<td>Intervention</td>
</tr>
<tr>
<td>--------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Xia (2015)</td>
<td>Acupuncture</td>
</tr>
<tr>
<td>Cook (2015)</td>
<td>Acupuncture</td>
</tr>
<tr>
<td>Demir (2015)</td>
<td>Acupuncture</td>
</tr>
<tr>
<td>As (2015)</td>
<td>Acupuncture</td>
</tr>
<tr>
<td>Li (2009)</td>
<td>Acupuncture</td>
</tr>
<tr>
<td>Lin (2015)</td>
<td>Acupuncture</td>
</tr>
<tr>
<td>He (2015)</td>
<td>Acupuncture</td>
</tr>
<tr>
<td>Xu (2015)</td>
<td>Acupuncture</td>
</tr>
<tr>
<td>Xu (2015)</td>
<td>Acupuncture</td>
</tr>
<tr>
<td>Appendix to Chapter 2- Supplementary Table 2. Methods characteristics of RCT acupuncture studies on pain management in the emergency setting</td>
<td></td>
</tr>
</tbody>
</table>

Appendix 13
<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Condition</th>
<th>Experimental group</th>
<th>Control group</th>
<th>Secondary outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allain (2011)</td>
<td>Migraine</td>
<td>Mean age range: 15 - 60 yrs (80%)</td>
<td>Mean age range: 16 - 56 yrs (10%)</td>
<td>NI</td>
</tr>
<tr>
<td>Acclu (2005)</td>
<td>Back pain</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Medium</td>
</tr>
<tr>
<td>Bark (2006)</td>
<td>Hip fractures</td>
<td>86.5 ± 4.8 yrs (83%)</td>
<td>86.6 ± 4.8 yrs (90%)</td>
<td>2.8 Low</td>
</tr>
<tr>
<td>Geisse (2006)</td>
<td>Mixed</td>
<td>Not specified</td>
<td>32.8 ± 7.5 yrs (64%)</td>
<td>Medium</td>
</tr>
<tr>
<td>Gu (2005)</td>
<td>Lumbar pain</td>
<td>Not specified</td>
<td>Not specified</td>
<td>High</td>
</tr>
</tbody>
</table>

**Table Notes:**
- **Adverse events from acupuncture:** Not specified.
- **Adverse events from control intervention:** Not specified.
- **Mean pain relief:** 3.6.
- **No reduction in medication frequency:** Medium.
- **No adverse effects:** Medium.
- **Improved satisfaction:** 10.5/100 above sham p<0.01.
- **Heart rate variability:** No difference.
- **Improved Short McGill Pain questionnaire:** 16 mins ± 8 Ac vs 28 mins ±14.
- **Time to 50% reduction in pain score:** Acupuncture 16 mins ± 8 Ac vs 28 mins ±14.
- **No difference in length of stay:** Acupuncture 81.8% vs SAC 90%. No difference in length of stay: Acupuncture 256 ± 234 min.
- **No differences in vital signs:** Uncertain.
- **No difference in quality of life:** Medium.
- **No difference in beliefs of acupuncture:** Medium.
- **No improvement in satisfaction:** 16.7/100 above sham p<0.01.
- **Less medication at 6 hours:** p<0.009. No difference in time off work.
- **Less medication:** Not specified.
- **Improved Short McGill Pain questionnaire:** p<0.05. Improved range of movement (ROM) p<0.01.

**Appendix to Chapter 2- Supplementary Table 3. Results of RCT acupuncture studies on pain management in the emergency setting**

**Appendix**
<table>
<thead>
<tr>
<th>Comparator group</th>
<th>Subgroup</th>
<th>No. of studies</th>
<th>Authors</th>
<th>SMD</th>
<th>I square</th>
<th>WMD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acupuncture versus sham</td>
<td>Medium to High quality</td>
<td>8</td>
<td>Allais, Araki, Barker, Kober, Lang, Su, Li</td>
<td>1.01 (CI 0.50 - 1.52)</td>
<td>85.9%</td>
<td>1.50 (CI 0.81 - 2.19)</td>
</tr>
<tr>
<td>Acupuncture versus sham</td>
<td>High quality &amp; Fractures</td>
<td>3</td>
<td>Kober, Barker, Lang</td>
<td>2.06 (CI 1.43 - 2.69)</td>
<td>43.1%</td>
<td>2.45 (CI 1.59 - 3.30)</td>
</tr>
<tr>
<td>Acupuncture versus sham</td>
<td>sample size &gt; or = 40</td>
<td>5 studies (6 arms)</td>
<td>Allais, Araki, Liu, Su, Li</td>
<td>0.56 (CI 0.25-0.87)</td>
<td>60.0%</td>
<td>1.01 (CI 0.51 - 1.50)</td>
</tr>
<tr>
<td>Acupuncture versus sham</td>
<td>Ear acupuncture</td>
<td>2</td>
<td>Barker, Allais</td>
<td>1.4 (CI 0.50 - 3.31)</td>
<td>93.8%</td>
<td>2.7 (CI 2.01 - 3.40)</td>
</tr>
<tr>
<td>Acupuncture versus sham</td>
<td>Body acupuncture</td>
<td>6 (7 arms)</td>
<td>Araki, Li, Su, Liu, Kober, Lang</td>
<td>0.91 (CI 0.42 - 1.40)</td>
<td>82.2%</td>
<td>1.35 (CI 0.69 - 2.01)</td>
</tr>
<tr>
<td>Acupuncture versus sham</td>
<td>Back pain &amp; Same points sham (non penetrating)</td>
<td>3</td>
<td>Araki, Su, Liu</td>
<td>0.75 (CI 0.03 - 1.48)</td>
<td>77.3%</td>
<td>1.20 (CI 0.19 - 2.20)</td>
</tr>
<tr>
<td>Acupuncture versus sham</td>
<td>Migraines</td>
<td>2 (3 arms)</td>
<td>Li, Allais</td>
<td>0.41 (CI 0.19 - 0.64)</td>
<td>0.0%</td>
<td>0.77 (CI 0.27 - 1.28)</td>
</tr>
<tr>
<td>Acupuncture versus sham</td>
<td>Distant sham points</td>
<td>5 (6 arms)</td>
<td>Allais, Barker, Kober, Lang, Li</td>
<td>1.15 (CI 0.53-1.78)</td>
<td>88.0%</td>
<td>1.76 (CI 0.86 - 2.66)</td>
</tr>
<tr>
<td>Acupuncture versus SAC</td>
<td>Renal Colic</td>
<td>2 (3 arms)</td>
<td>Lee, Kaynar</td>
<td>-0.17 (CI -0.78 - 0.44)</td>
<td>77.1%</td>
<td>-0.51 (CI -1.94 - 0.92)</td>
</tr>
</tbody>
</table>

Appendix to Chapter 2 – Supplementary Table 4 Showing subgroup analyses of the RCTs comparator groups acupuncture versus sham and standard analgesia care.
Appendix to Chapter 2 – Supplementary Table 5  Showing RCT studies and bias according to the Cochrane assessment tool (H=high U=unclear L=low).

<table>
<thead>
<tr>
<th>First Author</th>
<th>Randomisation</th>
<th>Allocation</th>
<th>Patient</th>
<th>Practitioner</th>
<th>Assessor</th>
<th>Incomplete</th>
<th>Selective</th>
<th>Other</th>
<th>Summary Bias risk</th>
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<tr>
<td>Allais</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>Medium</td>
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<tr>
<td>Araki</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
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</tr>
<tr>
<td>Barker</td>
<td>U</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>Low</td>
</tr>
<tr>
<td>Goertz</td>
<td>L</td>
<td>L</td>
<td>H</td>
<td>H</td>
<td>L</td>
<td>L</td>
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<td>U</td>
<td>L</td>
<td>H</td>
<td>H</td>
<td>U</td>
<td>L</td>
<td>H</td>
<td>H</td>
<td>High</td>
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<tr>
<td>Gu</td>
<td>U</td>
<td>U</td>
<td>H</td>
<td>H</td>
<td>U</td>
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<td>U</td>
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<td>H</td>
<td>U</td>
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<td>H</td>
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<td>H</td>
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<td>L</td>
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<td>H</td>
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<td>L</td>
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</tr>
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<td>L</td>
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<td>H</td>
<td>H</td>
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<td>L</td>
<td>U</td>
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<td>L</td>
<td>H</td>
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<td>L</td>
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<td>H</td>
<td>H</td>
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<td>L</td>
<td>U</td>
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<td>H</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>L</td>
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</tr>
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<td>Su</td>
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<td>H</td>
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<td>Wang</td>
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<td>H</td>
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<td>L</td>
<td>L</td>
<td>L</td>
<td>Medium</td>
<td></td>
</tr>
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<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>Uncertain</td>
</tr>
<tr>
<td>Author (year)</td>
<td>Setting</td>
<td>Condition (sample size)</td>
<td>Intervention</td>
<td>Acupuncturist/practitioner qualification</td>
<td>Method / frequency</td>
<td>Length of time needles retained</td>
<td>Mean age ± SD (Age range)</td>
<td>Adverse events from acupuncture</td>
<td>Mean pain scores ± SD (pre-treatment, post-treatment change)</td>
</tr>
<tr>
<td>--------------</td>
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<td>--------------------------</td>
<td>---------------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Anmo (2016) ED USA</td>
<td>Limb trauma (20)</td>
<td>Acupuncture (historical controls)</td>
<td>‘Acupuncturist’</td>
<td>Individualised</td>
<td>Not specified</td>
<td>33 yrs SD (70%)</td>
<td>4.6 - 3.2 (1.4)</td>
<td>35.82 ± 11.98</td>
<td>Not specified</td>
</tr>
<tr>
<td>Burns (2013) Retrieved Germany USA</td>
<td>Varies pain types (75)</td>
<td>Acupuncture as adjacent to Standard Analgesic Care (SAC)</td>
<td>Non-acupuncturist, Nurse practitioners (2); Physician (1); trained in battlefield acupuncture</td>
<td>Up to 10: Ear; Cingulate, Balbana, Omega 2, Peri Jox, Shu &amp; Men</td>
<td>Not specified</td>
<td>5.54 ± Age: 21-30 yrs (14.9%)</td>
<td>Not specified</td>
<td>4.0 ± 2.17 (1.9%)</td>
<td>p &lt; 0.0001</td>
</tr>
<tr>
<td>Fleckenstein (2015) Prehospital</td>
<td>Varies pain types (21) and otherwise non-painful conditions (total 60)</td>
<td>Acupuncture as adjacent to SAC</td>
<td>Medical acupuncturist</td>
<td>Individualised</td>
<td>Not specified</td>
<td>55.4 ± 23.0 yrs</td>
<td>Not specified</td>
<td>19/21 improvement of pain</td>
<td>No significant change in vital signs</td>
</tr>
<tr>
<td>Gonzales (2015) ED Dental pain (611)</td>
<td>Acupuncture</td>
<td>Not specified</td>
<td>Two: Li 4</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>69/81 pain score reduced ≥ 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gral (2016) ED</td>
<td>Migraine (19)</td>
<td>Acupuncture</td>
<td>‘Physician’</td>
<td>Maximum six from each acu: Thalamus and trigeminal nerve</td>
<td>2 weeks or till felt better</td>
<td>14 ± 2.9 yrs (99%)</td>
<td>7.63 ± 1.2 - 0.55 ± 14.3 ± 2.7 yrs</td>
<td>Improved anxiety scores.</td>
<td></td>
</tr>
<tr>
<td>Grillo (2013) After hours dental clinic</td>
<td>Dental pain (120)</td>
<td>Acupuncture</td>
<td>‘Experienced acupuncturist’</td>
<td>Three: LA, CV2, ST 44 unilateral on side of pain, with deqi</td>
<td>2 weeks or till better</td>
<td>35.82 ± 11.96 (642%)</td>
<td>6.56 ± 1.88 - 0.96 ± 2.16 (560.2 ± 2.1)</td>
<td>Satisfaction: 99.17% would recommend for same condition</td>
<td></td>
</tr>
<tr>
<td>Monse (1990) Dental clinic</td>
<td>Dental pain (115)</td>
<td>Acupuncture</td>
<td>‘Experienced acupuncturist’</td>
<td>Ten: SI 18, CV 24, ST 6, 5 with tender point and closest acupoint on side of pain, with deqi</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Pain improvement: EA 54.3% + Pirprofen 53.3% (Pirprofen77% &amp; Pirprofen 70%, &amp; Caffeine 70%</td>
<td></td>
</tr>
<tr>
<td>Ratnave (2016) ED</td>
<td>Dental pain types (182)</td>
<td>Acupuncture as adjacent</td>
<td>Acupuncture in Chinese Medicine</td>
<td>Indi individualised</td>
<td>25 min + 8.9 (consultation and treatment)</td>
<td>4.55 ± 1.67 yrs (676%)</td>
<td>Not specified</td>
<td>6.80 ± 5.28 - 4.28 (SD not specified) (25.2 ± 2.25)</td>
<td>No significant difference in pain scores change. No statistically significant difference in maximal anxiety scores</td>
</tr>
<tr>
<td>Senti (2009) ED Abstract only</td>
<td>Varies pain types (524)</td>
<td>Acupuncture as adjacent</td>
<td>Acupuncture in Chinese Medicine</td>
<td>Indi individualised</td>
<td>Not specified</td>
<td>26.5 ± 6.25</td>
<td>4.82 pain, not/history, 1 day</td>
<td>6.00 ± 2.91 - 3.79 ± 3.56 (3.15 ± 3.01)</td>
<td>Satisfaction: 97.5% would have acupuncture again</td>
</tr>
<tr>
<td>Zhang (2014) ED</td>
<td>Varies pain types (210)</td>
<td>Acupuncture (historical controls)</td>
<td>Emergency physicians with acupuncture qualifications or acupuncture in Chinese Medicine</td>
<td>Indi individualised</td>
<td>20 min</td>
<td>Range: (16-30 yrs) (0-100 yrs) (no cohorts) (21.5%) (18.8%) (57%)</td>
<td>Not specified</td>
<td>4 min (2 slight bleeding, 2 mild pain)</td>
<td>7.01 ± 2.02 ± 6.72 ± 2.62 ± 2.37</td>
</tr>
</tbody>
</table>

**Appendix to Chapter 2 Supplementary Table 6** Methods and results of observational acupuncture studies on pain management in the emergency setting.
Appendix to Chapter 2 - Section B

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Appendix 19

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Michelle

Michelle Head
Journal Publishing Manager

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Subject: Re: Copyright permission for PhD thesis

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Australia
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Appendix to Chapter 2 - Section C

Letter to the editor publication:

Acupuncture for analgesia in the emergency department: a multicentre, randomised, equivalence and non-inferiority trial

TO THE EDITOR: We commend Cohen and colleagues1 on their recently published study, which is the largest randomised controlled trial (RCT) of acupuncture in the emergency department (ED). We recently completed a systematic review and meta-analysis on the role of acupuncture for analgesia in the emergency setting.2 Our meta-analysis incorporated 19 RCTs and included non-English language publications. The trial by Cohen and colleagues1 was not published at the time of our review; however, it strengthens our main conclusion that acupuncture was non-inferior to standard analgesia in the emergency setting. We also found similar evidence of improved patient satisfaction. It was interesting that the authors reported an adverse effects rate of 51% for acupuncture, whereas our study found an overall rate of 5%, with significant adverse effects being 1%. Our figures are consistent with other reviews3 and almost certainly highlight the difficulties in developing agreed definitions on adverse effects in acupuncture. Our review found that acupuncture in two out of four RCTs decreased pain medication requirements, whereas Cohen and colleagues’ study had the potential to inform this outcome, but did not report such data.

The study by Cohen and colleagues1 illustrates many of the challenges in acupuncture trials, including having no sham comparator group. Some acutely painful conditions might resolve simply because of time or careful patient attention. Sham acupuncture is difficult to deliver as a control4 and needs to be plausible, realistic and, if possible, blinded. Our meta-analysis showed acupuncture to be superior, with clinically significant reductions in acute pain scores compared with sham.

This latest significant RCT gives further impetus to carefully designed research on acupuncture in the emergency setting, which will require acupuncture techniques applicable to the time-constrained ED environment (eg, ear acupuncture), provision of a suitable sham acupuncture technique, and minimisation of assessment bias. We suggest that the specific outcomes to be assessed should include the impact of acupuncture as an adjunct to standard analgesia, side effects recorded using standard definitions, and reductions in medication use. Most importantly, the analgesic effect of acupuncture is unlikely to be equal for all pain presentations in the emergency setting and, therefore, the conditions for which its role is most beneficial need to be delineated.

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Competing interests: No relevant disclosures.
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Appendix to Chapter 2 - Section D

Conference presentation:

Are we happy with opioids and NSAIDS? Is there a need to investigate acupuncture?

Are we happy with patient satisfaction and our current pain management?

• Who cares – why?
• Satisfaction intimately linked with pain management but not pain score targets, or opioid use but human factors.


What we know and don’t know about acupuncture!

• Benefits chronic pain*
• Used extensively by general practitioners, physiotherapists and acupuncturists
• Its evidence for effectiveness in acute pain is emerging^

^Schug. Acute Pain Management: Scientific Evidence 2015
Acupuncture – Questions of the World Literature?

Q1. Quality of studies?
Q2. Acupuncture pain relief vs sham?
Q3. Acupuncture versus standard care?
Q4. Acupuncture as an adjunct?
Q3. Reduction in medication?
Q4. What conditions?
Q5. Patient satisfaction?
Q6. How complex and skill required?
Q7. Costs, time to deliver?
Q8. Side effect profile

What is the quality of studies we’re looking at?

Cochrane Assessment of Bias

- Adequate Randomisation
- Allocation Concealment
- Participant Blinding
- Practitioner Blinding
- Outcome Assessor Blinding
- Incomplete Outcome Data
- Free of Selective Reporting
- Other

Legend:
- High risk of bias
- Unclear risk of bias
- Low risk of bias
Does it work?

• How are we going to judge it?


Acupuncture versus Sham

vs

Placebo Effect
Acupuncture vs. Sham Acupuncture

<table>
<thead>
<tr>
<th>Study</th>
<th>SMD (95% CI)</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Araki (2001)</td>
<td>0.01 (-0.61, 0.63)</td>
<td>10.95</td>
</tr>
<tr>
<td>Kober (2002)</td>
<td>2.37 (1.54, 3.19)</td>
<td>9.60</td>
</tr>
<tr>
<td>Barker (2006)</td>
<td>2.41 (1.75, 3.08)</td>
<td>10.66</td>
</tr>
<tr>
<td>Lang (2007)</td>
<td>1.44 (0.65, 2.24)</td>
<td>9.81</td>
</tr>
<tr>
<td>Li (2009)</td>
<td>0.49 (0.11, 0.86)</td>
<td>12.34</td>
</tr>
<tr>
<td>Li (2009)</td>
<td>0.30 (-0.07, 0.67)</td>
<td>12.37</td>
</tr>
<tr>
<td>Su (2010)</td>
<td>1.21 (0.65, 1.76)</td>
<td>11.37</td>
</tr>
<tr>
<td>Allais (2011)</td>
<td>1.03 (0.59, 1.48)</td>
<td>12.00</td>
</tr>
<tr>
<td>Liu (2015)</td>
<td>1.02 (0.40, 1.65)</td>
<td>10.90</td>
</tr>
<tr>
<td>Overall (I² = 86.2%, p = 0.000)</td>
<td>1.10 (0.61, 1.58)</td>
<td>100.00</td>
</tr>
</tbody>
</table>

NOTE: Weights are from random effects analysis

Better than placebo?

Acupuncture versus medication?
### Traditional Acupuncture vs. Standard Care

<table>
<thead>
<tr>
<th>Study</th>
<th>SMD (95% CI)</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
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<td>Lee (1991)</td>
<td>0.61 (-0.05, 1.27)</td>
<td>16.30</td>
</tr>
<tr>
<td>Harkin (2007)</td>
<td>0.32 (-0.32, 0.97)</td>
<td>16.51</td>
</tr>
<tr>
<td>Kaynar A (2015)</td>
<td>-0.45 (-0.90, -0.01)</td>
<td>20.97</td>
</tr>
<tr>
<td>Kaynar D (2015)</td>
<td>-0.53 (-0.97, -0.08)</td>
<td>20.92</td>
</tr>
<tr>
<td>Grissa (2016)</td>
<td>0.25 (0.02, 0.47)</td>
<td>25.30</td>
</tr>
<tr>
<td>Overall (I-squared = 77.5%, p = 0.001)</td>
<td>0.01 (-0.41, 0.43)</td>
<td>100.00</td>
</tr>
</tbody>
</table>

NOTE: Weights are from random effects analysis.

#### Acupuncture & Standard Care versus Standard Care

![Acupuncture & Standard Care versus Standard Care](image)
Acupuncture as an Adjunct to Standard Care vs. Standard Care

<table>
<thead>
<tr>
<th>Study</th>
<th>SMD (95% CI)</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goertz (2006)</td>
<td>1.48 (1.04, 1.92)</td>
<td>48.04</td>
</tr>
<tr>
<td>Ho (2016)</td>
<td>1.56 (0.93, 2.16)</td>
<td>27.55</td>
</tr>
<tr>
<td>Moss (2015)</td>
<td>2.10 (1.43, 2.77)</td>
<td>24.41</td>
</tr>
<tr>
<td>Overall (I-squared = 16.0%, p = 0.304)</td>
<td>1.65 (1.30, 2.00)</td>
<td>100.00</td>
</tr>
</tbody>
</table>

NOTE: Weights are from random-effects analysis

---

Does it reduce Medication usage?
**Does it reduce Medication usage?**

- Four studies and mixed results – no conclusion

**What conditions was acupuncture used for?**

<table>
<thead>
<tr>
<th>Randomised Clinical trials</th>
<th>Observational Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of RCT studies</strong></td>
<td><strong>Condition</strong></td>
</tr>
<tr>
<td>4</td>
<td>Spine (Back and Neck)</td>
</tr>
<tr>
<td>3</td>
<td>Mixed painful conditions</td>
</tr>
<tr>
<td>3</td>
<td>Limb Fractures / contusions</td>
</tr>
<tr>
<td>3</td>
<td>Migraine</td>
</tr>
<tr>
<td>3</td>
<td>Renal Colic</td>
</tr>
<tr>
<td>1</td>
<td>Chest trauma</td>
</tr>
<tr>
<td>1</td>
<td>Abdo pain</td>
</tr>
<tr>
<td>1</td>
<td>Pharyngitis</td>
</tr>
<tr>
<td><strong>Number of UO studies</strong></td>
<td><strong>Condition</strong></td>
</tr>
<tr>
<td>5</td>
<td>Mixed painful conditions</td>
</tr>
<tr>
<td>1</td>
<td>Limb Fractures / contusions</td>
</tr>
<tr>
<td>1</td>
<td>Migraine in children</td>
</tr>
<tr>
<td>3</td>
<td>Dental Pain</td>
</tr>
<tr>
<td>1</td>
<td>Appendicitis children</td>
</tr>
</tbody>
</table>
How satisfied are the patients with this form of treatment?

• About a 1/3 of the RCT or Observational studies measured satisfaction. When measured, there was an improvement in satisfaction or patients ‘would use this treatment again’.
Does it take too much time?

ED’S
1 SECOND
ACUPUNCTURE
TREATMENT

How complex was the acupuncture used?

vs

Appendix 37
Does acupuncture have low side effects?

• In both the RCT’s and Observational studies the incidence of potentially significant side effects was about up to 7 in over 2000 patients. This is consistent with the literature quotes serious adverse events 0.02%. Significant ones that require treatment at 2.2%*.


Summary: Pros and cons

• Acupuncture from this review provides genuine analgesia, is comparable with standard care, improves analgesia as an adjunct.
• Some studies had flaws. Therefore drop level of recommendation
• Use where benefits outweigh risks. Further research likely to have an impact, clinicians should follow stronger recommendations first.
• Where measured patient satisfaction improves
• Not sure whether it reduces medication usage
• Low side effect profile
• Efficacious when simple techniques used - ? For ED staff to try after a short course eg ear acupuncture!
ED Acupuncture: Hope you got the Point

Andrew Jan
drandrewjan@gmail.com

Questions?
Summary: Pros and cons

- Some studies had flaws. Therefore drop level of recommendation
- Acupuncture from this review provides genuine analgesia, is comparable with standard care, improves analgesia as an adjunct.
- Use where benefits outweigh risks. Further research likely to have an impact, clinicians should follow stronger recommendations first.
- Where measured patient satisfaction improves
- Not sure whether it reduces medication usage
- Low side effect profile
- Efficacious when simple techniques used - ? For ED staff to try after a short course eg ear acupuncture!

How Does Acupuncture Work?

- Central: neuroplasticity & altering pain matrix, anti-nociceptive neurotransmitters
- Descending neuro-inhibitory pathways
- Spinal Cord: Endorphins & Gate theory
- Reduction of Inflammatory cytokines, neuropeptides other inflammatory mediators
- spiritual – mind – body – chi!
Appendix to Chapter 2 - Section E

Conference poster presentation:

- Aldridge ES (Presenter), Jan AL, Rogers IR, Visser E, Bulsara M. Is there a point? The role of acupuncture for acute pain in the emergency department: a systematic review and meta-analysis. Poster presented at: The 33rd Annual Scientific Meeting of the Australasian College for Emergency Medicine; 2016 Nov 20; Queenstown, New Zealand.
The Role of Acupuncture for Acute Pain in ED: Systematic Review and Meta-Analysis

E Aldridge BHThSc, A Jan MBBS FACEM BA FAMAC M Phil, I Rogers MBBS FACEM, E Visser MBBS FANZCA FFPMANZCA, M Bulsara PhD MSc BSc
St. John of God Murdoch Hospital, University of Notre Dame Australia, St. John of God Subiaco Hospital
Emogene.Aldridge@sjog.org.au

Background
Pain is the primary reason why patients attend ED. Despite this, pain is often poorly managed and undertreated. The current ED pain management armamentarium is centred on pharmacological interventions such as opioids, NSAIDS and paracetamol.

Supported by evidence of efficacy, acupuncture is often used to treat chronic pain disorders, such as headache, back, neck and shoulder pain.

The role of acupuncture in acute pain management is less clearly defined, particularly in the emergency setting.

Methods
7 health databases were searched up to 31 July 2016 using 3 main themes, pain management, acupuncture and emergency setting. Randomised controlled trials from white or grey literature were included.

Excluded studies were those which studied animals, perioperative pain, chronic pain, non-emergency medical conditions, non-acupuncture holistic therapies or where pain was not assessed within the first 24 hours. No language restrictions were used.

AIM
The aim of this review was to evaluate the effectiveness of acupuncture for pain management in the emergency setting, by both assessing the efficacy of acupuncture as a stand alone therapy as well as an adjunct to standard care.

Primary measure was the difference in mean pain score in three comparator groups (acupuncture vs. sham acupuncture, acupuncture vs. standard care, acupuncture as adjunct to standard care vs. standard care).

Results
884 unique articles were identified and 70 read in full.

Thirteen studies were included in the meta-analysis with a total of 1407 patients. Acupuncture, when compared to sham, caused a higher mean decrease in pain (SMD=1.19). Standard care and acupuncture were found to be comparable (SMD=0.01).

Acupuncture as an adjunct to standard care compared with standard care was found to be more effective (SMD=1.74).

Limitations
Acupuncture studies present unique challenges regarding blinding and the use of sham, which result in the majority of studies included having a moderate to high risk of bias when assessed using the Cochrane Bias Assessment. As the study had no language restrictions, there were difficulties with accurate translation of non-English papers.

Random effects model was used for meta-analysis, with high heterogeneity noted across all groups.

Implications for Future Research
Future research will help to define which techniques can be most effectively and easily applied to an ED setting.

What Does This Mean for You
This review suggests that acupuncture provides genuine analgesia and is comparable with standard care in efficacy. When utilised as an adjunct to standard care it can significantly reduce acute pain in an ED specific time frame.

The integration of acupuncture into ED pain management strategies still requires consideration of benefit versus cost in terms of procedure time and training.
Appendix to Chapter 2 - Section F

Publicity:

The pointy end of pain management

Pain management in the ED is always going to be a hot topic.

What happens when analgesia doesn’t work?

What do you do for patients who are pregnant, elderly or have drug allergies and who can’t take opioids?

Add to this, the use of opioid analgesia in general has become increasingly notorious due to its addictive properties. Some emergency departments in the United States have even trialled going completely opioid-free. The world over, ED doctors are searching for alternatives to opioid pain management.

FACEM Dr Andrew Jan and his research colleagues are exploring one of the alternative solutions and they are quietly excited about it.

Dr Jan has been offering the ancient art of acupuncture in his ED for more than 20 years. He is a FACEM and was DEM at St John of God in Perth from 2002-2011. He is also a Fellow of the College of Medical Acupuncturists.

Dr Jan is 18 months into a PhD on the subject and has seen firsthand the results it can have on patients in pain.

“Often I’ll have a patient who has migraine or back pain that is just not going away. I’ll say ‘look I’m an emergency specialist, I also happen to be a medical acupuncturist. We’ve tried several analgesia
but you’re clearly still in pain. Would you like to try some acupuncture? ’ I have seen that it can be very effective pain relief for many patients’

What is Acupuncture exactly?

Acupuncture is a traditional Chinese medicine practice. It has been used in Chinese medicine for 1000s of years but has only been explored by Western medical practitioners in the last few decades.

It involves inserting very fine needles into the body at designated pressure points. Modern practices also use a nifty device called an AcuLaser, an instrument the size of a pencil that uses electromagnetic waves and acupressure.

Dr Jan is the first to acknowledge that acupuncture is still an outlier in Western medicine. While several studies have demonstrated some relief for certain kinds of pain, many of these lacked strong methodology.

There are also varying Western theories as to what makes acupuncture effective in the first place. Theories range from the stimulation of nerve fibres, to the production of endorphins, to simply a response to human touch.

From Dr Jan’s perspective, a more rigorous approach to acupuncture can only be a good thing.

“The art of acupuncture is now being given the once over to make it accountable. And I think that’s absolutely appropriate. Better studies, rigorous testing. I think the western approach could take this from something that has been a bit woolly into something that can benefit everyone.”

The Rigors of research

The main focus of Dr Jan’s PhD research will be the use of ear acupuncture, specifically a technique called battlefield acupuncture.

Battlefield acupuncture is used by American military paramedics to relieve pain in the field. The treatment is incredibly popular with soldiers because it means they can stay in the field rather than having to be taken to a medical facility for monitoring with opioids.

Dr Jan and his colleagues are concentrating on whether ear acupuncture pain relief can have lasting or merely temporary effects.

“What we want know is what are they feeling like in 24 or 48 hours after treatment? For some people the pain comes back, for other people it’s completely gone. What makes this treatment stick? That’s the question.”

East meets West

Dr Jan has Chinese heritage and grew up in Australia. For Dr Jan, combining Chinese and Western culture has been a theme throughout his life.

Dr Jan spent 1997-2000 in China working in international retrieval medicine and running a small ED. This job gave him the opportunity to observe the unique integration of eastern and western medical practices.

Dr Jan believes acupuncture is a perfect fit for emergency medicine due to its portable and non-obtrusive nature.
“If the patient is lying down you can treat them with ear acupuncture while everything else is going on. They can have their bloods taken, their obs done, nothing stops.”

**Alongside not instead of**

Dr Jan is careful to emphasise that he is not suggesting replacing all pain management with acupuncture.

While acupuncture has been shown to help with chronic pain, renal colic, fractures and migraines, delivering it in the ED may not be appropriate in some circumstances. It has to be delivered by someone trained in medical acupuncture, which many EDs may not have access to. It also may not be suitable if a patient is in extreme pain and time is limited.

“This is absolutely going to be an adjunct to simple analgesia, it’s not going to be one or the other. For acupuncture you need about 5-10 minutes. You need time around it if it doesn’t work.”

“But if a patient is in pain and analgesia isn’t helping. I have to ask myself, could I help this person if I find that extra 10 minutes to try it?”
Appendix to Chapter 3 - Section A

Supplementary material for the publication:

Appendix to Chapter 3 Figure 1 Forest plot of ear acupuncture versus sham with calculated weighted mean difference (WMD) for pain score difference on a PS-10.
Appendix to Chapter 3 Figure 2 Forest plot of ear acupuncture versus standard analgesia care with calculated weighted mean difference (WMD) for pain score difference on a PS-10.
Appendix to Chapter 3 Figure 3 Forest plot of ear acupuncture (either sole or as an adjunct) versus control (sham or standard analgesia care) with calculated weighted mean difference (WMD) for pain score difference on a PS-10.

### Forest Plot

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Sample</th>
<th>WMD (95% CI)</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goertz et al.</td>
<td>2006</td>
<td>100</td>
<td>2.18 (1.60, 2.76)</td>
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<tr>
<td>Barker et al.</td>
<td>2006</td>
<td>38</td>
<td>2.80 (2.05, 3.55)</td>
<td>25.63</td>
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<tr>
<td>Alias et al.</td>
<td>2011</td>
<td>89</td>
<td>2.10 (1.28, 2.92)</td>
<td>23.65</td>
</tr>
<tr>
<td>Moss &amp; Crawford</td>
<td>2015</td>
<td>54</td>
<td>3.60 (2.64, 4.56)</td>
<td>20.50</td>
</tr>
<tr>
<td>Overall (I-squared = 61.2%, p = 0.052)</td>
<td></td>
<td></td>
<td>2.61 (2.00, 3.22)</td>
<td>100.00</td>
</tr>
</tbody>
</table>

**Note:** Weights are from random effects analysis.
Appendix to Chapter 3 - Section B

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Kind regards,

Karen Ballen
Manager, Reprints/ePrints, Permissions, and Liebert Open Access
Mary Ann Liebert, Inc.

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From: Andrew Jan <drandrewjan@gmail.com>
Subject: Copyright permission for PhD
Date: July 20, 2020 at 1:55:58 AM PDT
To: Yael Benporat <>
Andrew Jan <drandrewjan@gmail.com>  Mon, Jul 20, 2020 at 7:43 PM

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with best regards,

Peter Roth

Peter Roth
Publisher

MDPI Basel, Switzerland
Academic Open Access Publishing
St. Alban-Anlage 66
CH-4052 Basel, Switzerland

[Quoted text hidden]
Appendix to Chapter 3 - Section C

Publicity (declared high-impact article):

Our ear review was declared and advertised as a high impact article by the publisher because of the high number of purchases and downloads of the article.
Appendix to Chapter 3 - Section D

Conference abstract and presentation:

3.17. Does Ear Acupuncture Have A Role for Pain Relief in the Emergency Setting? A Systematic Review and Meta-Analysis

Jan, A.; Aldridge, E.; Rogers, I.; Visser, E.; Bulsara, M.; Niemtzow, R.

Objective: Ear acupuncture might be the form of acupuncture best suited to improving emergency pain management. Our primary aim was to assess the efficacy of acupuncture in the emergency setting while secondary objectives were to explore its suitability through patient satisfaction, adverse effects, cost, administration techniques and medication usage reduction.

Methods: Seven data bases and Google Scholar were searched up to 27th April 2017 using MeSH descriptors for three overarching themes concerning ear acupuncture, pain management and emergency medicine. Meta-analysis was performed in three comparator groups of: acupuncture versus sham, acupuncture-as-adjunct to standard care and acupuncture (both sole and adjuvant) versus control to calculate the standardised mean difference and weighted mean difference for pain scores out-of-ten.

Results: Six randomised controlled trials and two uncontrolled observational studies totalling 458 patients were retrieved after exclusions. The meta-analysis used data from four randomised studies representing 286 patients. The above three comparator groups resulted in standardised mean differences of 1.69, 1.68 and 1.66, and weighted mean differences of 2.47, 2.84 and 2.61 respectively with all figures favouring acupuncture.

Where measured, there were no adverse effects and patient satisfaction was improved. Results regarding reduction in medication use were equivocal. Significant study bias was found and Battlefield acupuncture was the most commonly used technique.

Conclusions: While study numbers are limited, ear acupuncture appears efficacious, either as stand-alone or as adjunct analgesia. It has potential benefits for its use in the emergency setting. Further studies will define this role and whether it reduces use of analgesic medications.

Appendix 57
Ear Acupuncture in the Emergency Setting - A Systematic Review and Meta-analysis

Andrew Jan  MBBS FACEM FAMAC BA MPhil
PhD candidate
(supervisors: Prof: Ian Rogers, Eric Visser, Max Bulsara, Richard Niemtzow & research assistant Emogene Aldridge)
University of Notre Dame
St John of God Hospital Murdoch
Australian Government Research Training Program.

Background:
Are we happy with opioids and NSAIDS? Is there a need to investigate acupuncture?

"Is analgesia in the ED helping our patients?—or killing them?"

Cameron. Emergency Physicians International 2016, October
Are we happy with patient satisfaction and our current pain management?

• Who cares – why?
• Satisfaction intimately linked with pain management


Does it work?

• How are we going to judge it?

Is it applicable to the ED?
**Pain score change: Clinical significance**

1.3


**Pain score change: Statistical significance**

\[
\text{Standardised Mean Difference} = \frac{\text{Acupuncture Pain score change - control}}{\text{Pooled standard deviation}}
\]

<table>
<thead>
<tr>
<th>SMD</th>
<th>Strength of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.2</td>
<td>slight</td>
</tr>
<tr>
<td>0.5</td>
<td>Moderate</td>
</tr>
<tr>
<td>&gt; 0.8</td>
<td>Large</td>
</tr>
</tbody>
</table>

Pain: patient satisfaction significance

Communication, Caring Comfort, Time to analgesia

Not pain score change, not pain score at discharge, not opioid use

Three groups to dissect

- Ear acupuncture versus sham
- Ear acupuncture versus Standard analgesia care (SAC)
- Ear acupuncture as adjunct to SAC versus SAC

What are the implications for these comparator groups?

To answer our research question we need information from prior reviews:

Information on acute pain (including peri-operative) and body acupuncture

2014 – Yeh
2016 - Murakami
2017 – Jan (All forms of acupuncture)

**Prior Reviews**

*Review Article*
Efficacy of Auricular Therapy for Pain Management:
A Systematic Review and Meta-Analysis

Chen Hsiang Yeh, Y.C. Shih Cheng, Samuel L. Hoffman, Zhan Liang, Mary Lou Klein

- **Auriculotherapy for all pain** (acute and chronic): **Good evidence**! 13 studies (806 patients included) : SMD 1.59
- **Types**
  - Acupuncture needles: **Good!** (494 patients), 7 studies: SMD 1.81
  - Electro Acupuncture: **Slight!** 2 studies (37 patients) SMD 0.39
  - Acupressure: **Good!** 4 studies (275 patients) SMD 1.85

**Yeh 2014: Ear Acupuncture**
• Acute pain 15 minutes: **Good!** 4 studies (193 patients): Allais migraine, burns dressing changes, gynae proced, chronic distal extremity pain: **SMD 2.84**
• Acute Pain relief 12-24/24, 4 studies **Good!** (post op X 3, dysmenorrhea), 314 patients **SMD 1.85**

Yeh 2014: Ear Acupuncture

Two Meta-analyses (predominantly perioperative some ED studies)
• One Post pain scores **Good!** 3 studies (204 patients) **SMD = 0.96**
• Analgesia Requirement: **Good!** 6 studies (159 patients) **SMD = 1.08**

Murakami 2016: Ear Acupuncture
Prior Reviews

- Body including ear acupuncture
- Acupuncture versus sham: Good! Eight RCT (526 patients) SMD 1.08 WMD 1.60 Patient satisfaction: 3 RCTs positive
- Acupuncture versus standard analgesia care: Non inferior! Four RCTs (505 patients) SMD 0.02 WMD 0.04 Patient satisfaction: 1 RCT positive
- Acupuncture as adjunct to SAC versus SAC: Limited evidence! Two RCTs (154 patients) SMD 1.08 WMD 2.84 Patient satisfaction: 1 RCT

Jan 2017: All forms of acupuncture

What Type of study, medical conditions and circumstances was ear acupuncture used for?

<table>
<thead>
<tr>
<th>First author</th>
<th>Acute pain type</th>
<th>Study setting</th>
<th>Study type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allais (2011)</td>
<td>Migraine</td>
<td>Ward</td>
<td>RCT ear acupuncture vs sham</td>
</tr>
<tr>
<td>Barker (2006)</td>
<td>Hip fractures</td>
<td>Ambulance</td>
<td>RCT ear acupressure vs sham</td>
</tr>
<tr>
<td>Goertz (2006)</td>
<td>Pain not requiring medical intervention</td>
<td>ED</td>
<td>RCT adjunct ear acupuncture &amp; SAC vs SAC</td>
</tr>
<tr>
<td>Gu (1993)</td>
<td>Biliary colic</td>
<td>ED</td>
<td>RCT ear acupuncture vs SAC</td>
</tr>
<tr>
<td>Moss (2015)</td>
<td>Sore Throat</td>
<td>GP Military</td>
<td>RCT ear acupuncture &amp; SAC vs SAC</td>
</tr>
<tr>
<td>Fox (2016)</td>
<td>Low back pain</td>
<td>ED</td>
<td>RCT ear acupuncture vs SAC</td>
</tr>
<tr>
<td>Burns (2013)</td>
<td>All types</td>
<td>Retrieval</td>
<td>Observational study: ear acupuncture &amp; SAC</td>
</tr>
<tr>
<td>Graf (2016)</td>
<td>Migraines</td>
<td>ED</td>
<td>Observational study with ear acupuncture alone</td>
</tr>
</tbody>
</table>

ED = Emergency Department, SAC = standard analgesia care, GP = General (Family) Practice
## Acupuncture versus Sham

### Placebo Effect

### Ear Acupuncture vs. Sham Acupuncture

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Sample Size</th>
<th>SMD (95% CI)</th>
<th>Weight %</th>
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<tr>
<td>Barker et al.</td>
<td>2006</td>
<td>38</td>
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<tr>
<td>Aitais et al.</td>
<td>2011</td>
<td>89</td>
<td>1.06 (0.62, 1.51)</td>
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</tbody>
</table>

Overall (I-squared = 87.0%, p = 0.006)

1.69 (0.37, 3.01) 100.00

**Note:** Weights are from random effects analysis.
Ear Acupuncture versus Sham Acupuncture

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Sample Size</th>
<th>WMD (95% CI)</th>
<th>Weight %</th>
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<tr>
<td>Barker et al.</td>
<td>2006</td>
<td>38</td>
<td>2.80 (2.05, 3.55)</td>
<td>53.25</td>
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<tr>
<td>Allais et al.</td>
<td>2011</td>
<td>89</td>
<td>2.10 (1.28, 2.92)</td>
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<tr>
<td>Overall (I-squared = 34.4%, p = 0.217)</td>
<td></td>
<td></td>
<td>2.47 (1.79, 3.18)</td>
<td>100.00</td>
</tr>
</tbody>
</table>

NOTE: Weights are from random effects analysis.

Ear Acupuncture versus SAC

Only one study by Gu 1993 which used outdated SAC
Ear Acupuncture as an Adjunct to Standard Analgesia Care vs. Standard Analgesia Care

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>sample</th>
<th>SMD (95% CI)</th>
<th>Weight</th>
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<tbody>
<tr>
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<td>Moss &amp; Crawford</td>
<td>2015</td>
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<td>2.00 (1.34, 2.66)</td>
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<tr>
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<td></td>
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<td>1.68 (1.18, 2.18)</td>
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NOTE: Weights are from random effects analysis

Encouraging
## Acupuncture as an Adjunct to Standard Analgesia Care vs. Standard Analgesia Care

<table>
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<tr>
<th>Author</th>
<th>Year</th>
<th>Sample</th>
<th>WMD (95% CI)</th>
<th>Weight %</th>
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<td>53.79</td>
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<tr>
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<td>2015</td>
<td>54</td>
<td>3.60 (2.64, 4.56)</td>
<td>48.21</td>
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<tr>
<td>Overall (I-squared = 83.8%, p = 0.013)</td>
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<td></td>
<td>2.84 (1.45, 4.22)</td>
<td>100.00</td>
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</tbody>
</table>

NOTE: Weights are from random effects analysis.

---

### Acupuncture +/- Standard Care versus Standard Care +/- Sham

**Placebo Effect vs. Effect**

+/- vs. +/-
### Risk of Bias

<table>
<thead>
<tr>
<th>First Author and year</th>
<th>Adequate Randomisation</th>
<th>Allocation concealment</th>
<th>Patient Blinding</th>
<th>Practitioner Blinding</th>
<th>Assessor Blinding</th>
<th>Incomplete Outcome Data</th>
<th>Selective Reporting</th>
<th>Other Sources</th>
<th>Summary Bias Risk</th>
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<tbody>
<tr>
<td>Allais 2011</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>L</td>
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<td>U</td>
<td>L</td>
<td>L</td>
<td>L</td>
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<td>L</td>
<td>L</td>
<td>Low</td>
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<td>Goertz 2006</td>
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<td>L</td>
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<td>Medium</td>
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<tr>
<td>Gu 1993</td>
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<td>U</td>
<td>H</td>
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<td>U</td>
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<td>U</td>
<td>U</td>
<td>Medium</td>
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<tr>
<td>Moss 2015</td>
<td>L</td>
<td>U</td>
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<td>H</td>
<td>H</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>High</td>
</tr>
<tr>
<td>Fox 2016</td>
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<td>U</td>
<td>H</td>
<td>H</td>
<td>H</td>
<td>L</td>
<td>U</td>
<td>L</td>
<td>High</td>
</tr>
</tbody>
</table>

### How complex was the ear acupuncture used?

- **1 study**
- **2 studies (Romoli)**
- **4 studies (Niemtzow)**
Practitioner ? Teaching ?

• Five studies used allied care personnel - non acupuncturists
• BFA already taught to over 2800 health care providers
US Military

Does it reduce Medication usage?

Moss: Sore throats - Yes!
Goertz: All pain – No!
Fox: Back Pain – No
Perioperative literature - Yes

Murakami: EA for acute pain. 2016 :
RCTs 303 patients SMD 1.08
How satisfied are the patients with this form of treatment?

- Burns UOBS: retrieval 62% “would have treatment again”, & 71% mostly satisfied or very satisfied
- Barker RCT: improvement over sham!

Is it time consuming? Does it prolong length of stay?

- The time to administer treatment was under 10 minutes in all ear forms
- Probably more important is no impediment to other observations or procedures
Side Effect Profile?

5% of 1/10,000
White 2004

0.1% Ernst 2003

Cost?

• Not all mention cost
• However Barker: 3 cents per patient, while Goertz $1.52 per patient. Moss $5 patient
• Labour time?

Information for future Trials

• Sham controls for the ear is problematic
• Assessor Blinding important!
• EA vs SAC to calculate RR adverse events
• Medication reduction, non-acupuncturists vs acupuncturists & vs body?


Conclusions - positives

• 8 studies, 6 RCT’s, 4 eligible for meta-analysis. All meta-analyses positive for pain reduction over control but not all had a p value < 0.05
• Interpret on the background of prior reviews by Jan, Murakami, Yeh and Asher
• Use as sole therapy or adjunct where adverse effects of standard analgesia are potentially harmful
• Half way there – Results encouraging - More studies required!
Questions?

Contact me down under please

drandrewjan@gmail.com
www.drandrewjan.com
Appendix to Chapter 4 - Section A

Supplementary materials, Ethics approval, Patient advice and consent:

Hello, my name is: Dr Andrew Jan, Prof Eric Visser, Prof Ian Rogers, Dr Michael Woosey, NP Paula Davis, RN Natasha Raja, Emogene Aldridge or research nurse.

**Triage:** We are conducting a quality audit project in to the management of pain in our emergency department. This audit will not interfere or delay your pain management today. We hope to use this information to improve future patients pain management care and develop research in this area. Your information will be anonymous, unidentifiable and confidential. We would like to take three minutes of your time **about an hour after your initial pain medicine is given** from the department to ask you some questions about your pain management. Is that OK?

**One-hour post analgesia:** As we mentioned at triage, we are conducting a quality audit project in to the management of pain in our emergency department. We hope to use this information from this audit to improve future patients pain management care and develop research in this area. Your information will be anonymous, unidentifiable and confidential. We would like to take three minutes of your time to ask you some questions about your pain management. Is that still OK?

1. Please let us know what pain medicines you took in the four hours prior to attending our department. If possible, give us the doses and times.

2. Please rate how satisfied or dissatisfied are you with the results of you pain treatment in our ED? Were you very satisfied, satisfied, slightly satisfied, slightly dissatisfied, dissatisfied or very dissatisfied?

<table>
<thead>
<tr>
<th>How satisfied are you with your pain management in our ED?</th>
</tr>
</thead>
<tbody>
<tr>
<td>very dissatisfied</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

3. Your pain management today predominantly consisted of **pain medicine tablets or injections**. Would you have been agreeable to receiving **NON drug pain relieving**
measures as well? Only prompt if question not understood - Examples of these include: talking distraction, hot and cold packs, comfort positions, relaxation techniques, guided visualisation and so on.

Yes or No?

4. Please rate on how agreeable you are to having non-pain medicines as part of your pain care?

| How agreeable are you to having non pain medicines as part of your pain care? |
|------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Very Disagreeable            | Disagreeable    | Slightly Disagreeable | Slightly Agreeable | Agreeable      | Very Agreeable  |
| 1                             | 2               | 3                | 4                | 5               | 6               |

5. Specifically, would you be agreeable to having acupuncture in addition to your pain medicines? Please rate how agreeable you are?

| How agreeable are you to having acupuncture in addition to standard pain killers? |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Very Disagreeable               | Disagreeable    | Slightly Disagreeable | Slightly Agreeable | Agreeable      | Very Agreeable  |
| 1                               | 2               | 3                | 4                | 5               | 6               |

6. Did you have any side effects from the pain medicines?

Yes / No?

7. If you did (answer yes to above) would this stop you from having these pain medicines again? Please rate on a likelihood scale?

| Likelihood of side effects stopping you having medicines again? |
|---------------------------------------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Very Unlikely                                                | Unlikely        | Slightly unlikely | Slightly likely | Likely         | Very likely     |
| 1                                                             | 2               | 3                | 4                | 5               | 6               |

8. How concerned are you for the risk of becoming addicted to any of the pain medicines given so far? Please rate the likelihood score?

| How concerned are you for the risk of becoming addicted any of the pain medicines given so far? |
|-------------------------------------------------------------------------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Very unconcerned                                                                              | Unconcerned     | Slightly unconcerned | Slightly concerned | Concerned      | Very concerned  |
| 1                                                                                             | 2               | 3                | 4                | 5               | 6               |

thank you for your time
8 February 2017

Dr Andrew Jan  
C/O Emergency Department,  
St John of God Murdoch Hospital  
100 Murdoch Drive  
MURDOCH WA 6150

Dear Dr Jan,

Re: Clinical audit of pain management in the emergency department as a prelude to acupuncture-as-adjunct analgesia trial (Our ref No: 1107)

Thank you for forwarding the above “low risk” study for review by the St John of God Health Care (SJGHC) Human Research Ethics Committee (HREC) (“the Committee”).

I am pleased to advise that at the Committee meeting on 8 February 2017, ethical approval for your study was granted following an expedited review process for “low risk” research, as per Section 5.1.7 of the National Health and Medical Research Council’s National Statement on Ethical Conduct in Human Research (NHMRC, 2007) (“the National Statement”).

The Committee had one suggestion which you may want to consider:

1. As the patients entering the Emergency Department (ED) may present with varying degrees of distress, a verbal consent for study participation on entry to ED would be appropriate. However, there may then be an opportunity once patients are settled, to provide more information on the study, for example, by way of a study synopsis brochure/flyer that participants can read and keep as a reference.

The study approval period is from 8 February 2017 to 30 August 2017. Should an extension of this timeframe be required, then you must seek continued approval from the Committee before the expiry of this time period.

In accordance with NHMRC guidelines, the Participating Site/Principal Investigator is responsible for:

1. Notification to the HREC of any adverse events or unexpected outcomes that may affect the continuing ethical acceptability of the study;  
2. The submission of any proposed amendments to the study or previously-approved documents;

.../2
3. The submission of an annual progress report for the duration of the study which is due on the anniversary of HREC approval;
4. Reporting of any protocol deviations or violations, together with details of the procedure put in place to ensure the deviation or violation does not recur;
5. Notification and reason for ceasing the study prior to its expected date of completion (if applicable);
6. The submission of a final report and translation of results (including publications) upon completion of the study.

The following study documents have been reviewed and approved:

<table>
<thead>
<tr>
<th>Title</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interview questions script protocol - Pain Management audit - prelude to acupuncture 21.1.17</td>
<td>1</td>
<td>21 January 2017</td>
</tr>
<tr>
<td>Participant Information consent Audit Pain Acupuncture 21.1.17</td>
<td>1</td>
<td>21 January 2017</td>
</tr>
<tr>
<td>Data Collection Sheet Protocol Pain Acupuncture Audit 21.1.17</td>
<td>1</td>
<td>21 January 2017</td>
</tr>
</tbody>
</table>

You are reminded that this letter constitutes *ethical approval only*. You must not commence this research study at SJGHC until separate authorisation in writing has been obtained.

I wish you well with your research.

Yours sincerely,

Clinical Professor Dr Simon Dimmitt
Chairman
St John of God Health Care Human Research Ethics Committee

cc. Ms Dani Meinema, Chair Murdoch Research Committee, SJG Murdoch Hospital (via email)
Emergency Department Pain Management Audit and Questionnaire

You have been flagged as having significant pain and will shortly be due to receive treatment.

This study will include a review of your pain management in ED, including how effective and what ways we can better manage your pain.

So as to not interfere with your pain management we will ask you questions after your pain relief is given.

This study will not in any way affect the care that you will receive from your doctors. All the information collected in the study is confidential and the analysis of the audit data will be undertaken on an anonymous basis. So as to not delay care, you will not be given any complicated forms to sign but simply asked whether you wish to participate in this review.

Thank you for kindly agreeing to participate in this study on pain in our ED.

More information
If you have any more questions about the audit, please e-mail drandrewjan@gmail.com
Appendix to Chapter 4 - Section B

Copyright permissions:

Copyright permission for PhD thesis

Head, Michelle <> To: "drandrewjan@gmail.com" <drandrewjan@gmail.com>

Dear Andrew,

Apologies for the delayed response to your email. I’d like to introduce myself as the Journal Publishing Manager for EMA, taking over from Alison Bell.

To use the submitted versions of your papers in your thesis, no permission is required. Please see the Wiley Article Sharing Guidelines here, noting the use for the different versions (submitted, accepted, published, etc):

The final version would also be allowed for the use you describe below under the same guidelines; no permission is required.

If you were going to be using them in a way that is not covered by these guidelines you would do so by navigating to the article on Wiley Online Library, and clicking on ‘Tools’ then ‘Request permission’ (screenshot below) – doing this ensures that you receive all the necessary paperwork to support the permissions request.

All the best with your thesis!

Appendix 83

https://mail.google.com/mail/u/0?ik=ac14b3c787&view=pt&search=all&permmsgid=msg-f%3A1673426064167410529&simple=msg-f%3A1673426064167410...
Kind regards,

Michelle

Michelle Head
Journal Publishing Manager

Wiley / 155 Cremorne Street / Richmond Victoria 3121 / Australia

www.wiley.com

From: Andrew Jan <drandrewjan@gmail.com>
Sent: Monday, 20 July 2020 9:08 PM
To: Bell, Alison <alibell@wiley.com>
Subject: Re: Copyright permission for PhD thesis

This is an external email.

[Quoted text hidden]
inclusion of article in appendix of PhD thesis

Andrew Jan <drandrewjan@gmail.com>  
To: editor@mforum.com.au  
Mon, Jul 20, 2020 at 7:05 PM

Dear Forum magazine (Editor)

As you may recall I have authored the following article with your magazine.

“More Integrated Pain Management”

I am seeking your permission to insert your final journal edited version in the appendix.


Please let me know if I have your permission

Sincerely

Andrew

Professor Andrew Jan
MBBS FACEM BA FAMAC MPhil
Adjunct Professor School of Medicine University of Notre Dame Fremantle,
Emergency Medicine Specialist, Medical Acupuncturist

Emergency Department, SJOG Murdoch Hospital
Barry Marshall Pde, Murdoch WA, 6150
E. drandrewjan@gmail.com
Hi Jan

I got your message via Joanne Henderson.

Thanks for letting me include the article in the PhD appendix.

Sorry don't know what's happening with your reply emails - I've checked the spam folder and they aren't there! weird!

warmest and thanks

Andrew Jan
[Quoted text hidden]
Appendix to Chapter 4 - Section C

Conference presentation:

Patient attitudes towards analgesia and their openness to non-pharmacological methods such as acupuncture in the emergency department

Andrew Jan
Adjunct Professor University of Notre Dame
SJOGH Murdoch
Western Australia

Appendix  88
Background

• Rising opioid deaths and adverse effects
• Acupuncture a novel solution
• Systematic review all forms of ED acupuncture
• Systematic review ED ear acupuncture
• Patient survey
• Teaching ED acupuncture
• Recently completed ED ear acupuncture trial
• Protocol for a larger randomized ? multi-centred trial

Is analgesia in the ED helping our patients or killing them?
Review Article

**Review article: Does acupuncture have a role in providing analgesia in the emergency setting? A systematic review and meta-analysis**

Andrew L Jan 1, Emogene S Aldridge, Ian R Rogers, Eric J Visser, Max K Bultsara, Richard C Niemtzow


Andrew L Jan, MBBS, FACEM, BA, FAMAC, MPhil, Emergency Physician, Staff Specialist, PhD Candidate; Emogene S Aldridge, BHlthSc, Academic Support Officer; Ian R Rogers, MBBS, FACEM, Professor; Eric J Visser, MBBS, FANZCA, FFPMANZCA, Professor/Churack Chair; Max K Bultsara, PhD, MSc, BSc, Professor; Richard C Niemtzow, MD, PhD, MPH, Director

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**Medical Acupuncture**


Published online 2017 Oct 1. doi: 10.1089/acu.2017.1237

PMCID: PMC5653340

PMID: 29067138

**Does Ear Acupuncture Have a Role for Pain Relief in the Emergency Setting? A Systematic Review and Meta-Analysis**

Andrew L. Jan, MBBS, FACEM, BA, FAMAC, MPhil, 1,2 Emogene S. Aldridge, BHlthSc, 1 Ian R. Rogers, MBBS, FACEM, 1,2 Eric J. Visser, MBBS, FANZCA, FFPMANZCA, 3 Max K. Bultsara, PhD, MSc, BSc 4 and Richard C. Niemtzow, MD, PhD, MPH 5,∗
To the Editor: We commend Cohen and colleagues on their recently published study, which is the largest randomised controlled trial (RCT) of acupuncture in the emergency department (ED). We recently completed a systematic review and meta-analysis on the role of acupuncture for analgesia in the emergency setting. Our analgesic effect of acupuncture is unlikely to be equal for all pain presentations in the emergency setting and, therefore, the conditions for which its role is most beneficial need to be delineated.

Andrew L Jan
Ian Rogers
Eric J Visser
1 Saint John of God Murdoch Hospital, Murdoch, WA.
2 University of Notre Dame Australia, Fremantle, WA.
drandrewjan@gmail.com

Competing interests: No relevant disclosures.

Accepted 1 March 2018

Recent papers ED Analgesia:

- Beltaief: Acupuncture non-inferior to morphine for renal colic (blinding not specified) at 1 hour.
- Fox: Improved pain scores 1 hour post intervention (not blinded)
Acupuncture trialled in the Emergency Department

Acupuncture is currently being trialled as an alternative holistic treatment option for pain management in St John of God Murdoch Hospital’s Emergency Department.

One of Murdoch’s Emergency Physicians Adjunct Professor Andrew Jan, who is also a Medical Acupuncturist, is conducting the trial, which uses a technique known as ‘Battlefield acupuncture’.

Prof Jan is passionate about reducing the number of strong, potentially addictive painkillers used to alleviate pain.

Methods

• Prospective survey using a convenience sample of adult patients presenting to our private ED over a 9 month period.
• Inclusion criteria were presenting to the ED with acute pain, assigned ATS 3–5 and NPRS ≥4/10.
• Patients were interviewed approximately 1 h after analgesia was first offered.
• Pain scores, analgesia given, demographics recorded
Questionnaire

Likert scales were used to document patient satisfaction, willingness to receive non-pharmacological analgesia and acupuncture as an adjunct to UAC, concern regarding addiction to UAC given in ED and if patients reported an adverse effects to their analgesia – their willingness to receive this medication again.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Median score</th>
<th>Percentage ≥ 4/6 on Likert scale (95% binomial exact confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity of pain on ED presentation</td>
<td>7 NPRS</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Severity of pain one-hour after analgesia</td>
<td>4 NPRS</td>
<td></td>
</tr>
<tr>
<td>Time from triage assessment to first dose of pharmacological analgesia, minutes</td>
<td>45 min</td>
<td></td>
</tr>
<tr>
<td>Time from pharmacological analgesia order to administration, minutes</td>
<td>8 min</td>
<td></td>
</tr>
<tr>
<td>Satisfaction out of 6 Likert scale</td>
<td>6/6</td>
<td>93.8%</td>
</tr>
<tr>
<td>Patients’ openness to non-pharmacological methods</td>
<td>5/6</td>
<td>84.7%</td>
</tr>
<tr>
<td>Patients’ willingness to use acupuncture</td>
<td>4/6</td>
<td>68.9%</td>
</tr>
<tr>
<td>Patient’s concern regarding addiction</td>
<td>1/6</td>
<td>21.4%</td>
</tr>
<tr>
<td>Likelihood they would avoid this medication in the future.</td>
<td>4/6</td>
<td>51.2% (of the 39 = 19.9% that had reported side effects)</td>
</tr>
</tbody>
</table>
Discussion: Percentages > 4/6 Likert results

• 84.7% open to non-pharmacological - holistic and interpersonal care and to avoid UAC adverse effects including addiction.
• 68.9% open to acupuncture - acupuncture frequently used and reasons for not using: needle phobia, ineffective past experience.
• Concern addiction UAC 21.4% - unexpectedly low.
• Adverse effects 19.9% within first hour - nausea, vomiting, dysphoria.

<table>
<thead>
<tr>
<th></th>
<th>Satisfied</th>
<th>Very satisfied</th>
<th>Patients taking opioids ≤ 4/24 prior to ED</th>
<th>Patients receiving opioids in ED</th>
<th>Patients willing to use non-pharmacological</th>
<th>Patients willing to use acupuncture</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (%)</td>
<td>93.9%</td>
<td>52.8%</td>
<td>24.5%</td>
<td>57.7%</td>
<td>84.7%</td>
<td>68.9%</td>
</tr>
<tr>
<td>Very Satisfied</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Age 30-49</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.26</td>
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<tr>
<td>Age ≥ 50</td>
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<tr>
<td>4.67</td>
<td></td>
<td></td>
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<tr>
<td>Gender (ref female)</td>
<td>8.44</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.40</td>
</tr>
<tr>
<td>Adverse effects</td>
<td></td>
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<tr>
<td>Concern for addiction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.43</td>
</tr>
<tr>
<td>Achieved 'adequate analgesia'</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3.92</td>
</tr>
</tbody>
</table>

Appendix 95
Discussion: Odds ratios associations

• Association between general satisfaction and being male. Increasing age was associated with being ‘very satisfied’ with ED pain management
• No association of satisfaction with administration of opioids. But yes with adequate analgesia!
• Patients concerns about addiction
• Females more interested in non-pharmacological methods

Questions?

• Does intradepartmental use increase recurrent use? Hence Opioid light ED’s. Further research required.
• Does patient demand for analgesia increase inappropriate opioid analgesia? Do we remove pain as the fifth vital sign or take away pain management from satisfaction surveys?
• Do non-pharmacological techniques reduce opioid use? Does it improve long term quality of life scores?
• Is acupuncture ready for mainstream usage in the ED?
Have matters really changed?
Guideline review

Primary care management of non-specific low back pain: key messages from recent clinical guidelines

Matheus Almeida, Bruno Saragiotto, Bethan Richards, Chris G Maher

1 Management of non-specific low back pain

First line care
Advice, reassurance, self-management, return to work and encouraging physical activity should be provided for all patients.

Stepped approach
Stratify by symptom duration: acute, subacute and chronic.

Acute/subacute (< 12 weeks)
- Superficial heat
- Massage
- Spinal manipulation
- Acupuncture

Chronic (> 12 weeks)
- Structured exercises
- Spinal manipulation
- Psychological therapies (cognitive behaviour therapy, mindfulness)

Risk stratification approach
START Back, Orebro Musculoskeletal Pain Screening Questionnaire or PICKUP

Low risk: simpler and less intensive support
- Manual therapy (spinal manipulation, massage)
- Group exercises

Medium/high risk: more complex and intensive support
- Structured exercises
- Psychological therapies (cognitive behaviour therapy, mindfulness)
- Multidisciplinary treatment (combining physical and psychological therapies)

Consider pharmacological therapies if non-pharmacological options are unsuccessful
- Non-steroidal anti-inflammatory drugs
- Skeletal muscle relaxants (acute pain only)
- Opioids:
  - only use when other medicines are contraindicated/not tolerated/ineffective
  - require careful risk–benefit assessment, discouraged for chronic LBP
- Paracetamol is not recommended
non-pharmacological modalities for pain may enhance a person’s life and turn pain into growth and meaning!

Contact me
drandrewjan@gmail.com
www.drandrewjan.com.au
Appendix to Chapter 4 - Section D

Magazine publication:

ED: More Integrated Pain Care

Dr Andrew Jan, an Emergency Physician currently researching medical acupuncture in the ED setting, touches on his view on pain management.

Pain sends patients to Emergency Departments (EDs) and up to 75% who attend have pain. Current pain relief measures are predominantly pharmacological along with procedural and surgical interventions. However, our current approach to pain relief may have negative consequences.

Over the past two decades opioid prescribing has markedly increased. The director of the US Centre for Disease Control and Prevention, Tom Frieden, says of opioid prescribing: “We know of no other medication that’s routinely used for a non-fatal condition that kills patients so frequently.” In Australia, there were 605 oxycodone deaths 2001 to 2011 and this figure is rising.

EDs commonly use oxycodone as an analgesic although they only prescribe a small proportion of all oxycodone used in Australia. We do know that opiates initiated in ED increase the risk of later misuse and addiction.

Are we helping or hurting patients with our current approach, given both the short and long-term side effects of pain medications? Do we need other models of care in the ED and for pain medicine in general?

Prior to the medical (or Cartesian) model introduced in 16th century, pain management was dominated by various cultural and spiritual aspects. We now know tissue injury and pain does not have a one-to-one relationship – that there are emotional, cultural and spiritual dimensions for pain.

is our medical model becoming a short-sighted assembly-line medicine for managing body parts? Should we consider therapies from other paradigms that have some evidence of efficacy and do less harm, while encouraging personal growth?

Even in the ED there are opportunities to introduce such alternative pain therapies for a patient’s pain crisis, as a stand-alone or as an adjunct to simple analgesia (while there will always be a place for standard analgesia, opioids and procedural interventions).

These therapies may include guided imagery, breathing and relaxation techniques, acupuncture, explanation, comfort positions, attentional techniques and cognitive behaviour interventions.

This more integrated approach offers a middle path where the ‘whole person’ is treated and their individual life story is foremost with the medical model assisting their journey. Further research into alternative pain therapies to investigate their efficacy and suitability in this setting is needed.

Are we helping or hurting patients with our current approach...?

For example, the narrative medicine model highlights the humanistic psychology perspective. The humanists would see the pain experience as a ritualised initiation into some sort of mystery, that patients must on their own, ‘figure out’ and then move onto a new direction in their life. Pain may be regarded positively as an education or even a gift – as negotiating the path between pain and pleasure, happiness and despair is an inherent human condition.

ED. References available on request from the author at drandrewjan@gmail.com
Appendix to Chapter 5 - Section A

Abstract, Lectures (content covered elsewhere in thesis is excluded), Take home manual and Feedback results:

Title
ED Acupuncture for Emergency Physicians
- A Half Day Practical workshop

Prof Andrew Jan, A/Prof Allen Yuen, Dr Michael Ben-Mier, Ian Russell RN Dip TCM

Summary of workshop content
A practical half day introductory workshop on ED ear and body acupuncture. The attendees will be taught some basic skills and knowledge for both safe and potentially effective acupuncture in the emergency setting. Prescriptions for nausea and pain (head, low back, neck, hip, knee and shoulder) will be taught and practiced. Pre-workshop material will be provided on the following topics: Analgesia in the ED – role of acupuncture; Theories on acupuncture mechanism; Safety with acupuncture; Scientific evidence for efficacy of acupuncture; and Surface anatomy of common acupuncture points.

Participant numbers
Minimum number of participants 9 and maximum 18.

Pre-course:

Talk over power points on (10 minutes talk over ppt)
1. Analgesia in the ED – Role of acupuncture MBM
   - Assessing Analgesic efficacy (Pain scores, patient satisfaction, adverse event rates)
   - Adverse effects of standard analgesic care

2. Theory on mechanism – IR
   - Gate Control theory
   - Local pain inhibitors
   - Ascending pathway inhibition
   - Alteration Brain Matrix
   - Central brain stimulation
   - TCM theories

3. Evidence for efficacy - AJ
   - Jan et al
   - Cohen et al
   - Vickers et al
   - Usage in Australia, USA
   - Roberta Chow
   - Specific conditions: back, neck, shoulder, knee, hip, nausea and vomiting

4. Safety, Dangerous points, adverse events - AJ
   - Incidence per treatment
• Dangerous points
• Pregnancy
• Lost needles
• Retained needles
• Avoiding Fainting
• Avoid breaking needles

5. Meridians, Point selection for below conditions - IR
   • Meridians
   • Surface anatomy and needling technique for local and distal points for all conditions below – approximately 40 points?
   • TCM theories on point selection
   • Use reputed point selection from published trials wherever possible

Feedback form: End of course evaluation feedback form – AJ
• Pre-course material
• Lectures
• Skills section practicing on each other
• Skills section practicing on real X 3 patients (ear, knee, headaches)

Lectures and skills for half day workshop
Summary and repeat including questions:
6. Why Learn acupuncture (including ED pain management) - MBM
7. Theory on mechanism - AY
8. Evidence for efficacy AJ
9. Safety, Dangerous points, adverse events AJ
10. Meridians, Point selection including basic body needling technique including laser for below conditions - IR

11. Battle Field Ear Acupuncture including ear needling for all pain types – AJ
   • Evidence of efficacy
   • Using semipermanent ear needles
   • Ear points: Cingulate, Thalamus, Omega, Shenmen, Point zero

12. Headaches and Migraines\textsuperscript{2} - MBM
    Show point selection and needling techniques. Reduce list to maximum 5 local points and Max 3 distal points
    Take history to identify distribution of pain
    • Local points: Taiyang, ST8, GB8, BL2, GB14, TE 23, GB 20
    • Distal points: LV3, LI4, SJ5, , GB41, BL 62

Appendix 104
13. Back Pain - MBM
Show point selection and needling techniques. Reduce list to maximum 5 local points and Max 3 distal points
- Local points: Huatoujiaji, GB 30, BL54, GV3 and GV4, BL30
- Distal points: BL40, BL62, BL40, BL62, and LR 3

14. Neck pain - AJ
15. Shoulder pain – AJ
- Li14,15, SI9, SI11, TE 15
- Li4, TE5

16. Knee pain - IR
- Reduce list to maximum 5 local points and 3 distal points
- Local points: SP9, 10 ST35, LR, 8, KI10BL39, 40, GB34,
- Distal points: ST40, LR3, SP6, GB41, BL60

17. Hip pain - IR
- Reduce list to maximum 5 local points and 3 distal points
- Local points: BL 29, 54, 30, GB: 30 31
- Distal points: GB 41, 44, 34, Hip Ear Point

Logistics:
18. ? Volunteer patients – AJ / IR
19. Needles - Donation by Helio (agreed) – (ASP, sample general, sharps containers) AJ
21. 2 portable massage tables – AJ/ IR
22. Alco-wipes
23. Gauze dressings / dressing packs X 12
24. Dot Band-aids
25. Hand wash disinfectant
26. Sharps containers
27. Back up needles

Draft timetable for ½ day workshop:
http://www.acem2018.com/workshops/
Meeting room 10 Perth convention centre
Conclusions - positives

• 8 studies, 6 RCT’s, 4 eligible for meta-analysis. All meta-analyses positive for pain reduction over control but not all had a p value < 0.05
• Interpret on the background of prior reviews by Jan, Murakami, Yeh and Asher
• Use as sole therapy or adjunct where adverse effects of standard analgesia are potentially harmful
• Half way there – Results encouraging - More studies required!

Battlefield acupuncture (BFA)
The Technique
**Indications**

- All pain types
- Where intended standard analgesia care has adverse effects, unwanted risks associated and patient choice.

**Contra-indications**

- Undiagnosed pain (needs follow up)
- History of fainting to needles
- Needle phobia
- Infection at needle insertion site
- Bleeding predisposition (relative)
- Pregnancy - currently there has been little research on BFA and pregnancy. Therefore until further research, BFA should not be administered to pregnant patients.
Advantages

- Requires only exposed ear – hence clothes, rest of body available for examination and procedures.
- Low risk of adverse effects
- No drug interactions

Adverse effects

- Pain at needle insertion site
- Bleeding
- Lightheadedness or fainting
- Euphoria
- Infection
- Discolouration or keloids at needle site
Needling Technique

• ASP Gold Needles

2-3 finger technique
Practice on a rubber eraser to start
Stabilise or stretch skin prior to needle release
Relax your shoulders, elbows and take your time!
Video Demonstration of Insertion of the 5 BFA Points by Colonel Richard Niemtzow - Note this would be done bilaterally!

**BFA Sequence**

- Select patient appropriately
- Counsel and obtain informed consent
- Clean hands and clean ear
- Place needles bilaterally at each point with patient sitting but wary that patient may faint so – sitting on trolley is ideal. Patient can also be horizontal.
- Walk or get patient to move arms or take 5 deep breaths after each bilateral point insertion.
- Assess pain level
- Proceed to next point in CG – T – O – P – S sequence.
**Point Location**

- CG-T-O-P-S
- Insert CG walk or get patient to move arms / take deep breaths and ask pain score after each point bilaterally

**Reasons to stop**

- Patient asks to stop
- Pain is decreased to 0-1/10
- Significant lightheadedness or feeling faint
Aftercare

- Activity – normal
- Needles – remove after 3 days or earlier if bothersome or concerns
- Inflammation – early signs
- Medications – take according to directions

Potential Adverse effects: The semi-permanent needles are made from stainless steel or gold and reaction rates are very low. It is best to tape the needles in to prevent them falling out inadvertently. If the surrounding skin on the ear becomes red and painful the ear needle should be removed. It is advised that you should remove them after 3 days to prevent infection. At this time their stimulation stops anyway. Because of the risk of infection, patients with valve disease or poor immunity probably shouldn’t have these needles. Please remove the needles with tweezers and place in the container to return to the clinic or Dr. Jan for safe sharp disposal. Patients with potential blood borne diseases such as Hep B, C or HIV should also not have this therapy. On the very rare occasion where a needle falls into the external ear or more commonly on the floor / pillow - use the magnet provided to pick it up. Do not try and remove objects from the deep inner ear with tweezers. Be careful with young children as they can be curious and pull the needles out. Dr. Jan can be contacted via Ellen Health or St John of God Murdoch Emergency Department for any major urgent problems.

Questions?

Contact me down under please

drandrewjan@gmail.com
www.drandrewjan.com
ED Acupuncture
Safety, Adverse effects, Dangerous points

Andrew Jan
MBBS FACEM FAMAC BA MPhil
Adjunct Professor School of Medicine
University of Notre Dame
Staff Specialist in Emergency Medicine, Medical acupuncturist
St John of God Hospital Murdoch

Case report 1- Fainting

• A 44 year old lady has a painful shoulder. She has already had 3 steroid injections 2 into sub acromial bursa the other into shoulder joint without success. She is intolerant of NSAIDs because of GORD and Panadol isn’t helping. Opioids including ‘atypicals’ make her nauseated and vomit.

• The doctor treats this patient in fast track area. He uses acupuncture: Li 14, Li 4, TE 5 and GB 34. Upon inserting the needle in GB 34 she says she feels sick, falls to the floor and hits her head. She suffers a minor head laceration.
Case report 2 – Broken needle

• A 25 yo non-pregnant female presents with migraine with vomiting. The headache is bilateral and parieto-frontal in distribution. You prescribe her IV paracetamol, metoclopramide and decide to use acupuncture as an adjunct.

• You use three ear points: thalamus, cingulate and migraine points as well as TE5 bilaterally. Everything goes smoothly till she vomits and grabs the vomit bag and breaks the needle in TE5.

• Fortunately you are able to slightly squeeze the surrounding tissue and pull out the retained needle!

Case report 3: Forgotten needle - stick

• A 38 year old unemployed man who presented with low back pain receives acupuncture in the ED. The department got busy so the nurse removed the needles under direction. The treating doctor did not advise the nurse how many needles were used. Unfortunately one needle was missed and hidden in the linen. The subsequent nurse who was changing the linen for the next patient sustains a needlestick injury. The patient was not contactable for serology testing for communicable blood diseases.
Case report 4 - Perichondritis

• A 37 year old somewhat unkempt man presented with low back pain and received ear acupuncture i.e. Battlefield acupuncture with semi-permanent needles. Six needles were inserted, patient’s pain improved considerably. Two weeks later he represents with a perichondritis. One needle remained in situ with a tape.

Objectives

• Define adverse events with acupuncture and their severity.
• Give approximate incidence of adverse effects of acupuncture versus standard analgesia care
• Outline steps to avoid these adverse effects.
Definitions

The definition of an AE is “any unfavourable and unintended sign, symptom or disease that presents during or after treatment with acupuncture regardless of a causal relationship”.

He W. J Altern Complement Med [Internet]. 2012 Oct

Mild side effects

Many events are mild and self-limiting, and their main significance is simply that patients should be warned to expect them e.g. pain, bleeding, bruises.#

Others may include: forgotten needle (but removed after prompting by patient), patients left too long with needles in situ.*

# White, A. Acupuncture in Medicine. 2004; 22(3), 122-133.
**Significant adverse events**

Examples of significant - those that require treatment events included needling problems (broken needles requiring surgical retrieval, fainting, convulsion, drowsiness causing hazard eg on the road, severe nausea, and worsening of symptoms (unexpected or prolonged aggravation).

# White, A. Acupuncture in Medicine, 2004; 22(3), 122-133.

**Serious**

A ‘serious’ adverse event is clearly defined by its consequences: it ‘results in death, requires, hospital admission or prolongation of existing hospital stay, results in persistent or significant disability or incapacity, or is life threatening’.

White, A. Acupuncture in Medicine, 2004; 22(3), 122-133.
Hazards to practitioners & others

Needle stick injury & blood borne diseases.

### Incidence of significant and serious adverse Events

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Patients (treatments)</th>
<th>mild</th>
<th>significant</th>
<th>serious</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endres (2004)</td>
<td>190,000 (multiple treatments over 6 weeks)</td>
<td>7.40%</td>
<td>0.02%</td>
<td></td>
</tr>
<tr>
<td>White (2004)</td>
<td>(1.1 million)</td>
<td></td>
<td>0.0005%</td>
<td></td>
</tr>
<tr>
<td>White (2001)</td>
<td>32,000</td>
<td>0.14%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Witt (2009)</td>
<td>230,000 (ave 10 treatments each)</td>
<td>2.2%</td>
<td>0.0001%</td>
<td></td>
</tr>
<tr>
<td>Park (2014)</td>
<td>Pregnant (22,300)</td>
<td>1.50%</td>
<td>0.03%</td>
<td>0%</td>
</tr>
<tr>
<td>Jan (2017)</td>
<td>675</td>
<td>1%</td>
<td>0%</td>
<td></td>
</tr>
</tbody>
</table>

Witt CM. *Forsch Komplementmed* 2009;16:91-97
Incidence of adverse effects with standard analgesia care (SAC)

- Relative risk for adverse effects acupuncture vs SAC = 0.09.#
- Adverse effects opioids up to 53%. *
- Adverse effects NSAIDs issue in elderly, those with GORD and renal disease
- Most RCTs of acupuncture versus medication are not geared to compare adverse event rates. Most are not for acute pain in the emergency setting.

* Upshur CC. J Gen Intern Med 2006

Types and frequency of adverse events - primary case reports by White (1994-2004)

Trauma:
- Pneumothorax (54 primary case reports)
- Pericardial tamponade (9 primary)
- Blood vessels 10 (DVT, arterial thrombosis, compartment syndrome)
- Nervous system: 12 (epidural, transverse myelopathy)

Infections:
- Perichondritis ear 14
- Septic arthritis 3
- Hepatitis 148
- Abscess 7

Other
- Collapse, seizure 7

Deaths
- Pneumothorax 4, pericardial tamponade 2, sepsis 5, asthma 1

White, A. Acupuncture in Medicine, 2004; 22(3), 122-133
Dangerous points classically taught

- **Face**: Points within orbit BL 1, ST 1
- **Neck**: CV 22, LI 18, SI 17, GV 15, GV 16
- **Chest**: all points not protected by bone and cartilage
- **Abdomen**: ST 21


Pregnancy

- Traditional acupuncture texts also list specific acupuncture points such as LI4, SP6, GB21, BL32, BL60, and BL67 may induce labour. Recently strongly disputed!*
- Avoid points directly over the uterus
- Avoid points over sacrum and LSS*
- Therefore except for directly over the uterus benefit likely to outweigh harm!

Prohibited areas

• Include nipples, the umbilicus and the external genitalia.

Universal precautions

• Universal blood and body fluid precautions (universal precautions) should be followed. When treating patients with a high risk of being infectious, the practitioner should protect himself or herself by using appropriate barriers, such as gloves or finger cots.#

• At risk situations: ears (penetrate through), removing needles.

Other dangers

- Patients with pacemakers should not receive electro-acupuncture.
- Patients with bleeding tendencies or blood thinners such as clopidogrel, NOACs or warfarin pose risks. Avoid or justify risk / benefit - use fine gauge needles are recommended and apply pressure to the site of insertion after withdrawing the needle.# Avoid needling into joints to minimise the risk of haemarthrosis.
- Needling into an artificial joint is a contraindication due to the risk of infection. Needling around an internal fixation device poses some risk.
- Patients allergic to metals, may have a reaction to needles.

Skin preparation (alcohol, chlorhexidine, iodine)

- Routine alcohol preparation of skin for simple needling in healthy patients offers no advantages.¹
- While definitive studies of the effects of the practitioner touching the needle shaft remain to be done, acupuncture needle characteristics, proper hand washing, and hand drying minimize the risk of patient infections and justify the continued practice of touching the needle shaft.
- For patients with compromised immune systems, skin preparation with chlorhexidine-alcohol or providone-iodine scrubs is superior to 70% isopropyl alcohol.
- However use skin prep for: semi-permanent needles eg BFA, penetrating near joint, near epidural space

¹McDaniels A. Medical Acupuncture. 2011 Mar 1;23(1):7-11.
Further take home points for safe practice

- Use acupressure / laser for potentially dangerous points. Novice better to use needles on safer distal points.
- Needling chest: shallow, away from lung or over bone / cartilage
- Avoid deep needling of foramina: infra-supra orbital nerve, scapula, sternum.
- Avoid deep needling (~25-45mm) around spine (midline, inner Bladder channel), near vital organs (kidney, liver, spleen, heart, bladder, intestine)
- Avoid inflamed, rashes, lymphoedema
- Avoid breast, genitals


Further take home points for safe practice

- Patients are adequately positioned to prevent injury should fainting occur.
- Check patients before they are discharged. Advise them that if they feel drowsy or spacey that they should not drive home. They either wait in the waiting room or seek alternative transport.
Management of fainting, broken and stuck needles

• Fainting: beware the warning signs - stop needling and remove all needles, lie patient down.
• Broken needle: If the broken needle is exposed remove the broken section with tweezers, if it is not exposed press the tissue around the insertion site until the broken section is exposed and remove with tweezers. If the needle can’t be removed - surgical referral.
• Needle is stuck: Try rotating the needle, alternatively relax the tissue around the needle with massage, ice or by inserting 1-2 needles around the stuck needle, then remove.

Case report 1

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Conclusion

• Acupuncture has a low risk of adverse effects.
• This is likely to be substantially less than SAC.
• Nevertheless acupuncture does have adverse effects so practitioners should deliver with care.
• Emergency physicians intuitively are ideal practitioners given knowledge of surface and general anatomy, exposure and experience with invasive procedures.
• The rare complications of fainting, pneumothorax, infection, bleeding, broken needles and needlestick injuries should be avoided.
References

Theories on mechanism of Pain reduction

How acupuncture works!

Andrew Jan
Adjunct Professor Notre Dame University
Staff Specialist
St John of God health Care Murdoch

Definitions of pain

- The International Association for the Study of Pain defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage”
- Nociceptive pain is usually caused by damage to body tissue and involves specific peripheral nociceptors that detect and transform noxious stimuli as electrical signals via nerve axons.
- Neuropathic pain usually occurs when there is nerve damage or recurrent pain sensitization to the peripheral and/or central nervous systems.
Darwinian understanding of pain

- Pain creates an “escape” response eg insect bite, stinging plant
  - A delta fibers to spinal cord to create flight or fright
- Pain creates a sickness response to help deal with the injured part eg food poisoning, limb injury
  - Deep pain activates the ventrolateral PAG column through C-fibers to trigger sickness behaviour.

Peripheral mechanisms

- Pain mediated by bradykinin, serotonin, cytokines, and prostaglandins are released after peripheral tissue injury.
- Acupuncture releases vasoactive peptides, mast cell release, bradykinins, prostaglandins, cytokines, calcitonin G related peptide - improving blood flow
- Analgesia: adenosine release (neuromodulator – membrane stabilizer)
- re-establishing body part neuro-localization
- dielectric properties of acupoints differ from non-acupuncture sites Most have rich nerve innervation mainly in the deep tissues. (Murakami 2017)
Gate control theory - PAG

Gate located in dorsal horn
Larger faster fibres arrive at gate and inhibit pain from slow fibres
Acupuncture like heat, pressure, vibration etc inhibits perception of pain by stimulating A- beta fibres
However acupuncture also likely stimulates C and A-delta fibers with De qi

Katz et al 2015
Young et al 2010
Murakami et al 2017
Spinal cord inhibition

- Raises spinal cord endorphins - the reversible effect of naloxone on the acupuncture induced analgesia is well known. (Murakami et al 2017)
- Activation of cholinergic muscarinic receptors, and anti-inflammatory signalling (reversible with atropine) (Murakami et al 2017)
- Inhibition of activated glial cells (Zhang et al 2017)
- Increase GABA (Qiaou et al 2017)

These central factors (documented fMRI) influence pain perception

- Metanalysis FMRI acupuncture activates: cingulate (true > sham), thalamus, insula, amygdala, hippocampus (Huang 2012)
Central mechanisms

- Acupuncture activates parasympathetic nervous system including vagal nerve (Usichenko et al 2017)
- Acupuncture balances monoamine neurotransmitters including dopamine (acupuncture effects modified by chlorpromazine and haloperidol (Murakami 2017)
- Noradrenaline plays crucial role in acupuncture analgesia brainstem (Murakami 2017)
- Acupuncture treatments can modulate the content and the activity of central 5-HT (Murakami 2017)
- Acupuncture increases levels of brain derived neurotrophic factor (BDNF) (Chassot 2015)
- Acupuncture modifies glial cells in rats (Gim 2011)
TCM approach

- Pain due to chi blockage
- Turn the mind / senses inwardly
- Reframes pain as a healing therapy rather than noxious stimuli
- Connects master to student
- 5 element theories

Summary

- Acupuncture works from a diverse range of mechanisms from peripheral to spinal to central.
- These mechanisms have been shown in human and animal models with an array of techniques ranging from biochemical to fMRIs.
- TCM mechanisms based on Taoist mystical philosophy in part. They may play a contribution to the large placebo effect found in acupuncture efficacy.
ED Acupuncture Workshop

17 November 2018
Perth

Prof Andrew Jan FACEM FAMAC
Dr Michael Ben-Mier FACEM
Ian Russell TCM practitioner
* Health professionals trained in acupuncture includes two groups: traditionally Chinese medically trained i.e. TCM practitioners and those medically trained completing at least the first part Fellowship of Medical Acupuncture i.e. FAMAC.

* Other Allied health practitioners can perform acupuncture but cannot call themselves “acupuncturists”. Accreditation within their respective organisations is unique - for example Physiotherapists after 20 hours of physically attended courses and attending annual updates can perform acupuncture and term this technique “dry needling”.

* For emergency physicians working in private emergency departments, reimbursement through medicare requires endorsement by the Joint Committee of General Practice and Medical Acupuncture. Currently those accredited for acupuncture are able to access reimbursement for item number 173 (rebate approximately $21) but cannot charge both consultation and acupuncture items simultaneously. Certified GPs can charge for combined consultation and acupuncture.

* At this stage there are no guidelines within the College of Emergency Medicine governing utilisation of acupuncture techniques. Thus ability to perform acupuncture or ‘dry needling’ would likely require local ED Director and hospital approval.

* This course is an introductory course and we would recommend those who are interested to seek further training - particularly through the College of Medical Acupuncture.

Included in this handout:
1. Administration
2. Dangerous points
3. Pregnancy dangerous points
4. Battlefield (ear) acupuncture
5. Headaches
6. Neck pain
7. Shoulder pain
8. Low back pain
9. Hip pain
10. Knee pain
General Guidance

General Introduction Acupuncture Teaching Manual:

Cun the Chinese inch, is a traditional unit of length for acupuncture point location. Its traditional measure is the width of a person's thumb at the knuckle, whereas the width of the two forefingers denotes 1.5 cun and the width of four fingers (except the thumb) side-by-side is three cuns.

Each of the following pages gives general guidance for points selection. Note general rules are: take history and examine patients for distribution of pain and location of tender points.

Usage of local points is more efficacious if they are tender. Distal points are used to remove pain from that meridian or area. Distal points for face: LI 4, Side of head TE 5, Back of neck: SI 3, front of the chest and abdomen PC 6.

Abbreviations:
T= Transverse insertion
P= Perpendicular insertion
O= Oblique insertion
Comments on:


We recently completed a systematic review and meta-analysis on acupuncture in the emergency setting.¹ It is an important exercise to contrast and compare this landmark RCT with other similar studies.

**Numbers of studies:** The authors stated that there were just two acupuncture studies for analgesia in the ED setting. In our review we identified 19 RCTs and 11 uncontrolled observational studies totalling 3169 patients. Their paper is as they state – the largest RCT to date!

**Acupuncture versus standard analgesia care (SAC):** Their most important finding is that acupuncture analgesia is non inferior to SAC. Our meta-analysis of acupuncture versus SAC which was performed on data from 14 RCTs representing 1210 patients showed similar results and supports their finding.

**Medication usage reduction:** Their study potentially had data to show whether acupuncture resulted in medication reduction when used as an adjunct. In our review there were four studies which used medication reduction as an outcome with two studies showed reduction and two no difference.

**No sham group:** As the authors mention – some results may be due to non-specific effects and a placebo group would ideally be required. Some acutely painful conditions might resolve with time and the non-specific effects of attention. Our review performed meta-analysis on eight RCTs including 526 patients and compared the change in PS-10 for acupuncture versus sham giving a large effect size difference showing that acupuncture is more effective than sham

**Adverse events:** We would have liked the authors to have describe adverse events as minor (such a pain and slight bleeding from needling) or significant (requiring treatment). They reported an overall adverse event rate of 50-51%. We were able to show 7/675 patients (1%) had significant adverse events from acupuncture in the pooled RCTs (three needle breakages and four faints) and a relative risk for overall side effects for acupuncture versus SAC as 0.09. Other reviews focusing on large observational studies give the rate of significant adverse between 0.02% - 2.20%.²

**Patient satisfaction:** This study showed patient satisfaction was better for the acupuncture intervention when measured at 48 hours. Our review identified five studies which measured patient satisfaction all of which showed improvement.

**Quality:** Most acupuncture studies do not blind patients or acupuncture practitioners. This study for the remainder was of high quality. Most studies did not publish a formal pretrial protocol and some did not blind their assessors.

Andrew L Jan

ED Acupuncture all types - the evidence AJ 10.5.18

This is a summary of the all forms of acupuncture systematic review published EMA 2017 along with a brief dissertation of ED acupuncture trials since then.

Objective: Acupuncture might offer a novel approach to improve ED pain management. Our primary aim was to assess the efficacy of acupuncture in the emergency setting while secondary objectives were to explore its suitability through its side effect profile, patient satisfaction, cost, administration time and points used.

Methods: Seven data bases and Google Scholar were searched up to 31 July 2016 using MeSH descriptors for three overarching themes concerning acupuncture, pain management and emergency medicine. Meta-analysis was performed on randomized trials for three comparator groups: acupuncture versus sham, acupuncture versus standard analgesia care and acupuncture-as-an-adjunct to standard care, to calculate the standardised mean difference and weighted mean difference for pain scores out of 10. Data for secondary outcomes was extracted from both randomised and observational studies.

Results: Nineteen randomised controlled trials (RCTs) and 11 uncontrolled observational studies totaling 3169 patients were retrieved after exclusions. Meta-analyses were performed on data from 14 RCTs representing 1210 patients. The three resulting comparator groups (as above) resulted in standardised mean differences of 1.08 (sham), 0.02 (vs SAC) and 1.68 (adjunct), and weighted mean differences of 1.60, -0.04 and 2.84 respectively (all positive figures favour acupuncture). Where measured acupuncture appears to be associated with improved patient satisfaction (about a 1/3 of RCTs and Observational studies), lower cost (most expensive Ear acupuncture Gold ASP needles $5/patient) and a low adverse effects profile (7/2000 – significant). The data available were inadequate to conclude the effect of acupuncture on analgesia use (2/4 yes). Significant study bias was found, especially with respect to practitioner and patient blinding.

Conclusions: For some acute painful conditions in the ED, acupuncture was clinically effective compared to sham and non-inferior to conventional therapy. As an adjunct, limited data was found indicating superiority to standard analgesia care. Further studies will elucidate the most appropriate acupuncture training and techniques, use as an adjunct and the clinical situations in which they can be best applied.

Studies since then:
Cohen 2017 (~500) patients: non-inferior for ankle sprains, migraine and LBP
Beltiaef 2018 (~100) acupuncture non-inferior to morphine
Fox 2018 (~30 patients) LBP improved pain scores
Safety of acupuncture:

Frequent significant and serious adverse effects:
Pneumothorax
Fainting
Forgotten needles – sharp injuries
Broken needles
Infections with retained needles

Types of side effects: mild (self-limiting) – significant (require treatment) e.g. pain, bleeding
Serious = life threatening
Incidence: significant 1%, serious < 0.02%.

Injure: lung, major vessels, major solid organs: pneumothorax, bleeding (confined spaces), infection, nerve trauma.
Needlestick injuries
Classically taught dangerous points: eye, neck, chest and back, gall bladder (through nerve foramina – sternum, scapula
Pregnancy: ?? ppt labour, penetrate uterus and baby
Modesty and pain: nipples, umbilicus, genitalia
Others: prostheses (infection), pacemakers (electroacupuncture or piezoelectric causing pacemaker malfunction or arrhythmia), blood thinners (haemorrhage)

Prevention: use skin prep for semi-permanent, near joints and those with immune suppression. Don’t touch shaft needle, avoid inflamed skin, never needle into/near a prosthetic joint. Fainting: warn and best to do on trolley so can lie down – or do supine. Needle stick – don’t use too many needles – do a count. Avoid dangerous points – use distal and even acupressure on local tender points e.g. thorax, neck! Give patients buzzer which is easily reachable, so they can call for help and not move!
Dangerous Points

Face: Points within orbit BL 1, ST 1
Neck: CV 22, LI 18, SI 17, ST 9
GV 15, GV 16
Chest: all points not protected by bone and cartilage, CV 17, SI 11, GB 21
Abdomen: ST 21
The effects of Battlefield acupuncture (ear) in pregnancy is unknown. There is a paucity of research on ear acupuncture in pregnancy.

Pregnancy potential dangerous points

* LI4, SP6, GB21, BL32, BL60 and BL67 may induce labour.
* Avoid points directly over the uterus and lumbosacral spine
* Dangerous points for non pregnant apply
* The effects of Battlefield acupuncture (ear) in pregnancy is unknown. There is a paucity of research on ear acupuncture in pregnancy.

LI4 dorsum of hand, radial to midpoint 2nd mc
SP6 posterior to tibial border, 3 cun above medial malleolus
GB21 midpoint B/W C7 DS and lateral edge of acromion (see dangerous points)
BL32 second sacral foramina
BL60 B/W lateral malleolus and achilles
BL67 base of nail of little toe lateral

REF: Betts D, Budd S. Forbidden acupuncture points in pregnancy: historical wisdom?. Acupuncture in Medicine. 2011 Mar 1:acupmed38/14
ASAP Guidelines for Safe Acupuncture and Dry Needling Practice 2013

Appendix 143
4. Acupuncture Pain reduction mechanisms AJ

- Pain does not necessarily include tissue damage but does include a negative emotional response. Nociceptive pain usually denotes tissue injury while neuropathic pain implies nerve injury.

- There may have been an evolutionary advantage to the pain response to encourage pain and unpleasant visceral response to motivate the host to escape further injury. Alternatively, significant injury encouraged a pain with a ‘stay put and recover’ response till the body had time to repair.

- Acupuncture causes peripheral tissue injury with similar release of local inflammatory mediators to painful tissue injury. Note acupoints are both often tender and richly innervated and felt as the origin of pain. However, acupuncture is performed in a healing pleasant environment and at a lower intensity.

- It is postulated that acupuncture can close the pain gate at the dorsal horn.

- Central mechanisms and acupuncture (like music, words, emotions) influence perception of pain at many sites in the brain including: cingulate, thalamus, amygdala, hippocampus and frontal cortex.

- Chinese medicine attributes pain to chi and blood stagnation to both organs and their corresponding meridians. Thus, the mechanism of acupuncture is balance to the organs and meridians thus improving chi flow and reduction in pain.
Acupuncture and Traditional Chinese Medicine.

Ian Russell TCM practitioner

The most important medical books for Acupuncture and Traditional Chinese Medicine date from 200 BCE e.g. Huangdi Neijing - the Inner Canon of the Yellow Emperor

The Ancient Chinese used observations of natural phenomenon in nature to try and explain normal physiology of the body.

Each internal organ is represented by a natural element, i.e. fire, water, earth, wood and metal.

Each organ has correspondences and is interrelated to: seasons, colours, weather, food, housing etc.

Each organ is reflected by particular pathways in the body. These are now called meridians/channels.

These pathways can be affected by internal organ problems or by local structural issues.

Acupuncture is a potential way to manipulate circulation in the body, either for local structural or internal organ problems.
3. Ear acupuncture evidence and how to do Battlefield ear acupuncture AJ 23.5.18

This one pager is both a summary of the ear systematic review and Battlefield acupuncture – how to do!

Systematic review on Ear acupuncture:

Objective: Ear acupuncture might be the form of acupuncture best suited to improving acute pain management in the emergency department. Our primary aim was to assess the analgesic efficacy of ear acupuncture in this setting. Secondary outcomes included measures of patient satisfaction, adverse effects, cost, administration techniques and medication usage reduction.

Methods: Seven databases and Google Scholar were searched up to 27th April 2017 using MeSH descriptors for three overarching themes (ear acupuncture, pain management and emergency medicine). Meta-analysis was performed in three comparator groups: ear acupuncture versus sham, ear acupuncture-as-adjunct to standard care, and ear acupuncture (both sole therapy and adjuvant) versus control to calculate the standardized mean difference and weighted mean difference for pain scores out-of-ten.

Results: Six randomized controlled trials and two observational studies totalling 458 patients were retrieved after exclusions. The meta-analysis used data from four randomized studies representing 286 patients. The above three comparator groups resulted in standardized mean differences of 1.69 (sham), 1.68 (adjunct) and 1.66 (sham and adjunct) and weighted mean differences of 2.47, 2.84 and 2.61 respectively, all favouring acupuncture. Battlefield (ear) acupuncture was the most commonly used technique and often performed by non-acupuncturists. Romoli’s technique using the ear homunculus for point location was the second most common. Range of conditions: fractures, abdo pain, LBP, sore throats and migraines. There were no significant adverse effects and patient satisfaction improved. Results regarding whether acupuncture reduced medication use were equivocal (2 no 1 yes – perioperative studies yes!). Significant study bias and heterogeneity was found.

Discussion: Other reviews:
Yeh 2014 13 studies (~800patients) all pain types SMD 1.58 Acute pain 4 studies good SMD 1.85.
Murakami 2016: 6 studies (~160patients) analgesia requirements reduced.

Conclusions: While study numbers are limited, ear acupuncture either as stand-alone or as-adjunct technique, significantly reduced pain scores and has potential benefits for use in the emergency setting. Further studies will define its role and whether it reduces use of analgesic medications.

Battlefield ear acupuncture: Can be used for all pain types. Indicated when adverse effects of standard therapy outweigh benefit and patient choice. Ear acupuncture use with caution in: pregnancy, bleeding tendency, immune suppression, heart valves and history fainting. Semi-permanent needles may cause ear infections. Sequence of 5 anatomical ear points with up to 10 needles. Stop upon patient request or pains score 1-2/10.
Battlefield Acupuncture - all pain types

1. Cingulate
2. Thalamus
3. Omega
4. Point zero
5. Shenmen

Alcohol prep the ear. Stop when pain score < 2 or when patient requests.

1. ASP GOLD needles are inserted into the auricular Cingulate Gyrus on both sides and tapes applied. NPRS taken
2. ASP GOLD are inserted in the Thalamus point on both sides and tapes applied. NPRS taken
3. ASP GOLD are inserted in the Omega point on both sides and tapes applied. NPRS taken
4. ASP GOLD are inserted in Point zero on both sides and tapes applied. NPRS taken
5. ASP GOLD are inserted into Shenmen on both sides and tapes applied.

Best to use ASP gold plated ear acupuncture needles

Contra-indications / Precautions: ear infection, pregnancy, anticoagulants, immune suppression. Remove needles in < 3 days.

References: Jan AL, Aldridge ES, Rogers IR, Visser EJ, Bulsara MK, Niemtzow RC. Does ear acupuncture have a role for pain relief in the emergency setting? A systematic review and meta-analysis. Medical acupuncture. 2017
Neck Pain

Local Points
Use laser or acupressure:
GV 14: inferior aspect of C7 dorsal spine, GV 15: B/W C1 and C2 dorsal spine, GV 16: B/W occiput and C1
Bladder: BL10 outside trapezius level C2
Huatojiaji: 0.5 cun lateral to midline
CTP: tender cervical transverse processes
KI 27: for anterior pain - B/W clavicle and 1st rib

Distal points
SI 3: for posterior midline pain - Vth mcp at end of distal palmar crease
LU 7: for anterior pain - 1.5 cun superior to wrist crease on radial side of radius
BL 60: for bladder channel pain - midpoint between achilles and lateral malleolus (P)
TE 5: for lateral pain: dorsal aspect forearm - 2 cun proximal to wrist crease
Ear: ‘cervical spine’ tender, posteroinferior aspect of anti-helix

References

Appendix 148
Knee pain

Contraindications: penetrate near or into prosthetic joint
Precautions: use skin prep when likely penetrating joint

Local:
SP 9: posterior border of tibia and inferior aspect of medial condyle (P)
SP 10: anteromedial aspect of thigh 2 cun above patella (P)
ST 35: in the depression, latero inferior to the patella (P)
ST 34: 2 cun above the lateral upper pole of patella
LR 8: joint margin (tibia), anterior to semimembranosis and tendinosus (P)
KI 10: joint margin, between semimembranosis and tendinosus
BL 39: medial aspect of biceps at joint line (P)
BL 40: mid aspect of popliteal crease (S or T - avoid vessels, nerves)
GB 34: in depression antero-inferior to head of fibula

Distal:
ST 44: proximal to web margin, 2nd and 3rd toes (P)
LR 3: midpoint between 1st and 2nd metatarsals (P)
SP 6: 3 cun above medial malleolus, posterior border tibia (P)
BL 60: midpoint between achilles and lateral malleolus (P)
Ear Knee: tender point - superior crura of antihelix

Reference: Camp V. Acupuncture of the knee. Acupuncture in Medicine. 1992 Nov 1,10(2) 57-62

Appendix 149
Local Points
GB 31: mid point TFL when arm by side - tip of middle finger.
GB 30: 2/3 distance from sacral hiatus to greater trochanter
GB 29: mid point ASIS to greater trochanter
BL 54: 3 cun from midline level of S4

Distal Points
GB 34: fibula anterior asoect junction of head and neck
GB 41: b/w 4th and 5th mt proximally
BL 36 Midpoint of gluteal fold.
BL 60: b/w achilles and lateral malleolus
Ear: tender point at apex of the triangula fossa

References:
Lower back pain

Local points:
Midline points: GV 4: b/w L 2 & L 3, GV 3: b/w L4/L5 (P)
Huatoujiaji: 0.5 cun lateral to midline: (P)
Inner bladder channel 1.5 cun: BL 23 L2/L3, BL 24 L3/4 BL 26 L5/S1 (P)
Outer bladder channel 3 cun: BL 53: S2 foramina, BL 54: S4 foramina
GB 30: outer 1/3 sacral hiatus to greater trochanter (GT) (P)
GB 29: midpoint ASIS to GT

Distal points:
BL 40: mid aspect of popliteal crease (S or T - avoid vessels, nerves)
GB 34: in depression antero-inferior to head of fibula
BL 60: midpoint between achilles and lateral malleolus (P)
Ear L spine: tender, crus of antihelix in triangular fossa.

References: Qaseem A, Wilt TJ, McLean RM, Forciea MA. Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the American College of Physicians. Annals of internal medi-
Headaches

**Local points:**
- ST8: 0.5 cun superior corner head (T)
- GB8: 1.5 cun superior to apex of ear (T)
- BL2: Medial end of eyebrow (P)
- GB14: 1.0 cun superior middle eyebrow (T)
- TE23: Outer aspect of eyebrow (T)
- GB20: Depression between SCM and trapezius (O tip of nose)

**Distal points:**
- LR3: Between 1st and 2nd metatarsals (P)
- LI4: Between 1st and 2nd metacarpals (P)
- TE5: 2 cun proximal dorsal wrist crease (P)
- GB41: Between 4th and 5th metatarsals lateral to extensor tendon (P)
- BL62: Between lateral malleolus and calcaneus (P)

**Nausea / Vomiting:** PC6: 2 cun proximal to wrist crease b/w FCR and PL (?T)

**References:**
Shoulder pain

Local Points
LI 14: antero-distal insertion of deltoid
LI 15: anterior depression (arm abducted) b/w acromion and greater tubercle of humerus
TE 14: posterior depression b/w acromion and greater tubercle of humerus
SI 9: 1 cun superior to posterior axillary crease, posterior to deltoid
SI 11: over the large inferior blade of the scapula - 1/3 distance from scapular spine to inferior angle
CTPs (acupressure or laser only)

Distal points:
TE 5: 2 cun proximal to wrist crease on mid dorsal aspect
LI 4: mid point of 2nd MC on radial side
GB 34: anterior to the neck of the junction of head and neck of fibula
Ear shoulder: distal antihelix tender point

Ten important distal points in pain!

- LI 4
- LU 7
- ST 36
- SP 6
- ST 44 (pelvis and abdomen)
- PC 6
- BL 40
- TE 5
- SI 3
- LR 3

**Face and neck anterior:** LI 4: 0 radial side 2nd MC

**Front of chest:** LU 7, proximal radial styloid laterally

**Abdomen:** PC 6 b/w palmaris longus and FCR, 2 cun from wrist crease. ST 36: 3 cun distal to latero-inferior border of patella.

**Pelvis:** SP 6: 3 cun from medial malleolus opposite medial border of tibia

**Back of neck and upper thoracic:** SI 3: palmar crease adjacent to 5th MC neck.

**Lateral aspect of head and shoulder:** TE 5: 2 cun dorsum of forearm from wrist crease

**Pelvis and abdomen anteriorly:** ST 44: proximal web space dorsally b/w 2nd and 3rd toes.

**Face, eyes, chest and pelvis anteriorly:** LR 3 b/w 1st and 2nd MT
### Feedback Questionnaire: ED introductory acupuncture course

**ED /critical care / retrieval: Drs X 9, ED Nurses X 2 – Total 11 attendees**

Please rate your experience of learning for the following sections:

<table>
<thead>
<tr>
<th>Section</th>
<th>Slightly satisfied</th>
<th>Satisfied</th>
<th>Very Satisfied</th>
<th>No response</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-course video lectures</td>
<td>1</td>
<td>4</td>
<td>6</td>
<td></td>
<td>Good theory content; excellent distribution of lectures and hands on; would be good to give overview of meridians in summary lecture</td>
</tr>
<tr>
<td>Summary presentations delivered on the day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Battlefield acupuncture with introduction to neck pain</td>
<td></td>
<td>4</td>
<td>6</td>
<td>1</td>
<td>Would have been more informative over 7 hours with greater emphasis on practice; more time for hands on; need more practical time; too much content for time allocated; would like more time to practice locating and needling points; needs more workshops and communication; excellent distribution of lectures and hands on; useful tools given; appropriate hours; would be great to have demonstration of non-invasive seeds and laser; too short; agree whole day would be ideal.</td>
</tr>
<tr>
<td>Knee pain and introduction to hip pain</td>
<td>1</td>
<td>6</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Back pain and introduction to headaches and shoulder pain</td>
<td>1</td>
<td>6</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Administration, handouts, venue</td>
<td></td>
<td>4</td>
<td>7</td>
<td></td>
<td>Venue was great; good group size, great take home pack; useful tools given; would love to know ‘next steps’ part – how to train to a minimum standard (not expert)? where to get stuff?</td>
</tr>
</tbody>
</table>

**Other comments:** Well-rounded introduction to acupuncture – has made me want to learn more; thank you; good course; valiant effort in condensing a huge body of information into a short summary relevant to ED including some hands on practice; great introduction; will definitely start using again; amazing; great workshops; excellent...
Feedback faculty Questionnaire: ED introductory acupuncture course ACEM 35 Perth 17.11.193 FACEM acupuncturists, 1 TCM practitioner (note 1 FACEM acupuncturist contributed to workshop development only and hence did not comment on workshop day)

Please rate your experience of teaching for the following sections:

<table>
<thead>
<tr>
<th>Section</th>
<th>Satisfied</th>
<th>Very Satisfied</th>
<th>No response</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-course video lectures</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>One faculty member didn’t finish prior.</td>
</tr>
<tr>
<td>Summary presentations delivered on the day</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>Went smoothly and according to time</td>
</tr>
<tr>
<td>Battlefield acupuncture with introduction to neck pain</td>
<td>3</td>
<td>1</td>
<td></td>
<td>Students enjoyed this “one method fixes all’ approach; Participants seemed happy to try BFA however post workshop. This in part was facilitated by the take home silicon ears with acupoints ready marked; main improvements include additional time to practice needling</td>
</tr>
<tr>
<td>Knee pain and introduction to hip pain</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>Faculty member (TCM) appeared a bit awkward with presenting; more time to deliver and explain the material; main improvements include additional time to practice needling; I have some concerns with Chinese trained acupuncturists presenting. Whilst I sympathize with their perspective and the fact that most medical practitioners have little idea regarding their skills and abilities. What this often generates in them is a need to justify and a frustration at medical ignorance and mis practice. I find this expression counterproductive and not ideal in an educative setting. I’m conscious our Chinese medical colleagues have a lot of skill and experience but I’m yet to come across one that doesn’t have this “chip” on their shoulder. In reality their understanding of “western” medicine is very poor, and their communication of diagnosis is inaccurate and reflects poorly on them and any course they are teaching; Agree that more time required for emergency doctors to be competent and safe in body acupuncture and another 16 hours of hands on is a reasonable guestimate.</td>
</tr>
<tr>
<td>Back pain and introduction to headaches and shoulder pain</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>Well delivered; main improvements include additional time to practice needling; agree that more time required for emergency doctors to be competent and safe in body acupuncture and another 16 hours of hands on is a reasonable guestimate.</td>
</tr>
<tr>
<td>Administration, handouts, venue</td>
<td>3</td>
<td>1</td>
<td></td>
<td>Supportive conference organisers, great having extra volunteer, food great, good IT support, great got reimbursed for consumables</td>
</tr>
</tbody>
</table>

Further Comments including changes for future courses:

The course was well organized with adequate material provided: I presume it went well as there was such positive feedback! Now that we know there is interest, we should continue the workshops.
Appendix to Chapter 5 - Section B

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Karen Ballen
Manager, Reprints/ePrints, Permissions, and Liebert Open Access
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To: Yael Benporat <-

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Michelle

Michelle Head  
Journal Publishing Manager

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Appendix to Chapter 5 - Section C

Conference abstract and presentation:

and satisfaction with wound cosmesis, post-ED pain management, advice on wound care and follow-up, and overall management. A six-item satisfaction scale (very dissatisfied to very satisfied) was employed.

**Results:** Complete data were obtained on 84 participants. The numbers (%) of patients very satisfied with aspects of their management were: cosmetic appearance 46 (54.8%), post-ED pain management 52 (62.7%), wound care advice 48 (57.1%), follow-up advice 38 (45.2%) and overall management 58 (69%). Infection, dehiscence and untied sutures occurred in 3 (3.6%), 7 (8.3%) and 7 (8.3%) cases, respectively. These complications were not associated with being very satisfied overall (P = 0.83).

Being very satisfied with wound cosmesis, post-ED pain management, wound care advice and follow-up advice were each significantly associated with being very satisfied overall (P < 0.001). Older age and a longer laceration length were associated with being very satisfied with cosmesis (P = 0.03 and P < 0.01, respectively).

**Conclusion:** Most patients are very satisfied with their laceration management. However, there is scope for improvement, especially in the areas of follow-up and wound care advice. Complications are infrequent and not associated with overall satisfaction.

**Teaching, trials and tribulations in utilising acupuncture for emergency department analgesia: Ready to go?**

A Jan

St John of God Murdoch/Notre Dame University, Murdoch, Australia

**Background:** There is increased evidence for, along with provider interest in the use of acupuncture analgesia in ED.1–3 This interest is enhanced by the current opioid crisis.4 A prior survey showed a majority (69%) of ED patients’ willingness to use acupuncture analgesia.5 Workshops on acupuncture for emergency doctors are uncommon and no minimum training standards currently exist.6

**Objectives:** To evaluate the obstacles, quality and success of ED acupuncture courses and make recommendations regarding course content and minimum training standards.

**Methods:** Two blended courses were provided. The first was a 4-h course (with an extra 4-h on-line) on body and

---

**TABLE 1** Training standards, using the title ‘acupuncturist’ and related Medicare benefits

<table>
<thead>
<tr>
<th>Standards</th>
<th>Medicare Item Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical practitioners can perform acupuncture (or ‘dry needling’) with minimum training (no minimum training requirement).</td>
<td>173</td>
</tr>
<tr>
<td>However, given the above point, an untrained medical practitioner could be considered irresponsible if an adverse event occurred secondary to acupuncture if performing acupuncture without a recognised (currently no standard) basic course. The medical board, medical insurers and host institution would be critical of a doctor carrying out procedures for which they are untrained.</td>
<td></td>
</tr>
<tr>
<td>Registered medical practitioners can charge Medicare item number 173 without any acupuncture qualifications.7</td>
<td></td>
</tr>
<tr>
<td>The title ‘Acupuncturist’ can only be used if endorsed by Medical Board of Australia.8 Current qualifications endorsed are the Australian Medical Acupuncture College (AMAC) first part (260 h) or full fellowship AMAC (~ further 280 h) or certified by the Chinese Medicine Board.</td>
<td></td>
</tr>
<tr>
<td>The World Health Organisation recommends 200 h of training before a medical practitioner is competent to perform acupuncture.9</td>
<td></td>
</tr>
<tr>
<td>Vocationally Registered General Practitioner and other similarly qualified ‘Acupuncturists’ can use Medicare item numbers which include consultations of various complexity: 193, 195, 197 and 199.7 No such schedule exists for specialists who are also ‘Acupuncturists’ - who cannot charge for acupuncture time with a consultation. Hospitals and emergency departments may have their own specific minimal training requirements for acupuncture however most have no written formal recommendations / guidelines. Some hospitals now require full AMAC fellowship for accreditation. Physiotherapists require 16 h (12 h face to face) as minimum training before western acupuncture or dry needling can be practiced.6,10</td>
<td></td>
</tr>
</tbody>
</table>
Battlefield (ear) acupuncture (BFA) at the Emergency Medicine 35th Scientific Meeting. The second 2-h course (with 2-h extra-online) was held at the trial site for ED staff applying BFA alone. Course quality was evaluated via Likert survey. Thematic analysis of comments from faculty and participants was performed. (See Figure 1).

Results: Participants and faculty rated courses highly. However consistent feedback requested more training hours for body acupuncture but not so for BFA. Obstacles largely of a political nature were encountered in the development of workshops.

Conclusion: ED physicians and staff are keen to embrace acupuncture for pain relief. Further support from the Australian medical acupuncture (AMAC) and emergency medicine colleges (ACEM) is needed. This could be through formation of a ‘special interest group’ within ACEM. It is suggested that the minimum training time for ED Doctors performing body acupuncture be 16-h (similar to physiotherapists), however 4-h is sufficient for BFA competency alone.

References
Teaching, trials and tribulations in utilising acupuncture for ED analgesia - ready to go?

Andrew Jan
Adjunct Professor University of Notre Dame Emergency Physician Medical Acupuncturist

disclosures

Appendix 164
Background

• Rising opioid deaths and adverse effects
• Acupuncture a novel solution
• Systematic review all forms of ED acupuncture
• Systematic review ED ear acupuncture
• Patient survey
• Teaching ED acupuncture
• Recently completed ED ear acupuncture trial
• Protocol for a larger randomized multi-centred trial

Is analgesia in the ED helping our patients or killing them?
Global Views

Acupuncture's Role in Solving the Opioid Epidemic: Evidence, Cost-Effectiveness, and Care Availability for Acupuncture as a Primary, Non-Pharmacologic Method for Pain Relief and Management—White Paper 2017

Arthur Yin Fan a, David W. Miller b, c, d, e, f, Bonnie Bolash g, Matthew Bauer g, h, John McDonald g, h, Sarah
Review article: Does acupuncture have a role in providing analgesia in the emergency setting? A systematic review and meta-analysis

Andrew L Jan, Emogene S Aldridge, Ian R Rogers, Eric J Visser, Max K Bulsara, Richard C Niemtzow


Yes, Ear Acupuncture Have a Role for Pain Relief in the Emergency Setting? A Systematic Review and Meta-Analysis

Andrew L. Jan, MBBS, FACEM, BA, FAMAC, MPhil,1,2 Emogene S. Aldridge, BHlthSc,1 Ian R. Rogers, MBBS, FACEM,1,2 Eric J. Visser, MBBS, FANZCA, FFPMANZCA,3 Max K. Bulsara, PhD, MSc, BSc,4 and Richard C. Niemtzow, MD, PhD, MPH5,6
Acupuncture for analgesia in the emergency department: a multicentre, randomised, equivalence and non-inferiority trial

Marc M Cohen, De Villiers Smit, Nick Anthiapolivou, Michael Ben-Meir, David McD Taylor, Shefton J Parker, Chalie C Xue and Peter A Cameron
Published online: 19 June 2017

Conclusion: The effectiveness of acupuncture in providing acute analgesia for patients with back pain and ankle sprain was comparable with that of pharmacotherapy. Acupuncture is a safe and acceptable form of analgesia, but none of the examined therapies provided optimal acute analgesia. More effective options are needed.

Utilization of Acupuncture Services in the Emergency Department Setting: A Quality Improvement Study

John R. Burns, DPT, MSOM,1 Jessica J. F. Kram, MPH,2,3 Vashir Xong, MSOM, LAc,4 Jeanne M.

Primary care management of non-specific low back pain: key messages from recent clinical guidelines

Matheus Almeida, Bruno Saragiotto, Bethan Richards, Chris G Maher

Battlefield acupuncture to treat low back pain in the emergency department

Lindsey M. Fox, MD,2,4,5 Mikiko Murakami, DO,1,2,4,5,6 Houman Danesh, MD,2,4,5,6, Alex F. Masiini, MD, MS

Acupuncture versus titrated morphine in acute renal colic: a randomized controlled trial

Journal of Pain Research
Our survey showed a majority (69%) of ED patients were willing to use acupuncture analgesia. Opioids failed to show a relationship to patient satisfaction.
Who is going to perform acupuncture in the ED?

- Two FACEM FAMAC (one retired from ED)
- ~10 with their 1st part FAMAC
- ED physicians suited
- NP’s? Nurses ??? BFA ? Physiotherapists?
- TCM / Medical acupuncturists part time
- Depends on department and collective openness to acupuncture / presence of a champion

Where do ED workers get trained?

- AMAC
- Workshops on acupuncture specifically for emergency doctors are uncommon. Do we create a specific course for them as we did last year?
- Overseas courses eg UK
- Many “dry needling courses”
- Chinese 3-month intensive courses
- TCM training
- BFA courses
Minimum training standards

• Battlefield acupuncture 4 hours
• Physiotherapists 16 hours with annual updates
• Nurses (Dry needling 80 hours)
• Massage therapists (Dry needling 80 hours)
• Chiropractors ~ 16 hours
• Osteopaths ~ 16 hours
• First part AMAC - 260 hours
• Second part another 280 hours

Course - What we taught

• Contribute 4 hours online and 4 hours face to face ED acupuncture training
• Produce a quality basic acupuncture course for ED Physicians that is evidence-based; ensures safety; and easy to learn prescriptions.
Course based on modern mixed teaching methods - how we taught!

- Quality courses are those utilise andragogical principles
- Has constructive alignment with learning objectives, assessment and outcome measures.
- Utilises modern proven methods eg simulation, hands on, discussion, videos, Peyton’s four method.
Developed a manual

- Manual that can be kept on mobile phone for immediate access in ED
- Point anatomy and simple prescriptions for pain syndromes where evidence exists
- Dangerous points
- Pregnancy
- Safety

<table>
<thead>
<tr>
<th>Group</th>
<th>Rating</th>
<th>Likert Score</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants n=11 (doctors, nurses) attending conference course</td>
<td>Average rating all thematic sections</td>
<td>5.5/6.0</td>
<td>8/11 attendees wanted more course hours</td>
</tr>
<tr>
<td></td>
<td>Average rating on-line course</td>
<td>5.5/6.0</td>
<td>2/11 positives on theory content</td>
</tr>
<tr>
<td></td>
<td>Average rating course lectures</td>
<td>5.6/6.0</td>
<td>1/11 wanted more information on meridians</td>
</tr>
<tr>
<td></td>
<td>Average rating Hands on practical skills</td>
<td>5.4/6.0</td>
<td>4/11 wanted more specific hands on practice, BFA rated highest satisfaction (5.6/6.0)</td>
</tr>
<tr>
<td>Faculty n=3 (FACEM X 2, TCM practitioner) providing conference course</td>
<td>Average rating all thematic sections</td>
<td>5.7/6.0</td>
<td>2/3 difficulties with TCM teacher</td>
</tr>
<tr>
<td></td>
<td>Average rating on-line course</td>
<td>5.7/6.0</td>
<td>1/3 One faculty member didn’t finish prior.</td>
</tr>
<tr>
<td></td>
<td>Average rating course lectures</td>
<td>5.7/6.0</td>
<td>1/3 Went smoothly and according to time</td>
</tr>
<tr>
<td></td>
<td>Average rating Hands on practical skills</td>
<td>5.7/6.0</td>
<td>BFA rated high 6.0/6.0. 1/11 “liked BFA with one method fixes all”; 1/11 liked take home silicon ear; 1/11 more time for practical skills needed; 2/11 some difficulties with TCM faculty member</td>
</tr>
<tr>
<td></td>
<td>Average rating take home manual, venue, administration</td>
<td>6.0/6.0</td>
<td>positives for organisers, venue, volunteer and IT.</td>
</tr>
<tr>
<td>Participants attending trial course n=12 (nurse X 2, Nurse practitioner x 2, doctors x 8)</td>
<td>Average rating all thematic sections</td>
<td>5.7/6.0</td>
<td>no attendees wanted more course hours</td>
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<tr>
<td></td>
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<td>2/12 good learning tools and videos</td>
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<td></td>
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<td>2/12 wanted more BFA theory</td>
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<td>Average rating Hands on BFA practical skills</td>
<td>5.9/6.0</td>
<td>4/12 positive comments on simulation and practice on each other</td>
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</table>
Where to from here? / Conclusion

• Some urgency given opioid crisis?
• More research?
• More courses? Wait?
• Large departments have more choices: Medical acupunctureist / TCM practitioner /Physiotherapists on staff - Fast track area
• Smaller departments: minimum training standards TBC
• ACEM / AMAC cooperation: Specialist Interest Group ACEM
Questions

• Hands up - Acupuncture ready to become a standard skill set that ED physicians should learn?
• Hands up wait for further research?
• Who thinks 16 hours is enough?
• Hands up - think 1st part FAMAC is appropriate?
• Anyone interested in special interest group - see me around

Contact me down under and over

drandrewjan@gmail.com
www.drandrewjan.com.au
Submitted ‘Letter to the editor’ – under review:

To the Editor,

We read with great interest the first systematic review and meta-analysis on Battlefield (ear) acupuncture (BFA) for pain management by Yang and colleagues (The American Journal of Chinese Medicine, Vol. 49, No. 1, 1-16). We recently published two papers on BFA. In our randomized controlled trial (RCT), BFA added no benefit as an adjunct analgesic in the first two hours (Jan et al., 2020). In the teaching BFA review, nine BFA RCTs were identified, of which six had positive primary analgesic outcomes while eight showed pain score reduction at 24 hours (or under) compared to control (Jan, 2020). Hence, we were eager to see the results of this meta-analysis. Yang’s review provided a good description of the rationale prompting BFA research, the characteristics and adverse effects of included studies, and bias assessment of the RCTs in the meta-analysis.

It was disappointing that of the seven acute pain RCTs that Yang deemed eligible on BFA for acute pain, only three were included in their meta-analysis. The seven acute pain RCTs used an array of time periods (minutes to a month) and presentation of the results, making the collation and synthesis of data difficult. It is unclear from the methodology and data extracted, what time periods were to be included in this meta-analysis for acute pain.

Unfortunately, the data from two of the three RCTs included in Yang’s meta-analysis are incorrect. The study by Goertz et al. presented their data as ‘pain score differences’, while Kim et al. reported theirs as the ‘days to 50% pain score reduction’ (Goertz et al., 2006; Kim et al., 2019). Both were misinterpreted by the authors as ‘mean pain scores post-intervention’, resulting in erroneous ‘mean differences’. In the third study by Crawford et al., the authors extracted a pain score from the one-month measure (Crawford et al., 2019).

Since only three studies were included in the meta-analysis on acute pain, with two of these using incorrect data and the third using a one-month time measure, the authors' conclusion regarding acute pain BFA analgesic efficacy requires reconsideration.
Yang’s paper should provide the impetus for further BFA RCTs and a repeat systematic review. As the authors succinctly recommend, the need for non-pharmacological analgesic methods such as acupuncture that can reduce pain while decreasing opioid utilization is of paramount importance. Along with this recommendation comes the necessity for high-quality RCTs and systematic reviews to justify BFA and traditional acupuncture analgesia. Systematic reviews ideally should use statisticians to assist with data interpretation and analyses, be preregistered on a database such as the International Prospective Register of Systematic Reviews (PROSPERO), abide by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, and subject their studies to such tools as the Assessment of Multiple Systematic Reviews (AMSTAR) checklist before the protocol and manuscript are published. There is now software available (Covidence - not-for-profit: Melbourne, Australia) to assist researchers with the demands of producing a high-quality systematic review.

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University of Notre Dame  
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**Eric Visser**, MBBS FANZCA FFPMANZCA  
Professor/Churack Chair of Chronic Pain Education and Research  
University of Notre Dame  
Fremantle, Western Australia

**Dana Hince**  
Biostatistician  
Institute for Health Research  
University of Notre Dame  
Fremantle, Western Australia

**References**


Appendix to Chapter 6 - Section A

Preregistered protocol, Supplementary material to publication, Trial website, Ethics approval, Patient advice sheet, Patient consent, Trial flyer and BFA competency test:

Register a trial

Acknowledgment
Step 1: Titles & IDs
Step 2: Health condition
Step 3: Intervention/exposure
Step 4: Outcomes
Step 5: Eligibility
Step 6: Study design
Step 7: Recruitment
Step 8: Funding & Sponsors
Step 9: Ethics & Summary
Step 10: Contacts
Step 11: Data sharing statement
Step 12: Summary Results
Review & Submit

Request number 375725
Current page Review

Trial registered on ANZCTR

Registration number ACTRN12619000051145
Ethics application status Approved
Date submitted 8/01/2019
Date registered 15/01/2019
Date data sharing statement initially provided 15/01/2019
Type of registration Prospectively registered

Titles & IDs
Public title Battle Field (Ear) Acupuncture as an adjunct to treat pain of the abdomen, limb trauma and lower back in the emergency department - a pilot study.
Scientific title Battle Field (Ear) Acupuncture as an adjunct to treat pain of the abdomen, limb trauma and lower back in the emergency department - a pilot study.
Secondary ID [1] Nil known
Universal Trial Number (UTN) U1111-1218-5037
Trial acronym EDEA
Linked study record Nil

Health condition
Health condition(s) or problem(s) studied:
abdominal pain
limb trauma pain
low back pain

Condition category Emergency medicine Anaesthesiology
Condition code Other emergency care Pain management

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=375725&isClinicalTrial=False
**Intervention/exposure**

**Study type**

Interventional

**Description of intervention(s) / exposure**

**Arm 1**
Ten ASP (Aigulite Acupuncture semi-Permanent) gold needles inserted according to the Battlefield ear acupuncture protocol (6 needles each ear i.e. cingulate gyrus, thalamus, omega, point zero and Shenmen), needles concealed with 10 DuoDerm tapes and then also receive standard analgesia care (see below).

Acupuncture practitioners will be usual health care providers i.e. non-acupuncturists (emergency doctors, nurse practitioners, registered nurses) trained by the principal investigator (a registered medical acupuncturist).


Note: Duoderm tapes are cut into approximately 1cm squares with a central mark to obscure needle. Product information on extra thin Duoderm dressings can be obtained from:

**Arm 2**
The second arm or sham group will have a piezoelectric device (Pulsar Plus Piezo Stimulator) sounded adjacent (1-2cm) to but not onto the ear. Normally the piezo stimulator generates a single electric impulse by compressing and releasing pressure on a piezo crystal inside the stimulator. However, because it is only activated in the air away from the patient, no electric current enters the patient and the only perceived intervention is a clicking sound - hence used as our sham device. 10 DuoDerm tapes will be applied similarly to the needle intervention arm and then will also receive standard analgesia care (see below).

Product information on the Pulsar Plus Piezo Stimulator can be obtained from:

**Arm 3**
The third arm is the standard analgesia care group alone. This group will have standard analgesia care and 10 DuoDerm tapes also applied. Standard usual analgesic care consists of:

Patients with a NPRS-10 greater or equal to 4 and less than or equal to 7 will receive paracetamol 1g orally / intravenously and Ibuprofen 400-800mg orally or Ketorolac 10mg intravenously / 15mg intramuscularly pending last dose of relevant / same analgesic.

Rescue medication is oral / under the tongue opioid after 30 minutes’ post triage: Oxycodone 5-10mg orally. Buprenorphine 200-400mg under the tongue or Tapentadol IR 50 - 100mg orally. Antiemetic if nauseated

Patients with a NPRS-10 > 7 will receive above regime for paracetamol / non-steroidal anti-inflammatory and rapid acting opioid: Fentanyl 1.5mcg/Kg/dose intranasally – max 2 doses or intravenously, Fentanyl 25mcg boluses to 100mcg total intravenously or Morphine 1-2.5mg boluses to 10mg total intravenously.

Further rescue doses of Fentanyl intravenously, Morphine intravenously and Oxycodone 5-10mg orally. Antiemetic if nauseated

The expected duration of application of the ear needles per patient is approximately 4 minutes. This application time is a secondary outcome. Needles will remain in situ for 2 hours and then removed.

**Update**

**Arm 1**
Ten ASP (Aigulite Acupuncture semi-Permanent) gold needles inserted according to the Battlefield ear acupuncture protocol (6 needles each ear i.e. cingulate gyrus, thalamus, omega, point zero and Shenmen), needles concealed with 10 DuoDerm tapes and then also receive standard analgesia care (see below).

Acupuncture practitioners will be usual health care providers i.e. non-acupuncturists (emergency doctors, nurse practitioners, registered nurses) trained by the principal investigator (a registered medical acupuncturist).


Note: Duoderm tapes are cut into approximately 1cm squares with a central mark to obscure needle. Product information on extra thin Duoderm dressings can be obtained from:

**Arm 2**
The second arm or sham group will have a piezoelectric device (Pulsar Plus Piezo Stimulator) sounded adjacent (1-2cm) to but not onto the ear. Normally the piezo stimulator generates a single electric impulse by compressing and releasing pressure on a piezo crystal inside the stimulator. However, because it is only activated in the air away from the patient, no electric current enters the patient and the only perceived intervention is a clicking sound - hence used as our sham device. 10 DuoDerm tapes will be applied similarly to the needle intervention arm and then will also receive standard analgesia care (see below).

Product information on the Pulsar Plus Piezo Stimulator can be obtained from:

**Arm 3**
The third arm is the standard analgesia care group alone. This group will have standard analgesia care and 10 DuoDerm tapes also applied. Standard usual analgesic care consists of:

Patients with a NPRS-10 greater or equal to 4 and less than or equal to 7 will receive paracetamol 1g orally / intravenously and Ibuprofen 400-800mg orally or Ketorolac 10mg intravenously / 15mg intramuscularly pending last dose of relevant / same analgesic.
Rescue medication is oral / under the tongue opioid after 30 minutes’ post triage: Oxycodone 5-10mg orally, Buprenorphine 200-400mcg under the tongue or Tapentadol IR 50 – 100mg orally. Antiemetic if nauseated

Patients with a NPRS-10 > 7 will receive above regime for paracetamol / non-steroidal anti-inflammatory and rapid acting opioid: Fentanyl 1.5mcg/Kg/dose intranasally – max 2 doses or intravenously, Fentanyl 25mcg boluses to 100mcg total intravenously or Morphine 1-2.5mg boluses to 10mg total intravenously. Further rescue doses of Fentanyl intravenously, Morphine intravenously and Oxycodone 5-10mg orally. Antiemetic if nauseated

The expected duration of application of the ear needles per patient is approximately 4 minutes. This application time is a secondary outcome. Needles will remain in situ for 2 hours and then removed.

Reason
Typographical error i.e. Buprenorphine 200-400 mcg (not mg!) Change (16.1.19) prior to trial and recruitment start date.

Intervention code [1]
Treatment: Other

Comparator / control treatment
Arm 2
The Sham group will have the Piezoelectric device sounded adjacent to but not onto the ear. 10 DuoDerm tapes will be applied similarly to the intervention arm. Then standard analgesia care will be administered.

Arm 3
This is the standard analgesia care group alone. This group will have standard analgesia care and 10 DuoDerm tapes also applied.

Control group
Placebo

Outcomes

Primary outcome [1]
The mean numerical pain rating scale out of 10 (NPRS-10) at rest for the three groups will be compared.

Timepoint [1]
Triage, Post tapes (i.e. immediately post intervention /sham /tapes only for SAC), 1 and 2 hours post-intervention.

Secondary outcome [1]
Percentage of group with ‘adequate analgesia’ (a decrease in the NPRS-10 is defined as that which decreases the triage pain score by greater than or equal to 2 and to a level less than 4).

Timepoint [1]
Post tapes (i.e. immediately post intervention /sham /tapes only for SAC), 1 and 2 hours post-intervention.

Secondary outcome [2]
Number needed to treat (NNT) to obtain a 30% drop in NPRS-10 from baseline compared to sham

Timepoint [2]
Post tapes (i.e. immediately post intervention /sham /tapes only for SAC), 1 and 2 hours post-intervention.

Secondary outcome [3]
Patient satisfaction using a six-point Likert scale.

Timepoint [3]
2 hours post-intervention

Secondary outcome [4]
Total oral morphine equivalent opioid dose (milligrams) in 2 hours from intervention. Total opioids administered within the 2-hour frame from intervention obtained retrospectively (post attendance) from the patient’s drug chart (hospital record) and will be calculated by converting the dosage of the various administered opioids in that 2 hour time frame to a oral morphine dose (milligrams) equivalent. The Faculty of Pain Medicine ANZCA opioid dose converter which is an evidence-based and authoritative opioid conversion application will be used i.e. http://www.opioidcalculator.com.au/

Timepoint [4]
2 hours post-intervention

Secondary outcome [5]
Adverse effects using a spontaneous (unsolicited) reporting method will be collected using a non-structured open-ended question for either intervention (acupuncture or sham) or pharmacological analgesia.


Timepoint [5]
2 hours post-intervention

Secondary outcome [6]
Time taken to apply ear acupuncture or sham using a stopwatch

Timepoint [6]
post triage

Secondary outcome [7]
Costings: Will include prices (AUD) of analgesics and needles used. Analgesics used during the 2-hour time period will be obtained from the medical record and prices calculated from analgesia imprest costs provided by the private pharmacy supplier for the ED. Acupuncture needle costs (fixed at 10 needles per patient) will be obtained from the private acupuncture supplier.

Timepoint [7]
2 hours post-intervention

Eligibility

Key inclusion criteria
Patients attending the emergency department with acute pain (a NPRS-10 greater than or equal to 4 at rest) of the: lower back, abdominal condition, or limb trauma, triage categories 3-5

Minimum age
18 Years

Maximum age
80 Years

Gender
Both males and females

Appendix 185
Can healthy volunteers participate? No

Key exclusion criteria
- Triage category 1 or 2
- Unable to comprehend consent due to a barrier in language (eg failure to access a quality translator) or cognition
- Immediate medical intervention required
- Pregnant
- Chronic pain (defined as on opioids and or pain is greater than 6 weeks’ duration)
- Chest pain
- Immune deficiency
- On anticoagulants such as warfarin, novel anticoagulants e.g. apixaban, dabigatran, rivaroxaban and anti-platelet agents clopidogrel, ticagrelor and prasugrel. Those on aspirin however, can be included.
- Artificial heart valve
- Permanent pacemaker
- Needle phobia
- Allergy to gold or tapes
- Known blood borne pathogen eg HIV, Hep C and Hep B antigen positive.
- Recent ear infection or trauma
- Deafness or uses hearing aids

Study design

Purpose of the study
Treatment

Allocation to intervention
Randomised controlled trial

Procedure for enrolling a subject and allocating the treatment (allocation concealment procedures)
The randomisation will be allocated prior to the trial with opaque sealed envelopes placed in a draw on site and opened post consent to enter the trial. The envelopes will be marked: low back pain 1-30, abdominal pain 1-30 and limb trauma pain 1-30.

Methods used to generate the sequence in which subjects will be randomised (sequence generation)
Ninety patients (30 from each pain condition) will be randomly allocated to one of the three treatment arms, such that each treatment arm comprises 10 patients from each pain condition, using a block size of six. The randomisation sequence will be determined using Stata (15.0 StataCorp™, College Station, TX, USA) by a statistician not involved in treatment allocation or data collection. Patients will only be invited to participate into the trial when a trained investigator is available.

Masking / blinding
Blinded (masking used)

Who is / are masked / blinded?
The people assessing the outcomes
The people analysing the results/data

Intervention assignment
Parallel

Other design features
Not Applicable

Phase

Type of endpoint(s)
Efficacy

Statistical methods / analysis
Data analysis will consist of using the independent Student’s t-test for continuous data and Chi-square for categorical data using the Stata software program. The continuous variables include: NPRS-10, morphine dose equivalent (mg).

Categorical variables will be used to compare the differences in proportions for demographics of the three treatment arms including sex, medical condition and age group. Non-parametric tests such as the Kruskall Wallis will be used to confirm results from the t test in case there is a violation of the normality assumption. Generalised Linear mixed models will be used to analyse NPRS-10s controlling for confounding variables such as time. Both parametric and non-parametric analysis will be performed on the satisfaction scores (six-point Likert scale). Costing will include prices of consumables and medications. Needling time will be compared to an approximated time taken for administration of opioids approximated from a prior audit. Data analysis will be blinded and using ‘intention to treat’ to avoid bias from any dropouts.

Recruitment

Recruitment status Not yet recruiting

Date of first participant enrolment
Anticipated 18/01/2019
Actual

Date of last participant enrolment
Anticipated 19/01/2020
Actual

Date of last data collection
Anticipated 19/01/2020
Actual

Appendix 186
https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=375725&isClinicalTrial=False
### Sample size

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**Recruitment in Australia**

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### Funding & Sponsors

**Funding source category [1]**

| Charities/Societies/Foundations |

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| Address [1] | 12 Kings Park Road West Perth WA 6005 | PO Box 508, West Perth WA 6872 |
|-------------|---------------------------------------|

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**Primary sponsor type**

| University |

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<th>Name [1]</th>
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| Address | School of Medicine  
The University of Notre Dame Australia  
PO Box 1225  
Fremantle WA 6959 |
|---------|---------------------------------------------|

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**Secondary sponsor category [1]**

| Hospital |

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| Address | St John of God Murdoch Hospital  
1 Barry Marshall Pde  
Murdoch WA 6150 |
|---------|-----------------------------|

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### Ethics approval

**Ethics application status**

| Approved |

**Ethics committee name [1]**

| SJGHC Human Research Ethics Committee |

**Ethics committee address [1]**

| C/O Suite H203, Level 2  
St John of God Subiaco Hospital  
12 Salvado Rd  
SUBIACO WA 6008 |
|--------------------------|

<table>
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### Summary

**Brief summary**

The primary objective is to test the efficacy and feasibility of Battlefield (ear) acupuncture (BFA) as an adjunct to standard analgesia care performed by usual Emergency Department health care providers. Secondary objectives include acupuncture application time, and changes in: opioid usage, costs, adverse events, and patient satisfaction. It is anticipated that ear acupuncture will be an effective add on to simple analgesia that reduces usage of opioid analgesia and improves patient satisfaction.

**Trial website**

www.edetrial.com.au

**Trial related presentations / publications**


**Public notes**


Appendix 187
Jan AL, Aldridge ES, Rogers IR, Visser EJ, Bulsara MK, Hince D. Patient attitudes to standard analgesia care and their openness to non-pharmacological methods such as acupuncture in the ED. Emerg Med Australas. In Press.

Private notes

Contacts

Principal investigator
Title: Prof
Name: Andrew Jan
Address: Emergency Department, St John of God Hospital Murdoch, 1 Barry Marshall Pde, Murdoch, WA 6150
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Fax: +61894389162
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Contact person for public queries
Title: Prof
Name: Andrew Jan
Address: Emergency Department, St John of God Hospital Murdoch, 1 Barry Marshall Pde, Murdoch, WA 6150
Country: Australia
Phone: +61894389110
Fax: +61894389162
Email: drandrewjan@gmail.com

Contact person for scientific queries
Title: Prof
Name: Andrew Jan
Address: Emergency Department, St John of God Hospital Murdoch, 1 Barry Marshall Pde, Murdoch, WA 6150
Country: Australia
Phone: +61894389110
Fax: +61894389162
Email: drandrewjan@gmail.com

Data sharing statement
Will individual participant data (IPD) for this trial be available (including data dictionaries)? Yes
What data in particular will be shared? primary and secondary outcomes
When will data be available (start and end dates)? 21 January 2020 till 21 January 2023 being after the trial results have been accepted for publication and at least “in press”, and release of data will be subject to formal approval from the SJOG ethics committee and meeting any requirements they may impose.
Available to whom? Other trial investigators, journals receiving publication
Available for what types of analyses? Checking primary and secondary outcomes
By what mechanism will data be made available? Excel sheets
What supporting documents
Appendix 188
https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=375725&isClinicalTrial=False
are/will be available?

- Study protocol
- Informed consent form
- Ethical approval

Attachments/websites

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Attachment [1]

Summary results

Not applicable
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<td>Age (years)</td>
<td>51.3 (SD=16.7)</td>
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<td>50.4 (SD=14.7)</td>
<td>51.5 (SD=14)</td>
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<tr>
<td>Australasian triage score</td>
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<td>3.8 (SD=0.38)</td>
<td>3.8 (SD=0.43)</td>
<td>3.8 (SD=0.38)</td>
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<td>Triage NPRS-10</td>
<td>6.3 (SD=1.5)</td>
<td>6.6 (SD=1.5)</td>
<td>6.3 (SD=1.8)</td>
<td>6.4 (SD=1.6)</td>
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<td>Sex Female (%)</td>
<td>15 (50.0%)</td>
<td>20 (66.7%)</td>
<td>20 (66.7%)</td>
<td>55 (61.1%)</td>
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<tr>
<td>Any analgesia prior* (&lt;4/24) to arrival (%)</td>
<td>10 (33.3%)</td>
<td>8 (26.7%)</td>
<td>16 (53.3%)</td>
<td>34 (37.8%)</td>
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<tr>
<td>Opioid medication (&lt;4/24 prior to arrival) (%)</td>
<td>6 (20%)</td>
<td>3 (10%)</td>
<td>5 (16.7%)</td>
<td>14 (15.6%)</td>
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</table>

Appendix Table 1. Baseline characteristics comparing treatment groups with age (years), Australasian triage score (range 1-5), NPRS-10, sex (female count), ‘any analgesia prior’ and opioids prior (yes/no). Standard deviations (SD) are shown for parametric data and percentages (%) for non-parametric data.
<table>
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<th>Group allocations</th>
<th>Triage NPRS-10</th>
<th>CI</th>
<th>SD</th>
<th>Post-intervention NPRS-10</th>
<th>CI</th>
<th>SD</th>
<th>1-hour NPRS-10</th>
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<td>Adjunct sham</td>
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Appendix Table 2. Mean NPRS-10 pain scores, standard deviations (SD), 95% confidence intervals (CI) for study time points: triage, immediate post-intervention, one-hour and two-hours.
### Appendix Table 3. Adjusted mean pain score with 95% confidence intervals (CI), Chi², p values and degrees of freedom (df) for the baseline characteristics of age, sex, ‘any analgesia prior’, opioids prior and pain type along with sensitivity analyses for incomplete treatments and potential retrospective exclusions.
<table>
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<tr>
<th>Table</th>
<th>Main effect of treatment</th>
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<tr>
<td><strong>Morphine Dose Equivalent (MDE)</strong></td>
<td>p=0.563, Chi$^2=1.15$, df=2</td>
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<tr>
<td>MDE - adjust for incompletes (I)</td>
<td>p=0.480, Chi$^2=1.47$, df=2</td>
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<td>MDE - adjust for protocol violations (PV)</td>
<td>p=0.710, Chi$^2=0.69$, df=2</td>
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<tr>
<td>MDE - adjust for both I &amp; PV</td>
<td>p=0.637, Chi$^2=0.90$, df=2</td>
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<tr>
<td>MDE - adjust for pain type (PT)</td>
<td>p=0.509, Chi$^2=1.35$, df=2</td>
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<tr>
<td><strong>Cost of pharmaceuticals (Cost)</strong></td>
<td>p=0.277, Chi$^2=2.57$, df=2</td>
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<tr>
<td>Cost - adjust for I</td>
<td>p=0.413, Chi$^2=1.77$, df=2</td>
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<tr>
<td>Cost - adjust for PV</td>
<td>p=0.534, Chi$^2=1.26$, df=2</td>
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<tr>
<td>Cost - adjust for both I &amp; PV</td>
<td>p=0.694, Chi$^2=0.73$, df=2</td>
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<td>Cost - adjust for PT</td>
<td>p=0.162, Chi$^2=3.64$, df=2</td>
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<tr>
<td><strong>Adverse effects</strong></td>
<td>p=0.348, Chi$^2=2.11$, df=2</td>
</tr>
<tr>
<td>Adverse effects - adjust for I</td>
<td>p=0.854, Chi$^2=0.31$, df=2</td>
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<tr>
<td>Adverse effects - adjust for PV</td>
<td>p=0.299, Chi$^2=2.41$, df=2</td>
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<tr>
<td>Adverse effects - adjust for both I and P</td>
<td>p=0.829, Chi$^2=0.38$, df=2</td>
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<td>Adverse effects - adjust for PT</td>
<td>p=0.343, Chi$^2=2.14$, df=2</td>
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<td><strong>Likert satisfaction</strong></td>
<td>p=0.395, Chi$^2=1.86$, df=2</td>
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<tr>
<td>Likert - adjust for I</td>
<td>p=0.419, Chi$^2=1.74$, df=2</td>
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<td>Likert - adjust for PV</td>
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<tr>
<td>Likert - adjust for both I &amp; PV</td>
<td>p=0.396, Chi$^2=1.85$, df=2</td>
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<td>Likert - adjust for PT</td>
<td>p=0.360, Chi$^2=2.04$, df=2</td>
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<td><strong>Adequate analgesia @1 hour (AA1)</strong></td>
<td>p=0.383, Chi$^2=1.92$, df=2</td>
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<td>AA1 - adjust for I</td>
<td>p=0.327, Chi$^2=2.24$, df=2</td>
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<td>AA1 - adjust for PV</td>
<td>p=0.299, Chi$^2=2.42$, df=2</td>
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<td>AA1 - adjust for both I and P</td>
<td>p=0.245, Chi$^2=2.81$, df=2</td>
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<td>AA1 - adjust for PT</td>
<td>p=0.385, Chi$^2=1.91$, df=2</td>
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<td><strong>Adequate analgesia @2 hour (AA2)</strong></td>
<td>p=0.564, Chi$^2=1.15$, df=2</td>
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<tr>
<td>AA2 - adjust for I</td>
<td>p=0.537, Chi$^2=1.24$, df=2</td>
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<td>AA2 - adjust for PV</td>
<td>p=0.639, Chi$^2=0.90$, df=2</td>
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<td>AA2 - adjust for both I and P</td>
<td>p=0.616, Chi$^2=0.97$, df=2</td>
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<tr>
<td>AA2 - adjust for PT</td>
<td>p=0.564, Chi$^2=1.15$, df=2</td>
</tr>
<tr>
<td><strong>30% Reduction NPRS-10@1hour (30%R1)</strong></td>
<td>p=0.563, Chi$^2=1.15$, df=2</td>
</tr>
<tr>
<td>30%R1 - adjust for I</td>
<td>p=0.352, Chi$^2=2.09$, df=2</td>
</tr>
<tr>
<td>30%R1 - adjust for PV</td>
<td>p=0.531, Chi$^2=1.27$, df=2</td>
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<td>30%R1 - adjust for both I and P</td>
<td>p=0.332, Chi$^2=2.20$, df=2</td>
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<td>30%R1 - adjust for PT</td>
<td>p=0.561, Chi$^2=1.16$, df=2</td>
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<td><strong>30% Reduction NPRS-10@2hour (30%R2)</strong></td>
<td>p=0.954, Chi$^2=0.09$, df=2</td>
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<td>30%R2 - adjust for I</td>
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<tr>
<td>30%R2 - adjust for PV</td>
<td>p=0.985, Chi$^2=0.03$, df=2</td>
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<tr>
<td>30%R2 - adjust for both I and P</td>
<td>p=0.713, Chi$^2=0.68$, df=2</td>
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<tr>
<td>30%R2 - adjust for PT</td>
<td>p=0.953, Chi$^2=0.10$, df=2</td>
</tr>
</tbody>
</table>
Appendix Table 4. P values, Chi² and degrees of freedom (df) for sensitivity analyses performed with either linear or logistic regression for secondary outcomes adjusted for: those that did not complete treatments; were potential exclusions; and pain type.
EDEA TRIAL
Emergency Department Ear Acupuncture Trial

RESEARCHERS

Professor Andrew Jan1, 2, Emogene Aldridge2, Professor Ian Rogers1, 2, Professor Eric Visser4, Professor Max Bulsara4, Dr Dana Hinch5, 6, A/Professor / Colonel Richard Niemtzow6,7, A/Professor Lorna Suen8, 9

1School of Medicine, The University of Notre Dame Australia, Fremantle, Western Australia, Australia, 2Emergency Department, St John of God Murdoch Hospital, Perth, Western Australia, Australia, 3Department of Chronic Pain Education and Research, The University of Notre Dame Australia, Fremantle, Western Australia, Australia, and 4Department of Biostatistics, Institute for Health Research, The University of Notre Dame Australia, Fremantle, Western Australia, Australia, 5United States Air Force Acupuncture and Integrative Medicine Center, Joint Base Andrews, Maryland, USA, 6School of Nursing The Hong Kong Polytechnic University Hung Hom, Hong Kong

EMERGENCY DEPARTMENT EAR ACUPUNCTURE TRIAL

This trial aims to investigate ear acupuncture either with needles or a piezoelectric device as adjunct with standard analgesia care versus standard analgesia care alone. In this trial, there are two acupuncture treatment groups (either tiny ear needles or electrical acupuncture stimulation) and a third comparison group. All groups will receive our usual high standard pain treatment. The group who receive needles will have them in place for 2 hours and on completion of the trial they will be removed. The second acupuncture group will have electrical acupuncture stimulation. Electrical-acupuncture uses a ‘piezoelectric device’, which delivers a very safe electrical discharge near your ear, which sounds like a pen clicking.

RECRUITMENT: Recruitment finished on the 27th of August 2019. Thanks for all those who participated. Data analysis has been completed.
TRIAL RESULTS: The trial results have been published. The abstract and link to the article are placed on the Publications page of this website.
DATA SHARING: Deidentified data for the purpose of a meta-analysis will be shared under certain conditions. Researchers, please go to the Data Sharing page.
CONTACT: To contact Professor Jan, please go to the Contact page.
Appendix

EDEA TRIAL
Emergency Department Ear Acupuncture Trial

PATIENT CONSENT

Emergency Department Ear Acupuncture (EDEA)
A research project led by Professor Andrew Jan

Why are we doing this research?
In this study we are trying to see whether ear acupuncture along with standard pain medications offers better pain relief than standard pain medications alone. Currently some of our pain medications cause side-effects in both the short and long term. Acupuncture has a low side effect profile but is not proven to work for acute pain. This study hopes to show that acupuncture is effective for pain relief and that less amounts of strong pain medications are used.

Do I have to take part?
No, you do not have to take part. It is your choice and if you don’t wish to enter the trial you don’t have to. If you choose not to enter the trial, there will be no repercussions and you will receive our high standard of care.

What are the main steps in the study?
You will be asked to enter the trial and then randomly assigned to one of the three pathways of the trial. All three routes will receive our usual best practice pain medications. However, one group, in addition to the usual pain medications, will receive ear acupuncture with needles. The second group will receive ear acupuncture with an electric stimulator in addition to usual care, and the third will have best practice pain medications alone. However, because this is a trial, all groups will have small ear tapes applied to prevent the nurses knowing which pathway you are in. The nurses will record your pain scores for 2 hours and then carry out a very brief questionnaire about satisfaction and any adverse effects.

Will there be any information about me?
We will keep any information confidential and securely stored. All of the collected data will be non-identifiable. Seven years post-publication the data will be destroyed.

What possible benefits might I get by taking part?
You might get to try a new mode of pain relief on top of usual pain medications. A big benefit is that you will feel good about contributing to research on pain medicine and acupuncture. Think such as these can make pain relief both more effective and safer for the future.

What risks do I run by taking part?
Acupuncture has a reputation of having few side effect profile but like all medical interventions there is always a possibility of a side effect to a very small one. The biggest risks to avoid a infection, so we have taken steps to minimize this by using sterile needles with alcohol pen and removing the needles at 2 hours, rather than 3 days. Acupuncture needles can hurt a little and have minor bleeding either on insertion or removal. The electric acupointure device is also safe but to be very safe we won’t be directly applying it to the skin or patients with pacemakers.

Will the results of the trial be published?
We intend for the study results to truth be published in a scientific journal and presented at scientific meetings. You will be notified of publication and stories on the research via the trial website: www.ear acupuncture.com.au

Consent form
I have been given information about Emergency Department Ear Acupuncture and discussed the research project. I have been advised of the potential risks associated with this research, including minor pain and bleeding, that there is an opportunity to ask any questions. I may have about the research and my participation, I understand that my participation in this research is voluntary, I am free to refuse to participate, and I am free to withdraw from the research at any time. My refusal to participate or withdrawal of consent will not affect my pain management or care. I am treated in any way.

If I have any queries about the research I can contact Andrew Jan (Ph: 94369130 or via website) or if I have any concerns or complaints regarding the way the research is or has been conducted, I can contact Dr. Nick Jenkins, Honorary Research Ethics Officer (Ph: 93038900).

I understand that the data collected from my participation will be used for publication, and I consent for this to be used in that manner.

By signing below, I am indicating my consent to participate in the study.

Signed: __________________________ Date: __________________________
Name (please print): __________________________
The trial has been published.
Click image below to read summary and directions for obtaining full article

Original Research

Battlefield acupuncture added no benefit as an adjunct analgesic in emergency department for abdominal, low back or limb trauma pain

Andrew L Jan, Emogene S Aldridge, Eric J Visser, Ian R Rogers, Dana A Hince, Michael V Woosey, Max K Bulsara, Lorna KP Suen

First published: 23 September 2020 | https://doi.org/10.1111/1742-6723.13642

Andrew L Jan, MBBS, FACEM, BA, FAMAC, MPhil, Adjunct Professor, Emergency Physician; Emogene S Aldridge, BHealthSc, MPH, Academic Support Officer; Eric J Visser, MBBS, FANZCA, FFPMANZCA, Professor, Churack Chair; Ian R Rogers, MBBS, FACEM, Adjunct Professor, Emergency Physician; Dana A Hince, BSc (Hons), PhD, Biostatistician; Michael V Woosey, MBBS (Hons), FACEM, FRACS, Emergency Physician; Max K Bulsara, BSc, MSc, PhD, Professor, Chair; Lorna KP Suen, RN, RM, BN, MPH, DipClinAcup, PhD, Associate Professor.
DATA SHARING STATEMENT: Individual participant data will be available that underlie the results reported in this article, after deidentification (text, tables, figures and appendices); beginning nine months and ending 36 months following article publication; and for investigators whose, proposed use of the data has been approved by an independent review committee identified for individual participant data meta-analysis. The study protocol is accessible through www.anzctr.org.au.

To contact the lead investigator, Professor Andrew Jan, please complete the contact form.

First Name
Last Name
Email
Phone
Subject
Message
Send
Dear Dr Jan,

Re: (EDEA) Battle Field (Ear) Acupuncture to treat abdominal pain, limb trauma and low back pain in the emergency department - a pilot study  
(Our ref: 1426)

Thank you for forwarding the above study for review by the St John of God Health Care (SJGHC) Human Research Ethics Committee (“the Committee”). Thank you also for your reply dated 5 November 2018 to a query from the Scientific Review Subcommittee.

I am pleased to advise that the Committee has granted ethical approval of your study as satisfying the ethical requirements under the National Health and Medical Research Council’s National Statement on Ethical Conduct in Human Research (NHMRC, 2007) (“the National Statement”). This ethical approval is inclusive of the documents included in your submission letter dated 4 September 2018.

The HREC approval period is from 26 November 2018 to 30 September 2019. Should an extension of this timeframe be required, you must seek continued approval from the Committee before the expiry of this time period.

In accordance with NHMRC guidelines, the Participating Site/Principal Investigator is responsible for:

1. Notification to the HREC of any adverse events or unexpected outcomes that may affect the continuing ethical acceptability of the study;
2. The submission of any proposed amendments to the study or previously-approved documents;
3. The submission of an annual progress report for the duration of the study which is due on the anniversary of HREC approval;
4. Reporting of all protocol deviations to the sponsor (if applicable) and all serious breaches reported to the HREC (preferably via the sponsor), together with details of the procedure(s) put in place to ensure the deviation or serious breach does not recur;
5. Notification and reason for ceasing the study prior to its expected date of completion (if applicable);

.../2
6. The submission of a final report and translation of results (including publications) upon completion of the study.

The following documents have been reviewed and approved:

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<td>Battlefield Ear Acupuncture Assessment Tool</td>
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<td>3/11/2018</td>
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You are reminded that this letter constitutes ethical approval only. You must not commence this research at SJGHC until separate authorisation in writing has been obtained.

I wish you well with your research.

Yours sincerely,

Clinical Professor Dr Simon Dimmitt
Chairman
St John of God Health Care Human Research Ethics Committee

cc. Alexis Cranfield, SJG Murdoch Hospital (via email)
cc. Dani Meinema, SJG Murdoch Hospital (via email)
Why are we doing this research?

In this study we are trying to see whether ear acupuncture along with standard pain medications offers better pain relief than standard pain medicines alone. Currently some of our pain medicines cause side-effects in both the short and long term. Acupuncture has a low side effect profile but is not proven to work for acute pain. This study hopes to show that acupuncture is effective for pain relief and that less amounts of strong pain medicines are used.

Do I have to take part?

No, you don’t have to take part. It’s your choice and if you don’t wish to enter the trial, you don’t have to. If you choose not to enter the trial, there will be no repercussions and you will receive our high standard of care.

What are the main steps in the study?

You will be asked to enter the trial and then randomly assigned to one of the three pathways of the trial. All three routes will receive our usual best practice pain medications. However, one group, in addition to the usual pain medicines, will receive ear acupuncture with needles. The second group will receive ear acupuncture with an electric device in addition to usual care, and the third will have best practice pain medicines alone. However, because this is a trial, all groups will have small ear tapes applied to prevent the nurses knowing which pathway you are in. The nurses will record your pain scores for 2 hours and then carry out a very brief questionnaire about satisfaction and any adverse effects.

What will happen to information about me?

We will keep any information confidential and securely stored. All of the collected data will be non-identifiable. Seven years post publication the data will be destroyed.

What possible benefits might I get by taking part?

You’ll might get to try a new mode of pain relief on top of usual pain medicines. A big benefit is that you will feel good about contributing to research on pain medicines and acupuncture. Trials such as these can make pain relief both more effective and safer for the future.

What risks do I run by taking part?

Acupuncture has a reputation of having a low side effect profile but like all medical interventions there is always a possibility of a side effect albeit a very small one. The biggest risk to avoid is infection, so we have taken steps to minimise this by wiping the ear with alcohol prior and removing the needles at 2 hours rather than 3 days. Acupuncture needles can hurt a little and have minor bleeding either on
insertion or removal. The electric acupuncture device is also safe but to be very safe we won’t be directly applying it to the skin or patients with pacemakers.

**Will the results of the trial be published?**

We intend for the study results to both be published in a scientific journal and presented at scientific meetings. You will be notified of publications and stories on this research via the trial website: www.edetrial.com.au

**Consent form**

I have been given information about *Emergency Department Ear Acupuncture* and discussed the research project. I have been advised of the potential risks associated with this research, including minor pain and bleeding. I have had an opportunity to ask any questions I may have about the research and my participation. I understand that my participation in this research is voluntary; I am free to refuse to participate; and I am free to withdraw from the research at any time. My refusal to participate or withdrawal of consent will not affect my pain management or how I am treated in any way.

If I have any enquiries about the research, I can contact Andrew Jan (Ph. 94389110 or via website) or if I have any concerns or complaints regarding the way the research is or has been conducted, I can contact Gorette De Jesus, Human Research Ethics Executive Officer (Ph. 93826940).

I understand that the data collected from my participation will be used for publication, and I consent for it to be used in that manner.

By signing below, I am indicating my consent to participate in the study.

Signed: ________________________________ Date: ____________________________

Name (please print): __________________________
Patient advice sheet - Ear Acupuncture and Piezo-electric Trial

- Firstly, thank you for participating in this trial.
- There are two ‘acupuncture treatment groups’ (either tiny ear needles or electrical acupuncture stimulation) and a third ‘comparison group’. All groups will receive our usual high standard pain treatment.
- Ear acupuncture remain in place for 2 hours. Electrical-acupuncture uses a ‘piezoelectric device’ and delivers a very safe electrical discharge near your ear which sounds like a ‘click’.
- To prevent our research team from knowing which group you were in, tapes will be applied to your outer ear. Please do not divulge your allocation.
- Please ring the nurse assist buzzer at approximately 1 and 2 hours after your first medication or ear acupuncture (including electrical acupuncture). The nurses can get busy at times so to assist the trial you could do this for us.

Pictures showing application of the ear (ASP) needles and a piezo electrical stimulator.

Who shouldn’t enter the trial: You should not have: allergies to tapes, alcohol or gold, chronic pain; a permanent pacemaker; chest pain; valvular heart disease; a bleeding disorder or taking blood thinners (except aspirin); a recent ear infection or trauma; hearing aids; HIV or Hepatitis C; significant immune deficiency or are pregnant.

Potential side Adverse effects:
- The needles are gold plated and allergic reactions to the gold in them are very low.
- We will remove them after 2 hours.
- Professor Andrew Jan is the principal investigator and can be contacted via St John of God Murdoch Emergency Department for any major urgent problems.

Further information see website: www.edetrial.com.au
Emergency Department Ear Acupuncture Trial (EDEA)

We are currently running a trial in ED, adding ear acupuncture to standard pain relieving medicines.

All patients entering the trial will receive our usual high standard pain relieving medicines, as well as the intervention.

Are you:

Older than 18 or younger than 80?

Have an:
- injured arm or leg,
- abdominal complaint or low back pain

In moderate or severe pain?

If you answer yes to all of these, and would like to participate, please tell the nurse and they will page our research practitioner.
Battlefield Ear Acupuncture Peer Assessment Tool

**Observation of workplace performance**

*Peer assessment* is a process where a caregiver makes assessment decisions on other caregiver’s work or performance using relevant criteria.

**Note:** Peer Assessor to document each category as either ‘P’ – Proficient or ‘NYP’ Not Yet Proficient. Please check in the final box as either ‘P’ or ‘NYP’

<table>
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<th>ELEMENTS</th>
<th>Performance Criteria</th>
<th>‘P’ OR ‘NYP’</th>
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<td>Risk Assessment</td>
<td>Identifies indications and contraindications for procedure</td>
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<tr>
<td>Legislation</td>
<td>Abides by legislation and policy</td>
<td></td>
</tr>
<tr>
<td>Consent &amp; ID</td>
<td>Patient consent, allergy and identification</td>
<td></td>
</tr>
<tr>
<td>Environment</td>
<td>Manages environmental risks</td>
<td></td>
</tr>
<tr>
<td>Procedure preparation</td>
<td>Performs hand hygiene</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cleans tray/trolley/work surface</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gathers equipment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Performs hand hygiene (needles, alcohol-wipes, tapes)</td>
<td></td>
</tr>
<tr>
<td>Patient preparation</td>
<td>Positions patient on trolley: sitting on side of the trolley, semi supine or supine.</td>
<td></td>
</tr>
<tr>
<td>Performs procedure</td>
<td>Perform hand hygiene</td>
<td></td>
</tr>
<tr>
<td>Battlefield (ear) Acupuncture</td>
<td>Prepare both ears including all surfaces that will be needed.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Removes and inspects ASP gold needle and introducer from packaging</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Inserts ASP needle into correct anatomical ear points in correct sequence (Cingulate, Thalamus, Omega, Point zero and Shenmen - including tapes)</td>
<td></td>
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<tr>
<td></td>
<td>Inserts needles in a safe manner by not placing finger behind insertion point posteriorly</td>
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<tr>
<td></td>
<td>Secures needles with cut 1cm X 1cm Duoderm tapes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Displays problem solving abilities - selects appropriate position for patient, selects appropriate patient for study, talks patient through</td>
<td></td>
</tr>
</tbody>
</table>
procedure, appropriate action taken if needle needs removal and reinsertion or key part or site contaminated.

<table>
<thead>
<tr>
<th>Documentation</th>
<th>Documents and communicates relevant information</th>
</tr>
</thead>
</table>
| Needle Removal | - Prepares equipment: trolley, kidney dish, dressing back, saline, non-toothed forceps, IV dot band-aids and non-sterile gloves.  
- uses gloves and forceps to remove acupuncture needles and then places needles in kidney dish then sharps bin  
- has knowledge that if needle falls, to use forceps or magnet on applicator to retrieve.  
- uses gloves while applying gauze or band-aids if necessary  
- disposes of forceps appropriately  
- cleans trolley surface  

Performs hand hygiene |
| Documentation | Documents and communicates relevant information |

<table>
<thead>
<tr>
<th>Standard Achieved</th>
<th>Proficient</th>
<th>Not Yet Proficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed assessment to be given to your L&amp;D Educator</td>
<td></td>
<td>Caregiver may benefit from revisiting</td>
</tr>
</tbody>
</table>

Feedback and comments

Caregiver signature

Assessor signature
Appendix to Chapter 6 - Section B

Copyright permissions:

- McDonald H. Today Tonight: Ear piercing and acupuncture could offer treatment for migraines [Television broadcast]. *Channel 7*; Western and South Australia; 2018 Mar 20.
Copyright permission for PhD thesis

Head, Michelle <>  To: "drandrewjan@gmail.com" <drandrewjan@gmail.com>

Tue, Jul 28, 2020 at 10:30 AM

Dear Andrew,

Apologies for the delayed response to your email. I'd like to introduce myself as the Journal Publishing Manager for EMA, taking over from Alison Bell.

To use the submitted versions of your papers in your thesis, no permission is required. Please see the Wiley Article Sharing Guidelines here, noting the use for the different versions (submitted, accepted, published, etc):

The final version would also be allowed for the use you describe below under the same guidelines; no permission is required.

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All the best with your thesis!

Appendix

https://mail.google.com/mail/u/0?ik=ac14b3c787&view=pt&search=all&permmsgid=msg-f%3A1673426064167410529&simpl=msg-f%3A1673426064167410...
Kind regards,
Michelle

Michelle Head
Journal Publishing Manager

Wiley / 155 Cremorne Street / Richmond Victoria 3121 / Australia

www.wiley.com

From: Andrew Jan <drandrewjan@gmail.com>
Sent: Monday, 20 July 2020 9:08 PM
To: Bell, Alison <>
Subject: Re: Copyright permission for PhD thesis

This is an external email.

[Quoted text hidden]
Hi Dr Jan,

Thank you for your email regarding the use of Today Tonight Ear Piercing story 20.3.18.

I have checked with the News Director and he has approved it’s use within your thesis.

Kind regards,

Marie Thorne

News Unit Manager, 7NEWS | Perth
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Hi Olivia

And can I presume I have permission to provide a link/copy of the article in the appendix of my PhD?


warmest

Andrew Jan

On Mon, Aug 3, 2020 at 9:03 AM Olivia Harvey (Murdoch) <Olivia.Harvey@sjog.org.au> wrote:

Hi Andrew,

Apologies, I have been ed up with strategy last week!

See a ached e-version of the magazine.

There's also an e-version of the ar cle here:

https://insidehealthmagazine.wordpress.com/2019/06/19/acupuncture-alongside-not-instead-of/
Hi Olivia

Just to check that you got the above email and request - or could you direct me to the right person to ask?

warmest

Andrew Jan

On Wed, Jul 29, 2020 at 10:09 AM Andrew Jan <drandrewjan@gmail.com> wrote:

Hi Olivia

Is it ok to include the article on the trial as attached in my PhD thesis appendix?

warmest

Andrew Jan

Professor Andrew Jan
MBBS FACEM BA FAMAC MPhil
Adjunct Professor School of Medicine University of Notre Dame Fremantle,
Emergency Medicine Specialist, Medical Acupuncturist

Emergency Department, SJOG Murdoch Hospital
Barry Marshall Pde, Murdoch WA, 6150
E. drandrewjan@gmail.com

www.sjog.org.au

On Tue, Jul 28, 2020 at 10:20 PM Lizzie Thelwell (Kings Square) <Lizzie.Thelwell@sjog.org.au> wrote:

Congratulations Andrew – that’s wonderful news.
I work for a different division now but I’ve cc’d Olivia, the manager at Murdoch.
Hope you are well and congratulations again.
All the best
Lizzie
On Mon, Dec 17, 2018 at 2:58 PM Lizzie Thelwell (Murdoch) <Lizzie.Thelwell@sjog.org.au> wrote:

Hi Andrew

Better late than never right? 😊

Happy for amendments to this and apologies again for the extreme delay!

Kind regards

Lizzie
Appendix to Chapter 6 - Section C

Trial teaching materials: slide presentation and videos:

ED ear acupuncture
- EDEA trial

**Background**

• Acupuncture is emerging as an analgesic alternative or adjunct in the emergency setting with potential for equal or improved efficacy with standard analgesia care (SAC), low adverse effects, cost savings and improved patient satisfaction.

• In the emergency setting - opioids are often used as analgesia for acute pain. This culture has contributed to the current patterns of opioid misuse in the community and as result, there is pressure to find an effective alternative.
Review Article

Review article: Does acupuncture have a role in providing analgesia in the emergency setting? A systematic review and meta-analysis

Andrew L Jan, Emogene S Aldridge, Ian R Rogers, Eric J Visser, Max K Bulsara, Richard C Niemtzow


Andrew L Jan, MBBS, FACEM, BA, FAMAC, MPhil, Emergency Physician, Staff Specialist, PhD Candidate; Emogene S Aldridge, BThSc, Academic Support Officer; Ian R Rogers, MBBS, FACEM, Professor; Eric J Visser, MBBS, FANZCA, FFPMANZCA, Professor/Churack Chair; Max K Bulsara, PhD, MSc, BSc, Professor; Richard C Niemtzow, MD, PhD, MPH, Director

Does Ear Acupuncture Have a Role for Pain Relief in the Emergency Setting? A Systematic Review and Meta-Analysis

Andrew L. Jan, MBBS, FACEM, BA, FAMAC, MPhil,1,2 Emogene S. Aldridge, BThSc,1 Ian R. Rogers, MBBS, FACEM,1,2 Eric J. Visser, MBBS, FANZCA, FFPMANZCA,3 Max K. Bulsara, PhD, MSc, BSc,4 and Richard C. Niemtzow, MD, PhD, MPH,5

Published online 2017 Oct 1. doi: 10.1089/acu.2017.1237

PMCID: PMC5653340
PMID: 29067138
Pre trial prospective audit. EMA: In Press


SHORT REPORT

Patient attitudes towards analgesia and their openness to non-pharmacological methods such as acupuncture in the emergency department

Andrew L JAN,1,2 Emogene S ALDRIDGE,2 Ian R ROGERS,1,3 Eric J VISSER,3 Max K BULSARA4 and Dana A HINCE4

Acupuncture for analgesia in the emergency department: a multicentre, randomised, equivalence and non-inferiority trial

Marc M Cohen, De Villiers Smit, Nick Andrianopoulos, Michael Ben-Meir, David McD Taylor, Shefton J Parker, Chalie C Xue and Peter A Cameron

Published online: 19 June 2017

Conclusion: The effectiveness of acupuncture in providing acute analgesia for patients with back pain and ankle sprain was comparable with that of pharmacotherapy. Acupuncture is a safe and acceptable form of analgesia, but none of the examined therapies provided optimal acute analgesia. More effective options are needed.
Letters

Acupuncture for analgesia in the emergency department: a multicentre, randomised, equivalence and non-inferiority trial

To the Editor: We commend Cohen and colleagues' on their recently published study, which is the largest randomised controlled trial (RCT) of acupuncture in the emergency department (ED). We recently completed a systematic review and meta-analysis on the role of acupuncture for analgesia in the emergency setting. Our analgesic effect of acupuncture is unlikely to be equal for all pain presentations in the emergency setting and, therefore, the conditions for which its role is most beneficial need to be delineated.

Andrew I Jan
Ian Rogers
Eric J Visser

1 Saint John of God Murdoch Hospital, Murdoch, WA.
2 University of Notre Dame Australia, Fremantle, WA.
drrewjan@gmail.com

Competing interests: No relevant disclosures.

doi: 10.5694/mja17.001661
Three conditions:
1. Limb trauma
2. Low back pain
3. Abdominal pain

Who can enter the trial?

- Patients aged ≥18 years with an upper age limit of 80 years,
- a NPRS-10 ≥ 4 at rest
- triage categories 3-5
Who is excluded

- Unable to comprehend
- Pregnant
- Chronic pain (defined as on opioids and or pain is greater than 6 weeks’ duration)
- Chest pain
- Immune deficiency
- On anticoagulants (patients on aspirin are allowed in trial)
- Artificial heart valve or Permanent pacemaker
- Known blood borne pathogen eg HIV, Hep C and Hep B antigen positive.
- Deafness or uses hearing aids, recent ear infection or trauma

Contra-indications

F. Fainting to needles
A. Allergy to tapes or gold
B. Bleeding predisposition (relative)
O. On opioids - chronic pain > 6/52
H. Heart valves prosthesis / Hearing aid / PPM

P. Pregnancy - currently there has been little study in pregnancy. Therefore until further research, to pregnant patients.
I. Infection at needle insertion site, blood infection (including heart valves)
N. Needle phobia
Consent form

• Emergency Department Ear Acupuncture (EDEA)
• A research project led by Professor Andrew Jan

Why are we doing this research?
Do I have to take part?
What are the main steps in the study?
What will happen to information about me?
What possible benefits might I get by taking part?
What risks do I run by taking part?
Will the results of the trial be published?

By signing below, I am indicating my consent to participate in the study.

---

Patient Advice Sheet

Firstly, thank you for participating in this trial.

There are two ‘acupuncture treatment groups’ (either tiny ear needles or electrical acupuncture stimulation) and a third ‘comparison group’. All groups will receive our usual high standard pain treatment.

Ear acupuncture remains in place for 2 hours. Electrical-acupuncture uses a ‘piezoelectric device’ and delivers a very safe electrical discharge near your ear which sounds like a ‘click’.

To prevent our research team from knowing which group you were in, tapes will be applied to your outer ear. Please do not divulge your allocation.

Please ring the nurse assisst buzzer at approximately 1 and 2 hours after your first medication or ear acupuncture (including electrical acupuncture). The nurses can get busy at times so please be patient.

Who shouldn’t enter the trial? You should not have: allergies to tapes, alcohol or gold, chronic pain; a permanent pacemaker; chest pain; valvular heart disease; a bleeding disorder or taking blood thinners (except aspirin); a recent ear infection or trauma; hearing aids; HIV or Hepatitis C; significant immune deficiency or are pregnant.

Potential side adverse effects:
• The needles are gold plated and allergic reactions to the gold in them are very low.
• We will remove them after 2 hours.
• Professor Andrew Jan is the principal investigator and can be contacted on 41085 St John of God Murdoch Emergency Department for any major urgent problems.

Further information see website: www.edeatrial.com.au

Appendix 225
Randomisation
• 3 piles (abdo pain, limb trauma and low back pain) of sealed envelopes with 30 each will consist of 10 acupuncture, 10 sham and 10 standard care allocations

Ear Acupuncture
• CGTOPS
  Cingulate Gyrus X 2 then tapes
  Thalamus X 2 then tapes
  Omega X 2 then tapes
  Point zero X 2 then tapes
  Shenmen x 2 then tapes
• Advise patient not to divulge group
Video Demonstration of Insertion of the 5 BFA Points
**Standard Analgesia Care**

- Apply tapes and advise patient not to divulge group

<table>
<thead>
<tr>
<th>Pain Score</th>
<th>General Protocol Based On Pain Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-3</td>
<td>Paracetamol 1g AND/OR Ibuprofen 400mg</td>
</tr>
<tr>
<td>4-5</td>
<td>Paracetamol 1g + Oxycodone 5-10mg OR Ibuprofen 400mg + Oxycodone 5-10mg OR Paracetamol 1g + Ibuprofen 400mg</td>
</tr>
<tr>
<td>6-7</td>
<td>Oral opioid: Oxycodone 5-10mg PO, Buprenorphine 200-400mg SL or Tapentadol IR 50 – 100mg</td>
</tr>
<tr>
<td>8-10</td>
<td>Further rescue doses of fentanyl, morphine and Oxycodone 5-10mg PO.</td>
</tr>
</tbody>
</table>

Note: should receive paracetamol, NSAID as per NPRS 4-7

Note can give up to 800mg ibuprofen. OR Ketorolac 10 mg IV, 15mg IM

Rescue medication after 30 minutes is oral opioid: Oxycodone 5-10mg PO, Buprenorphine 200-400mg SL or Tapentadol IR 50 – 100mg.
ED Acupuncturist fills out this form and places in trial tray

hands patient over for:
1. immediate repeat pain score and analgesia.
2. Gives patient timer set at 1 and 2 hours to remind nurse for pain scores

All arms get Standard Analgesia Care

• Apply tapes and advise patient not to divulge group

**General Protocol Based On Pain Score**

<table>
<thead>
<tr>
<th>Pain score</th>
<th>Paracetamol 1 g AND/OR Ibuprofen 400 mg</th>
<th>Paracetamol 1 g + Oxycodeone 5-10 mg OR Ibuprofen 400 mg + Oxycodeone 5-10 mg OR Paracetamol 1 g + Ibuprofen 400 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7-9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note can give up to 800mg Ibuprofen. OR Ketorolac 10 mg IV, 15mg IM**

**Rescue medication after 30 minutes is oral opioid: Oxycodeone 5-10mg PO, Buprenorphine 200-400mg SL or Tapentadol IR 50 – 100mg**

**Appendix 229**

**Note: should receive paracetamol, NSAID as per NPRS 4-7**

**Further rescue doses of fentanyl, morphine and Oxycodeone 5-10mg PO.**
Nurses fill out this form

1. Collect blinded pain scores:
   • Prior to first analgesia
   • 1 hour
   • 2 hours
2. After 2 hour score does 6 point Likert satisfaction score
3. Asks for adverse effects (whether they be due to medication or acupuncture) mild or significant?
4. Places sheet in trial tray for collection by research assistant
From drug chart document

• Calculate morphine equivalent dosage post attendance (<2/24)

Publication

• Anticipating EMA
• Thankyou time and effort - rewards are trial participation, experience, CME more important part of the endeavor towards better long term health and well being of our patients.
• We can give you - co-authorship in return.

• THANKYOU
Questions
**Trial Teaching videos**

Piezo-electric arm training
[https://youtu.be/XEUv5q_1_pM](https://youtu.be/XEUv5q_1_pM)

Needle intervention arm
[https://youtu.be/Rq0ghnVz0Fw](https://youtu.be/Rq0ghnVz0Fw)

Removing needles
[https://youtu.be/K2uD3uNCce0](https://youtu.be/K2uD3uNCce0)
Appendix to Chapter 6 - Section D

Publicity:

- McDonald H. Today Tonight: Ear piercing and acupuncture could offer treatment for migraines [Television broadcast]. Western and South Australia: *Channel 7*; 20 Mar 2018.
Today Tonight
Video on Television about ear acupuncture for pain relief.
Aired: 21.3.18

https://vimeo.com/498617698

Password: JanUNDThesis
Acupuncture to take sting out of ED pain

REGINA TITELIUS

Acupuncture is being tested at a Perth hospital emergency department as an alternative to painkillers including powerful narcotics.

The trial, which started in January at St John of God Murdoch Hospital, involves patients being offered the choice of “battlefield acupuncture” — a form of acupuncture often used by the American military to alleviate pain in the field.

SJOG Murdoch ED physician adjunct professor Andrew Jan was hopeful the trial would help reduce reliance on strong and addictive painkillers.

Professor Jan said battlefield acupuncture — small pointed needles which are injected in key points of the ear and could be left for up to three days — could provide “a viable alternative” to pharmaceutical pain relief or used in conjunction with medications.

He said about 75 per cent of ED patients experienced some form of pain and would normally be given a painkiller, which can vary from paracetamol and anti-inflammatories to powerful opioids such as oxycodone.

Professor Jan said the trial, which started in January and would finish its testing stage later this month, would determine if acupuncture improved pain relief in the first couple of hours and reduced the use of stronger painkillers.

He said there was no intention to replace all pain management with acupuncture. “It’s not for everyone,” he said. “But in our recent survey about 70 per cent of people were willing to use it as an adjunct.”
Acupuncture trialled in the Emergency Department

Acupuncture is currently being trialled as an alternative holistic treatment option for pain management in St John of God Murdoch Hospital’s Emergency Department.

One of Murdoch’s Emergency Physicians Adjunct Professor Andrew Jan, who is also a Medical Acupuncturist, is conducting the trial, which uses a technique known as ‘Battlefield acupuncture’.

Prof Jan is passionate about reducing the number of strong, potentially addictive painkillers used to alleviate pain.

Around 75% of people presenting to emergency are experiencing some level of pain. Traditionally, patients are given the most appropriate painkiller which can vary from paracetamol and anti-inflammatories, to much more powerful opioids such as Oxycodone.

“These painkillers can be misused, cause a number of side effects and can lead to addiction and even death,” Prof Jan said.

“Acupuncture can provide either a viable alternative to pharmaceutical pain relief or it can be used in conjunction with medications to effectively reduce or eliminate pain.”

Battlefield acupuncture is the process of inserting small pointed needles into several key points in the ear. These needles can be left in for up to three days.

“Battlefield acupuncture is used by the American military to relieve pain in the field rather than having to be taken to a medical facility for monitoring with opioids,” Prof Jan said.

“We were particularly interested in our current trial whether ear acupuncture pain relief improves pain relief in the first couple of hours and reduces usage of stronger pain killers.”

Previous research undertaken by the Emergency Medicine Research Group at Murdoch has shown that, either as stand-alone or as-an-adjunct technique, the administration of acupuncture significantly reduced pain scores and has potential benefits for use in ED.

Prof Jan believes acupuncture is a perfect fit for emergency medicine due to its portable and non-obtrusive nature, however he does not suggest replacing all pain management with acupuncture.

“If the patient is lying down you can treat them with ear acupuncture while everything else is going on. They can have their bloods taken and their observations done at the same time,” he said.

“It’s not for everyone, and that’s okay. But in our recent survey about 70% were willing to use it as an adjunct.”

“If it is used in conjunction with other non-pharmacological techniques, with analgesics kept to a minimum, then there is potential for development of the whole person.”

The trial commenced at the beginning of 2019 and is expected to wrap up within weeks. Patients admitted to our private ED who meet the eligibility criteria can participate. The results will be analysed over coming months and the results are expected to be available in early 2020.

A/Prof Andrew Jan administers acupuncture in ED, which is currently being trialled
Appendix to Chapter 6 - Section E

Conference presentation:

- Jan AL, Aldridge ES, Rogers IR et al. Battlefield acupuncture as an adjunct to treat pain of the abdomen, limb trauma and low back pain in the emergency department – a randomised controlled study. Paper presented via teleconference to: The Western Australia St John of God Health Care Research and Ethics; 2020 Mar 26; Perth, Australia.
Battlefield (Ear) Acupuncture as an adjunct to treat pain of the abdomen, limb trauma and lower back in the emergency department - a randomised controlled study.

**ED Ear Acupuncture – EDEA trial**

- Prof Andrew Jan
- Prof Eric Visser
- Prof Ian Rogers
- Prof Max Bulsara
- A/Prof Lorna Suen
- A/Prof Richard Niemtzow
- Dr Dana Hince
- Dr Michael Woosey

**Background**

- **Acupuncture** is emerging as an analgesic alternative or adjunct in the emergency setting with potential for equal or improved efficacy with standard analgesia care (SAC), low adverse effects, cost savings and improved patient satisfaction.

- In the emergency setting - opioids are often used as analgesia for severe pain or failed simple analgesia (paracetamol/NSAIDs).

- This culture has contributed to the current patterns of opioid misuse in the community and as result, there is pressure to find an effective alternative.
Appendix
Review Article

Review article: Does acupuncture have a role in providing analgesia in the emergency setting? A systematic review and meta-analysis

Andrew L Jan, Emogene S Aldridge, Ian R Rogers, Eric J Visser, Max K Bulsara, Richard C Niemtzow


Andrew L Jan, MBBS, FACEM, BA, FAMAC, MPhil, Emergency Physician, Staff Specialist, PhD Candidate; Emogene S Aldridge, BHHSc, Academic Support Officer; Ian R Rogers, MBBS, FACEM, Professor; Eric J Visser, MBBS, FANZCA, FFPMANZCA, Professor/Cherub Chair; Max K Bulsara, PhD, MSc, BSc, Professor; Richard C Niemtzow, MD, PhD, MPH, Director

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Andrew L. Jan, MBBS, FACEM, BA, FAMAC, MPhil, Emogene S. Aldridge, BHlthSc, Ian R. Rogers, MBBS, FACEM, Eric J. Visser, MBBS, FANZCA, FFPMANZCA, Max K. Bulsara, PhD, MSc, BSc, Richard C. Niemtzow, MD, PhD, MPH
SHORT REPORT

Patient attitudes towards analgesia and their openness to non-pharmacological methods such as acupuncture in the emergency department

Andrew L JAN,1,2 Emogene S ALDRIDGE,2 Ian R ROGERS,1,2 Eric J VISSER,3 Max K BULSARA,4 and Dana A HINCE

Acupuncture for analgesia in the emergency department: a multicentre, randomised, equivalence and non-inferiority trial

To the Editor: We commend Cohen and colleagues' on their recently published study, which is the largest randomised controlled trial (RCT) of acupuncture in the pharmacotherapy. Acupuncture is a safe and acceptable form of analgesia, but none of the examined therapies provided optimal acute analgesia. More effective options are needed.
Battlefield (Ear) Acupuncture as an adjunct to treat pain of the abdomen, limb trauma and lower back in the emergency department - a randomised controlled study.

- Ethics
- Trial registration ANZCTR
Trained Emergency Physicians, nurses and nurse practitioners (n=9)

- 2 hours face to face
- 2 hours on-line
- Included trial logistics
- Simulation with take home silicone ear

Three painful conditions:
1. limb trauma
2. low back pain
3. Abdominal pain
Who entered the trial?

- Patients aged ≥18 years with an upper age limit of 80 years,
- a NPRS-10 ≥ 4 at rest
- triage categories 3-5
- Abdo, low back and limb trauma pain!

Contra-indications

F. Fainting to needles
A. Allergy to tapes or gold
B. Bleeding predisposition (relative)
O. On opioids – chronic pain > 6/52
H. Heart valves prosthesis / Hearing aid / PPM

P. Pregnancy - currently there has been little research. Therefore until further research, BFA should not be used in pregnant patients.
I. Infection at needle insertion site, blood infection
   (Including heart valves)
N. Needle phobia
Prescribed Standard Analgesia Care

Opioids were administered in the ED to 63% (n=19) in the SAC arm, 50% (n=15) in the Adj-Sham, and 60% in the Adj-BFA (n=18) with a trial average of 56.7% (n=52).

Randomisation

• 3 piles (abdo pain, limb trauma and low back pain) of sealed envelopes with 30 each will consist of 10 acupuncture, 10 sham and 10 standard care allocations.

patients requested not to divulge allocation
Ear Acupuncture Protocol

• CGTOPS
  1-2 Cingulate Gyrus X 2 then tapes
  3-4 Thalamus X 2 then tapes
  5-6 Omega X 2 then tapes
  7-8 Point zero X 2 then tapes
  9-10 Shenmen x 2 then tapes

• Advise patient not to divulge group
• SAC

Video Demonstration of Insertion of the 5 BFA Points
Sham & SAC

CONSORT flow chart
Delivered Standard Analgesia Care

Tapes applied all groups

Opioids were administered in the ED to 63% (n=19) in the SAC arm, 50% (n=15) in the Adj-Sham, and 60% in the Adj-BFA (n=18) with a trial average of 56.7% (n=52).
Discussion – an unexpected result on pain score reduction with BFA!

- Result holds significant authority overall for ED acupuncture studies
- Our trial was arguably the most methodologically rigorous to date (sham, blinding, numbers, original outcomes).
- There are three peri-operative analgesia Adj-BFA RCTs which showed no significant improvement on predefined primary outcomes
Expected BFA it to work - Why didn’t it?

- It is effective but in the trial: Note 6 positive (5perioperative, 1GP) results.
- the analgesic effect of the adjunct was masked
- BFA doesn’t provide analgesia for any pain type
- BFA technique was modified
- Only minimal training in BFA
- ED is a challenging environment and may negate acupuncture

<table>
<thead>
<tr>
<th>First author, year &amp; ref.</th>
<th>Study type</th>
<th>Location</th>
<th>Acute pain type</th>
<th>Number of participants (enrolled)</th>
<th>Overall study pain score improvement result</th>
<th>Pain score reduction at 24 hours or less compared to control</th>
<th>Secondary outcomes</th>
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<td>Goertz, 2006²²</td>
<td>Adjunct</td>
<td>ED</td>
<td>Mixed</td>
<td>100</td>
<td>Benefit p&lt;0.05</td>
<td>Opioid use NSS</td>
<td></td>
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<td>ED</td>
<td>Low back pain</td>
<td>30</td>
<td>Benefit p&lt;0.05</td>
<td>Opioid use NSS</td>
<td></td>
</tr>
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<td>Crawford, 2019³⁶</td>
<td>Adjunct</td>
<td>PO</td>
<td>Lower limb</td>
<td>233</td>
<td>Benefit NSS</td>
<td>Opioid use NSS, Less NSAIDs</td>
<td></td>
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<td>Plunkett, 2018³⁷</td>
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<td>PO</td>
<td>Tonsillectomy</td>
<td>95</td>
<td>Benefit NSS</td>
<td>Opioid use NSS</td>
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<td>Kim, 2019³⁸</td>
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<td>PO</td>
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<td>PO</td>
<td>Abortion</td>
<td>153</td>
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<td>41</td>
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<td></td>
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<tr>
<td>Shah, 2019⁴¹</td>
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<td>PO</td>
<td>Tonsillectomy</td>
<td>134</td>
<td>Benefit p&lt;0.05</td>
<td>Opioid use NSS</td>
<td></td>
</tr>
</tbody>
</table>
Patients are demanding non-pharmacological methods for analgesia including:

- Acupuncture as a stand-alone
- Adjunct to simple non-opioid SAC and keep opioids merely for rescue analgesia.
- Choose painful conditions that are at risk of recurrent opioid use
- Use original technique
Recurrent use of non-pharmacological techniques likely to benefit both the individual and the community.

Questions?

EMERGENCY DEPARTMENT EAR ACUPUNCTURE
Conclusion

• This RCT of 90 patients did not show a significant difference in analgesia outcomes using Adj-BFA for acute pain in the ED.
• Likewise, secondary outcomes did not show an improvement in cost, adverse effects, patient dissatisfaction and opioid use.
• Given the mixed results of recent BFA trials, further similar research, using the highest standards of study design, the original BFA technique, varied conditions, both as stand-alone and as adjunct to non-opioid analgesia studies are needed.
Appendix to Chapter 7- Sections A-E:

Strengths and Weaknesses of Publications in This Thesis

Critical appraisal of evidence is the key point in this process. According to [the] characteristics of different study types, relevant evaluation tools are developed ... These tools give significant impetus to [the] practice of EBM.†

—Dr Xiantao Zeng, Centre for Evidence-Based and Translational Medicine, Wuhan University, 2015

What is already known on the topic
• The overall quality of research on ED acupuncture needs to improve.

What this research adds
• The application of quality assessment tools such as Cochrane RoB 2, SIGN and AMSTAR 2 have substantiated the quality of research in this thesis.*
• The publications presented in this thesis meet standards of reporting, including PRISMA, CONSORT and STRICTA.*
• The standard of the body of research presented in this thesis is comparable to, if not higher than, recent similar studies.
• Given the quality of the research based on standard assessment tools and comparators, valid conclusions can be drawn from the publications of this thesis.

Overview of Sections A–E

Objective: This appendix discusses the strengths and weaknesses of the individual publications. It also compares and examines similar contemporary studies that have influenced this research, providing further insights into the methodology and interpretation of findings from this body of research and the chosen studies. Understanding strengths and weaknesses assists in the interpretation of findings. Strengths become a solid foundation, while weaknesses become pivotal points for further clarification and research. The critique applies to methodology, design, analysis, results, interpretation, writing style and impact on readership. This appendix places little emphasis on the appraisal of findings and outcomes, which has already been presented in Section 7.5.

Background: The manuscripts have met certain standards by undergoing peer review with publication. However, given the variations between journal standards and reviewers, further self-reflection and critique post publication is warranted. Moreover, self-critique is an integral aspect of the academic mindset, a meta-cognitive process that has benefits for the author beyond the realms of a single publication or thesis. Self-critique is translatable and less biased when based on validated and standardised assessment tools. As mentioned in the opening quotation, relevant evaluation tools are available according to various study types.

Methods: The tools and checklists used in this section include the Cochrane RoB 2, PRISMA, AMSTAR 2, SIGN, STRICTA, CONSORT and the European Patients’ Academy on Therapeutic Innovation (EUPATI) checklist. If no developed standard assessment tool was available, an appropriate guide for assessing quality was chosen from the literature. Utilising these tools, the manuscripts presented in this thesis are compared with recent relevant articles.

Content: This section comprises a self-critique of the five publications included in this thesis:

- **Section A.** Does acupuncture have a role in providing analgesia in the emergency setting? A systematic review and meta-analysis.
- **Section B.** Does ear acupuncture have a role for pain relief in the emergency setting? A systematic review and meta-analysis.
- **Section C.** Patient attitudes towards analgesia and their openness to non-pharmacological methods such as acupuncture in the emergency department’.
- **Section D.** Lessons learned in teaching battlefield (ear) acupuncture to emergency medicine clinicians.
• **Section E.** Battlefield acupuncture added no benefit as an adjunct analgesic in ED for abdominal, low back or limb trauma pain.

**Conclusions:** Conclusions are made for each manuscript and provided at the end of each section. Key points from these conclusions have been extracted and placed under Section 7.4.
Section A

Outline

This section assesses the strengths and weaknesses of the following article: Jan AL, Aldridge ES, Rogers IR, Visser EJ, Bulsara MK, Niemtzow RC. Does acupuncture have a role in providing analgesia in the emergency setting? A systematic review and meta-analysis. Emerg. Med. Australas. 2017; 29(5): 490–8.

First, the importance and limitations of the review are discussed.1 Next, the review is compared with three similar concurrent reviews using AMSTAR 2 and Møller and Myles’s criteria for methodological quality.2,3 In their paper ‘What makes a good systematic review and meta-analysis?’, Møller and Myles include many but not all AMSTAR 2 parameters.4 For reporting standards, the PRISMA checklist is used.4 Both AMSTAR 2 and PRISMA are recommended by the NHMRC.5 Finally, the limitations imposed by word count and details of external researchers that have cited this publication are discussed.

Importance

Given the significant adverse effects from current ED pharmacological analgesics such as opioids and the need for alternative evidence-based analgesics, this review was of high importance. To date, the role of acupuncture in the ED environment is yet to be clarified. Given the limitations in the systematic review by Kim et al.,6 we saw the need to repeat and improve on it. The emergency medicine community needs high-quality systematic reviews and meta-analyses, the most highly ranked type of evidence for establishing guidelines on standards of care in ED pain management.7,8

Limitations

The limitations of this review included difficulties in ensuring the accurate translation of foreign language publications. The review was not preregistered with PROSPERO;9 however, the protocol was included in the PhD proposal. Subgroup analyses were not part of the original protocol but were included post hoc following recommendations by journal reviewers. Further, the review covered only a limited range of painful conditions. Our three meta-analyses had high heterogeneity, with forest plot I-squared values of 39.9%, 83.8% and 84.0%, respectively. The higher values may have been attributable to variations in demographics, sample size, time
intervals, acupuncture points, drug comparators and types of conditions. Because of this heterogeneity, a random effects model was used.

**Methodological quality**

Two aspects should be considered in the assessment of a systematic review. The first is whether included RCTs have sufficient quality, power, sample size and homogeneity to make valid conclusions. The second is whether the authors used appropriate methods, as recommended by AMSTAR 2, to design the study and analyse and interpret the findings. High-quality study design includes the use of PICO and the selection of inclusion criteria relevant to the research question. Analysis involves the use of appropriate statistical methods for forest plots. Interpretation involves considering the risk of bias, heterogeneity and conflicts of interest. If the risk of bias of the included RCTs were highly variable, then interpretation needs to be adjusted. Likewise, heterogeneity of studies also requires explanation and discussion. At the same time, conflicts of interest must be declared.

Three similar acupuncture reviews on acute pain management in the ED were published prior to and concurrently with our systematic review. In chronological order, these are:


- Lam, P. Integrating acupuncture into emergency department care: a systematic review [masters’ thesis]. Hong Kong: University of Hong Kong; 2016.


Standards for assessing the quality of systematic reviews are continually evolving, and more is expected from systematic review authors. AMSTAR is the most widely used tool for evaluating the methodological quality of systematic reviews. AMSTAR 2 was introduced following our publication on 21 September 2017. AMSTAR 2 added criteria to AMSTAR 1 on review design, analysis and interpretation of findings. However, AMSTAR 2 still has deficiencies such as details on the expertise and experience of the authors. Thus, we supplemented the AMSTAR 2 tool with additional parameters proposed by Møller and Myles.
**AMSTAR 2**

This section discusses the strengths and weaknesses of the publication compared with similar studies based on AMSTAR 2 criteria. The PICO format was used in two of the studies. Although we did not use PICO, we provided this information in an unstructured format. None of the reviews was preregistered with an international database such as PROSPERO. However, a protocol was developed for all reviews prior to being conducted. We provided an explanation for the inclusion of uncontrolled studies to substantiate secondary outcomes. Kim et al. and Lam included uncontrolled studies because of the envisaged paucity of RCTs.\(^6,11\)

All reviews except one (Kim et al.\(^6\)) used at least seven databases. Although Lam\(^11\) and Chia et al.\(^12\) included Chinese databases, their reviews included fewer RCTs compared with ours. Study selection and extraction were performed in duplicate in both our and Chia et al.’s review. All reviews described the included studies, assessed the risk of bias appropriately and commented on funding and conflicts of interest. Two reviews cited excluded studies, but we and Kim et al. provided reasons and numbers only.

Our review was the only one to include meta-analyses. Publication bias was reduced by searching the grey literature for conference proceedings, meeting abstracts and theses. However, funnel plot analysis was not performed. Funnel plots are not considered gold standard and are unreliable in many circumstances, especially when there are fewer than 10 studies in a meta-analysis.\(^15\) We grouped RCTs according to three study designs: acupuncture versus sham acupuncture, acupuncture versus SAC and adjunctive acupuncture versus SAC alone. Because each group contained small numbers of RCTs, funnel plot analysis would have been unreliable.\(^15\) We also discussed the impact of lower-quality studies on forest plot interpretation.

**Summary of strengths and weaknesses using AMSTAR 2**

All studies could have been improved by preregistration with PROSPERO. Preregistration fixes the protocol, preventing post-hoc changes and adding another layer of peer review. Our article may have been improved had research questions been presented in the formal PICO format and excluded studies had been listed. Nevertheless, overall, our review outscored the other reviews using the AMSTAR 2 checklist. Table A7-1 summarises the strengths and weaknesses of the publication compared with similar studies based on AMSTAR 2 criteria.
Table A7-1: AMSTAR 2: Comparison of Systematic Reviews on All Forms of Acupuncture

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</tr>
</thead>
<tbody>
<tr>
<td>1. Did the research questions and inclusion criteria for the review include the components of PICO?</td>
<td>×</td>
<td>×</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>3. Did the review authors explain their selection of the study designs for inclusion in the review?</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>×</td>
</tr>
<tr>
<td>4. Did the review authors use a comprehensive literature search strategy?</td>
<td>✓ 7 data bases and grey</td>
<td>✓ 4 data bases</td>
<td>✓ 7 data bases including 2 Chinese</td>
<td>✓ 6 databases including 2 Chinese</td>
</tr>
<tr>
<td>5. Did the review authors perform study selection in duplicate?</td>
<td>✓</td>
<td>×</td>
<td>×</td>
<td>✓</td>
</tr>
<tr>
<td>6. Did the review authors perform data extraction in duplicate?</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>7. Did the review authors provide a list of excluded studies and justify the exclusions?</td>
<td>✓ number and justification provided only</td>
<td>✓ number and justification provided only</td>
<td>✓ details provided</td>
<td>details provided</td>
</tr>
<tr>
<td>8. Did the review authors describe the included studies in adequate detail?</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>10. Did the review authors report on the sources of funding for the studies included in the review?</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>11. If meta-analysis was performed, did the review authors use appropriate methods for statistical combination of results?</td>
<td>✓</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?</td>
<td>✓</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>13. Did the review authors account for RoB in primary studies when interpreting/discussing the results of the review?</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?</td>
<td>✓</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Note: Critical domains are shaded. AMSTAR: Assessment of Multiple Systematic Reviews; PICO: problem/patient/population, intervention, comparator and outcomes; RoB: risk of bias, PROSPERO: Prospective Register of Systematic Reviews; -: partial completion.
This section discusses the strengths and weaknesses of the publication based on additional criteria recommended by Møller and Myles. Our review included studies in multiple languages and those on acute pain conditions typically seen in settings other than the ED, thus had the most studies. The number of RCTs, observational studies and patients for each review is as follows:

- Jan et al.: 19 RCTs, 11 observational studies, 3,169 patients.
- Kim et al.: two RCTs, two observational studies, 205 patients.
- Lam: four RCTs, two controlled trials, one observational study, 887 patients.
- Chia et al.: six RCTs, 651 patients.

Ours was the only study to include a statistician as co-author. All except one of the reviews included a subject expert (acupuncturist) as a co-author. Our team was the only one to have an investigator from an included trial. The other three reviews appeared to ask diverse research questions and explore multiple therapeutic possibilities for acupuncture (e.g. nausea, cardiac arrest and hypertension), thus precluding meta-analysis or meaningful conclusions on primary or secondary outcomes. Because our review was focused on analgesia, we obtained useful findings on acupuncture as a standalone analgesic, costs, adverse effects and patient satisfaction.

**PRISMA**

The PRISMA checklist is used to evaluate the quality of reporting of systematic reviews. Many of the PRISMA issues in our review compared with other reviews have been discussed under the AMSTAR 2 criteria. Our review did not use the PICO format for included studies and outcomes. Given the paucity of RCTs identified in the comparator studies, no principal study measures or summary data were reported. Specialised software such as Covidence is now available to assist with PRISMA compliance and reduce the time and labour preparing for a systematic review. Table A7-2 summarises the strengths and weaknesses of the publication compared with similar studies based on PRISMA criteria.
Table A7-2: PRISMA: Comparison of Systematic Reviews on All Forms of Acupuncture

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</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td>1. Identify the report as a systematic review, meta-analysis, or both.</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>ABSTRACT</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured summary</td>
<td>2. Provide a structured summary including, as applicable: background, objectives, data sources, study eligibility criteria, participants, and interventions, study appraisal and synthesis methods, results, limitations, conclusions and implications of key findings, systematic review registration number.</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>INTRODUCTION</strong></td>
<td>3. Describe the rationale for the review in the context of what is already known.</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td>4. Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICO).</td>
<td>~ unstructured but not in PICO format</td>
<td>×</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Protocol and registration</td>
<td>5. Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration in formation including registration number.</td>
<td>~ protocol part of PhD proposal but not PROSPERO</td>
<td>×</td>
<td>~ pre-established protocol but not PROSPERO</td>
<td>~ pre-established protocol but not PROSPERO</td>
</tr>
<tr>
<td>Eligibility criteria</td>
<td>6. Specify study characteristics (e.g., PICO, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Information sources</td>
<td>7. Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Search</td>
<td>8. Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.</td>
<td>✓</td>
<td>✓</td>
<td>~ gave two terms and the rest as 'variations'</td>
<td>✓</td>
</tr>
<tr>
<td>Study selection</td>
<td>9. State the process for selecting studies (e.g., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Data collection process</td>
<td>10. Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Data items</td>
<td>11. List and define all variables for which data were sought (e.g., PICO, funding sources) and any assumptions and simplifications made.</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Risk of bias in individual studies</td>
<td>12. Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Summary measures</td>
<td>13. State the principal summary measures (e.g., risk ratio, difference in means).</td>
<td>✓</td>
<td>✓ only 2 RCTs with qualitative summary</td>
<td>✓ 4 varied RCTs with qualitative summary</td>
<td>✓ 6 varied RCTs with qualitative summary</td>
</tr>
<tr>
<td>Synthesis of results</td>
<td>14. Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I²) for each meta-analysis.</td>
<td>✓</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
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</table>
Table A7-2 (cont.)

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</thead>
<tbody>
<tr>
<td>Risk of bias</td>
<td>15. Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Additional</td>
<td>16. Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.</td>
<td>✓</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>analyses</td>
<td></td>
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<tr>
<td>RESULTS</td>
<td></td>
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</tr>
<tr>
<td>Study selection</td>
<td>17. Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Study</td>
<td>18. For each study, present characteristics for which data were extracted (e.g., study size, PICO, follow-up period) and provide the citations.</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>characteristics</td>
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<tr>
<td>Risk of bias</td>
<td>19. Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).</td>
<td>✓</td>
<td>× only 2 RCTs with qualitative summary</td>
<td>× 4 varied RCTs with qualitative summary</td>
<td>× 6 varied RCTs with qualitative summary</td>
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<tr>
<td>within studies</td>
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<tr>
<td>Results of</td>
<td>20. For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>individual</td>
<td></td>
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<tr>
<td>studies</td>
<td>21. Present results of each meta-analysis done, including confidence intervals and measures of consistency.</td>
<td>✓</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Risk of bias</td>
<td>22. Present results of any assessment of risk of bias across studies (see Item 15).</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>across studies</td>
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</tr>
<tr>
<td>Additional</td>
<td>23. Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).</td>
<td>✓</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>analysis</td>
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<tr>
<td>DISCUSSION</td>
<td></td>
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<tr>
<td>Summary of</td>
<td>24. Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).</td>
<td>✓</td>
<td>×</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>evidence</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Limitations</td>
<td>25. Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Conclusions</td>
<td>26. Provide a general interpretation of the results in the context of other evidence, and implications for future research.</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>FUNDING</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Funding</td>
<td>27. Describe sources of funding for the systematic review and other support (e.g., supply of data), role of funders for the systematic review.</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Note: PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; PICO: problem/patient/population, intervention, comparator and outcomes; PROSPERO Prospective Register of Systematic Reviews; -: partial completion.

Appendix 264
Journal word limits

Journal word limits may also influence assessment. The lower the word limit, the greater the challenge in including the multiple dimensions required of a review. *Emergency Medicine Australasia* (which published our review) limits systematic reviews to 3,000 words, *Complementary Therapies in Medicine* (Kim et al.) to 3,500 words and *Acupuncture in Medicine* (Chia et al.) to 4,000 words. There is no word limit for a thesis publication (Lam).

Citations and impact

The number of citations is a further indicator of a publication’s impact and quality but does not necessarily account for dimensions such as originality, plausibility and societal value. The number of citations is also dependent on time since publication. It may be argued that a non-mainstream medical modality such as acupuncture has fewer financial incentives and inherent in-group and cognitive biases, generating fewer citations. Interest often depends on the number of people working in that specific area. Therefore, there may be fewer citations because there are few emergency physicians trained in acupuncture. Acupuncture has the potential to have a significant impact on society, reducing dependence on opioids and generating a new medical philosophy, but it may not have the citation numbers. With these provisos in mind, I discuss the number of citations and, more importantly, how our review has been used.

To date (27 September 2020), we have had 13 Google Scholar citations, while the older study by Kim et al. has had 17, Lam’s has had zero and Chia et al.’s has had four. The reason for the citations of our publication can be readily identified in four of these 13 citations. The value of the paper is reflected in part by who cited it and in what context. Five reviews have cited our publication. The first is a recently published fifth edition book on the scientific evidence for acute pain management. The second is an American white paper advocating non-pharmacological methods to assist in the management of the opioid crisis. There have been two narrative reviews on ED acupuncture, one for nurse practitioners and the other for emergency clinicians. The final review was on advances in acupuncture analgesia.

Conclusion

The weaknesses of our systematic review include the fact that it was not preregistered, it did not use the structured PICO format for study selection and outcomes and it only provided the number of excluded studies. Its strengths were that it was conducted by a high-profile panel of co-authors...
(including a statistician, content expert and prior investigator of an included trial) and it included a high number of RCTs and a meaningful meta-analysis. This review has made a significant impact by informing several subsequent reviews on the role of acupuncture for acute pain in the ED environment. Unlike its comparators, its focused research question enabled a meaningful result for the primary outcome — effectiveness of acupuncture as a standalone analgesic. Useful findings on secondary outcomes such as cost, risk profile and patient satisfaction were also obtained.
Section B

Outline

This section assesses the strengths and weaknesses of the following article: Jan A, Aldridge E, Rogers I, Visser E, Bulsara M, Niemtzow R. Does ear acupuncture have a role for pain relief in the emergency setting? A systematic review and meta-analysis. Med. Acupunct. 2017; 29: 276–89.

Similar approaches were used in the assessment of the strengths and weaknesses of the systematic reviews on ear acupuncture and all forms of acupuncture. First, the importance and limitations of the review are discussed, then the review is compared with three other reviews using AMSTAR 2 and added criteria suggested by Møller and Myles. For reporting standards, the PRISMA checklist is used. A discussion of the impact of the review concludes this section.

Importance

This review was important because it continued the search for evidence on acupuncture as a potential analgesic and solution to the opioid crisis. Our prior systematic review concluded that ear acupuncture may be the most suitable form of acupuncture in the ED environment. Ear acupuncture is easy to learn, can be initiated at triage and enables other procedures to occur concurrently. To date, there are no other reviews on the use of ear acupuncture in the ED.

Limitations

A limitation of the systematic review was that the protocol was not registered with PROSPERO. Factors limiting the extrapolation of results include the low number and high heterogeneity of included RCTs and the lack of statistical significance in one of the meta-analyses. Further, the meta-analyses covered only a limited range of acutely painful conditions.

Three systematic reviews on ear acupuncture are used as comparators. Two of these are cited frequently in our review because they provide indirect evidence of ear acupuncture efficacy. The third is a recent review of BFA:


**Methodological quality**

**AMSTAR 2**

This section discusses the strengths and weaknesses of the publication compared with similar studies based on AMSTAR 2 criteria.

All reviews defined the research questions, but none used the PICO format.10 None of the systematic reviews were preregistered with PROSPERO. Our study was the only one to group RCTs according to study design for the meta-analyses (i.e. acupuncture v. sham acupuncture, acupuncture v. SAC and acupuncture as an adjunct v. SAC). The other three used mixed design types in the one meta-analysis against control. This design issue is relevant because Yeh et al. recommended the use of ear acupuncture as an adjunctive therapy but did not include a specific meta-analysis of this study design.25 Murakami et al. included a meta-analysis of pharmacological analgesia requirements, which supports a potential opioid reduction in the ED.24 Yeh et al. grouped meta-analyses by mode of ear intervention and pain relief duration (from immediate to 48 hours), which was informative in terms of the onset and durability of analgesia.25 Yang et al. divided meta-analyses into acute and chronic pain but did not define these terms.26 Unfortunately, Yang et al. made some gross errors in the extraction of data from the RCTs.26 Data from two of the three RCTs included in the acute pain meta-analysis were incorrect. The third study in the meta-analysis used pain measures at 4 weeks. These flaws prompted a letter to the editor (see Chapter 5 Appendix, Section D).

All reviews, except for Yang et al.’s, performed study selection in duplicate, measured the risk of bias and discussed the impact of meta-analyses.26 Yeh et al. searched an additional three Chinese databases (making their review more comprehensive than ours), provided a list of excluded studies, conducted a subgroup meta-analysis to reduce heterogeneity and performed a funnel plot assessment but did not comment on their data extraction methodology.25 Murakami et al. did not declare conflicts of interest or funding, gave no explanation of heterogeneity and
made no exploration for publication bias. We grouped the RCTs for meta-analysis by study design and performed a grey literature search for unpublished works.

**Summary of strengths and weaknesses using AMSTAR 2**

Therefore, according to AMSTAR 2, our study could have been improved by preregistration with PROSPERO, using more databases and providing a detailed listing of all excluded studies. Funnel plot analysis would have been unreliable given the few studies used in the meta-analyses, thus would not have added to the review. The research team included the appropriate expertise.

Table A7-3 summarises the strengths and weaknesses of the publication compared with similar studies based on AMSTAR 2 criteria.

**Møller and Myles**

Based on the additional criteria by Møller and Myles, the numbers of patients included in the meta-analyses were 802 (Yeh et al.), 344 (Yang et al.), 636 (Murakami et al.) and 281 (Jan et al.). However, our review included RCTs in the emergency setting only, which restricted the number of RCTs. All review teams included content experts, but both Murakami et al. and Yang et al. had no statisticians or co-authors from an included RCT in their teams.

**PRISMA checklist**

The PRISMA checklist did not highlight any further significant issues raised by the AMSTAR 2 tool. All reviews used an unstructured PICO for study selection and outcomes, none used the preregistered PROSPERO database, and each author used a different risk of bias tool. Yeh et al. did not provide individual study bias assessments, and Murakami did not designate funding.

Table A7-4 summarises the strengths and weaknesses of the publication compared with similar studies based on the PRISMA checklist.
Table A7-3: AMSTAR 2: Comparison of Systematic Reviews on Ear Acupuncture

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</thead>
<tbody>
<tr>
<td>1. Did the research questions and inclusion criteria for the review include the components of PICO?</td>
<td>Unstructured; not in PICO format</td>
<td>Unstructured; not in PICO format</td>
<td>Unstructured; not in PICO format</td>
<td>Unstructured; not in PICO format</td>
</tr>
<tr>
<td>2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review, and did the report justify any significant deviations from the protocol?</td>
<td>Protocol part of PhD proposal but not registered with PROSPERO</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>3. Did the review authors explain their selection of the study designs for inclusion in the review?</td>
<td>✓</td>
<td>X</td>
<td>X</td>
<td>✓</td>
</tr>
<tr>
<td>4. Did the review authors use a comprehensive literature search strategy?</td>
<td>Seven databases and grey literature</td>
<td>Eight databases and systematic reviews</td>
<td>10 databases and systematic reviews, including three Chinese</td>
<td>Four databases</td>
</tr>
<tr>
<td>5. Did the review authors perform study selection in duplicate?</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>6. Did the review authors perform data extraction in duplicate?</td>
<td>✓</td>
<td>✓</td>
<td>Not mentioned</td>
<td>✓</td>
</tr>
<tr>
<td>7. Did the review authors provide a list of excluded studies and justify the exclusions?</td>
<td>Number and justification provided only</td>
<td>Number and justification provided only</td>
<td>Details provided</td>
<td>Number only</td>
</tr>
<tr>
<td>8. Did the review authors describe the included studies in adequate detail?</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>9. Did the review authors use a satisfactory technique for assessing the risk of bias in individual studies that were included in the review?</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>10. Did the review authors report on the sources of funding for the studies included in the review?</td>
<td>✓</td>
<td>X</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>11. If meta-analysis was performed, did the review authors use appropriate methods for statistical combination of results?</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Mixed trial designs and undefined time periods</td>
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<tr>
<td>12. If meta-analysis was performed, did the review authors assess the potential impact of risk of bias in individual studies on the results of the meta-analysis or other evidence synthesis?</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>13. Did the review authors account for risk of bias in primary studies when interpreting/discussing the results of the review?</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>15. If they performed quantitative synthesis, did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?</td>
<td>Grey literature, conference proceedings, no funnel plot</td>
<td>✗</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Note: Critical domains are shaded. AMSTAR: Assessment of Multiple Systematic Reviews; PICO: problem/patient/population, intervention, comparator and outcomes.
Table A7-4: PRISMA: Comparison of Systematic Reviews on Ear Acupuncture

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<tbody>
<tr>
<td><strong>TITLE</strong></td>
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</tr>
<tr>
<td>Title</td>
<td>1. Identify the report as a systematic review, meta-analysis, or both.</td>
<td>✔</td>
<td>✔</td>
<td>❌</td>
<td>✔</td>
</tr>
<tr>
<td><strong>ABSTRACT</strong></td>
<td></td>
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<tr>
<td>Structured summary</td>
<td>2. Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria; participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.</td>
<td>✔</td>
<td>✔</td>
<td>❌</td>
<td>❌</td>
</tr>
<tr>
<td><strong>INTRODUCTION</strong></td>
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<tr>
<td>Rationale</td>
<td>3. Describe the rationale for the review in the context of what is already known.</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Objectives</td>
<td>4. Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICO).</td>
<td>~ unstructured but not in PICO format</td>
<td>~ unstructured but not in PICO format</td>
<td>~ unstructured but not in PICO format</td>
<td>~ unstructured but not in PICO format, no time definitions</td>
</tr>
<tr>
<td><strong>METHODS</strong></td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Protocol and registration</td>
<td>5. Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.</td>
<td>~ protocol part of PhD proposal but not PROSPERO</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
</tr>
<tr>
<td>Eligibility criteria</td>
<td>6. Specify study characteristics (e.g., PICO S, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Information sources</td>
<td>7. Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Search</td>
<td>8. Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Study selection</td>
<td>9. State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Data collection processes</td>
<td>10. Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Data items</td>
<td>11. List and define all variables for which data were sought (e.g., PICO S, funding sources) and any assumptions and simplifications made.</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Risk of bias in individual studies</td>
<td>12. Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.</td>
<td>✔ (Cochrane)</td>
<td>✔ (PEDro)</td>
<td>✔ (ter Riet quality score)</td>
<td>✔ (Cochrane)</td>
</tr>
<tr>
<td>Summary measures</td>
<td>13. State the principal summary measures (e.g., risk ratio, difference in mean).</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Synthesis of results</td>
<td>14. Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>❌</td>
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<tr>
<td>Risk of bias across studies</td>
<td>15. Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).</td>
<td>✓ (Cochrane)</td>
<td>✓ (PEDro)</td>
<td>✓ (see RQ quality score)</td>
<td>✓ (Cochrane)</td>
</tr>
<tr>
<td>Additional analyses</td>
<td>16. Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.</td>
<td>N/A</td>
<td>N/A</td>
<td>✓</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**RESULTS**

| Study selection | 17. Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram. | ✓ | ✓ | ✓ | ✓ |
| Study characteristics | 18. For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations. | ✓ | ✓ | ✓ | time period not stated |
| Risk of bias within studies | 19. Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12). | ✓ | ✓ | ✓ (pooled results only) | ✓ |
| Results of individual studies | 20. For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot. | ✓ | ✓ | ✓ | ✓ |
| Synthesis of results | 21. Present results of each meta-analysis done, including confidence intervals and measures of consistency. | ✓ | ✓ | ✓ | ✓ |
| Risk of bias across studies | 22. Present results of any assessment of risk of bias across studies (see Item 15). | ✓ | ✓ | ✓ | ✓ |
| Additional analysis | 23. Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]). | N/A | N/A | ✓ | N/A |

**DISCUSSION**

| Summary of evidence | 24. Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers). | ✓ | ✓ | ✓ | ✓ |
| Limitations | 25. Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias). | ✓ | ✓ | ✓ | ✓ |
| Conclusions | 26. Provide a general interpretation of the results in the context of other evidence, and implications for future research. | ✓ | ✓ | ✓ | ✓ |

**FUNDING**

| Funding | 27. Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. | ✓ | ✓ | ✓ | ✓ |

Note: PICO: problem/patient/population, intervention, comparator and outcomes; PROSPERO: Prospective Register of Systematic Reviews; --: partial completion.
Citations and impact

Comparing the numbers of citations with the other two reviews is problematic because the use of ear acupuncture is more established in perioperative and outpatient settings than in emergency medicine. Nevertheless, as of 5 January 2020, our review had 20 Google Scholar citations, Murakami et al. had 40, Yang et al. had zero and Yeh et al. had 84. The publishing journal promoted our review as a high-impact article. Interpretation is variable on what a high impact article is. In our case this was due to the high number of downloads. (see Chapter 3 Appendix, Section C).

Our review has been frequently cited and includes the following reviews: Acute Pain Management: Scientific Evidence (5th edn.) by the Australian and New Zealand College of Anaesthetists, a recent systematic review and meta-analysis on BFA, and another on the adverse effects of ear acupuncture. It has also been cited in various trials, observational studies, protocols, case reports and an editorial letter.

Conclusion

Our study was the first systematic review of studies specifically on the use of ear acupuncture for pain relief in the ED. It used a similar methodology to the systematic review on all forms of acupuncture and contained similar weaknesses, including the lack of a formal PICO format or preregistration. The lack of studies on ear acupuncture in the ED limited the strength of our conclusions. This limitation provided an impetus for further research, including our RCT. This article was of high impact, likely because of the popularity of BFA use and courses in the US.
Section C

Outline

This section assesses the strengths and weaknesses of the following article: Jan AL, Aldridge ES, Rogers IR, Visser EJ, Bulsara MK, Hince DA. Patient attitudes towards analgesia and their openness to non-pharmacological methods such as acupuncture in the emergency department. Emerg. Med. Australas. 2019; 31: 475–8.

There are no standardised tools or checklists for assessing medical questionnaires. However, I have critiqued this publication according to the guidelines presented by Tsang et al.40 This paper is titled, ‘Guidelines for developing, translating, and validating a questionnaire in perioperative and pain medicine’. The critique will include their domains of content validity, construct validity and reliability. Similar to prior sections, I discuss the importance and limitations, citations and impact of the publication.

Importance

There is a growing faction within the ED medical community that is prioritising alternatives to opioids, including non-pharmacological methods, in the ED analgesic armamentarium.41,42 Guidelines for acute pain management are changing. The Annals of Internal Medicine and the Medical Journal of Australia have published guidelines for the treatment of acute back pain, recommending that non-pharmacological therapies such as acupuncture be the first-line treatment and downgrading opioids.43,44 However, for the community to achieve successful opioid reduction, patients must also be both cognisant of and motivated towards this change. This survey provided important evidence about patient perspectives. For changes in emergency physician prescribing habits to occur, we need to know how willing patients are to use non-pharmacological analgesic modalities.45

To date, no published surveys have examined patient attitudes towards addiction concerns to ED administered opioids or non-pharmacological methods such as acupuncture. However, there are publications on ED patients’ addiction concerns to take-home opioid prescriptions,46 and the rate of consent to acupuncture in observational studies.47-49
Limitations

Our study had several weaknesses, including the use of a convenience sample, the use of an unvalidated questionnaire, the distribution of the questionnaire shortly following analgesia and the post-hoc analysis. Although the questionnaire was not formally validated, it underwent many aspects of validation, which involves the assessment of content validity, construct validity and reliability (discussed in the following section).40

Methodological quality

Content validity

Content validity, which is usually performed by a panel of experts, assesses whether questions are representative of the theoretical construct, are understandable and answerable by patients, cover the essential facets of patients presenting with pain to the ED, do not violate patient privacy and answer the research questions.40 Our research team took on the role of the panel of experts. Each co-author had specialised survey experience in the areas of pain, emergency medicine and statistical analysis. Questions were based on the wording of another questionnaire validated by the American Pain Society but were carefully modified to align with our research questions on non-pharmacological modalities, adverse effects and addiction.50 Further, the co-authors ensured that questions were easy to understand and answer. The eight items aimed to cover all phases of the patient journey, including analgesia received prior to ED attendance, patient satisfaction with the analgesia received, attitudes towards and acceptance of non-pharmacological analgesia and acupuncture, side effects of administered medications and concerns about addiction. The collection of data approximately one hour post analgesia was both a strength and a weakness. Its strength was that it enabled a high response rate—of the 202 surveys distributed, there were only six refusals. However, individual attitudes are likely to change over time. Surveying patients one hour following analgesia may not have been representative of the entire ED stay, on which our theoretical construct was based. For example, adverse effects may be perceived as less important once they have passed. Likewise, non-pharmacological methods have been shown to be more satisfying once pain has resolved.51

No pilot study for this questionnaire was performed. Pilot studies are a further way to test content validity, but it was decided that the questions were sufficiently robust to preclude further evaluation.
Ethics approval for the study ensured patient privacy. Questions were aimed at predicting the acceptance of acupuncture, choosing three prevalent pain conditions seen in the ED for the upcoming RCT and obtaining information about opioid attitudes, use and adverse effects.

**Construct validity**

Construct validity assesses whether the questionnaire tool can consistently and accurately measure what it purports to measure. In our study, this was patient attitudes and satisfaction. Consistently accurate tools are more likely to have been used in multiple surveys and persist over time. Our questionnaire used Likert scales, which were developed in 1932 and have since stood the test of time.\(^5^2\) Likert scales are frequently used in pain medicine, emergency medicine and satisfaction surveys and have an excellent correlation with global subjective outcomes.\(^5^0,5^3–5^6\) To determine the accuracy of the questionnaire, we would have had to compare it with a detailed questionnaire on patient satisfaction with ED pain management, which has never been done. Six-point Likert scales rather than five were used (removes the category of uncertain), to enable binary logistic regression analysis while maintaining a quantitative measure of patient attitudes and satisfaction. In six-point scales, satisfaction responses are typically skewed towards higher scores, which we accommodated by distinguishing between a score of 6 (*very satisfied*) and a score of 5 (*satisfied*) in our analyses.

**Reliability**

Reliability is the third critical component in a validated questionnaire. Reliability considers the extent that the questionnaire tool elicits consistent results both between survey personnel and for retests.\(^4^0\) The questionnaire was validated for inter-rater reliability. Using logistic regression analysis, we compared patient satisfaction scores for acupuncture performed by doctors versus that performed by nurses and research assistants and found a non-significant difference (\(p = 0.38\)). However, a more acceptable statistical method would be to use kappa statistics.\(^4^0\) Measuring test-retest reliability would not have been possible because participants were surveyed for a once-only acute pain episode with one specific time point.\(^4^0\) Missed or misunderstood questions was not an issue because the questionnaire was administered as a direct interview by ED healthcare workers, enabling clarification of items if needed.

Survey reliability also depends on sample size, with larger samples having greater statistical power and reducing variability.\(^4^0\) Based on recommendations by Tsang et al.\(^4^0\) our eight-question survey would need a sample size of at least 40 participants, with 200 being a fair number. Similar
patient satisfaction and pain management questionnaires have used sample sizes ranging from 54 to 191 for single-centre surveys.\textsuperscript{57-60} The probability of convenience sampling errors arising from investigator availability is small because we ensured sampling took place on each day and evening (nights were excluded), and eligibility criteria were relatively specific (i.e. triage score of 3–5 and NPRS of $\geq 4/10$). However, because this study was carried out in a single private ED, a multicentre study that included public EDs would be more representative of the general population.

This study’s reliability is further demonstrated by the fact that the results were largely consistent with those of other studies. However, this assumes similar survey tools, patient demographics and case mix. Results that were not consistent add to the body of knowledge and invite further research to establish the true measure within a specified setting (see Table A7-5). The outcomes that were consistent with other surveys included the willingness of ED patients to accept acupuncture,\textsuperscript{47-49} women being more willing than men to receive acupuncture and non-pharmacological analgesic modalities,\textsuperscript{47} the achievement of adequate analgesia (defined as a reduction in NPRS-10 of $\geq 2$ and to $< 4$)\textsuperscript{56} and the lack of association between patient satisfaction and opioid administration.\textsuperscript{61,62} There was a higher rate of opioids use in the ED in our study compared with others. Bhakta and Marco’s study in Wisconsin used similar sample selection criteria, but opioid administration rate was lower at 40%.\textsuperscript{62} Fry et al.’s multicentred Australian survey also had lower opioid administration rates, but sampling was based on different conditions and eligibility criteria.\textsuperscript{63} Patients in our survey were less concerned about opioid addiction than those in an American study,\textsuperscript{46} which may reflect the heightened awareness in the US compared with Australia. Adverse event rates were difficult to compare because of inconsistent severity classification and variations in sampling. There were significantly fewer adverse reactions to opioids in another Australian study.\textsuperscript{64} However, our study included less severe adverse reactions such as nausea and dizziness.

To date (12 December 2020), there have been two citations of this article. This low number may be because of its recent publication and for similar reasons described for the systematic review on the role of acupuncture in the ED.

Despite the apparent lack of impact, the study laid the foundations for preparing our department for the upcoming trial. This research provided previously research-naive staff with a new mindset. Excellent EDs provide high-quality patient-centred care and have the enthusiasm and
vigour to contribute to research that establishes that quality. This questionnaire also confirmed the conditions, the likely consent rate and SAC for the upcoming RCT.

**Conclusion**

This study was the first survey globally to explore the acceptability of ED acupuncture from the patient perspective. The survey asked critical and previously unasked questions concerning the shift away from opioid-based analgesia towards non-pharmacological modalities such as acupuncture in the ED. Although the survey was not formally validated, the methodology adopted included many of the validation processes that would have taken place. Despite the post-hoc analyses, the survey had predetermined outcomes, as demonstrated by the nature of the survey questions. The results confirmed patients’ willingness to use acupuncture, as shown in cohort ED studies, but elicited new findings on addiction concerns and early adverse SAC symptoms. While having few citations to date, this survey was vital in establishing the role of acupuncture from the patient perspective. This study prepared our department for the upcoming trial by exposing staff to research and establishing the RCT conditions and likely consent rate.
<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Author, year</th>
<th>ED location</th>
<th>Sample characteristics (size)</th>
<th>Results</th>
<th>Our results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate analgesia and high satisfaction</td>
<td>Taylor, 2015</td>
<td>Melbourne, Australia</td>
<td>NPRS-10 ≥ 4 (1,317)</td>
<td>42.90%</td>
<td>39.40%</td>
</tr>
<tr>
<td>Association between satisfaction and opioid use</td>
<td>Bhakta, 2014</td>
<td>Toledo, Ohio</td>
<td>NPRS-10 ≥ 4 (289)</td>
<td>No association</td>
<td>No association</td>
</tr>
<tr>
<td>Rate of opioid administration</td>
<td>Fry, 2011</td>
<td>Australia wide</td>
<td>Migraine, abdominal pain and fractured femoral neck (2,066)</td>
<td>32.70%</td>
<td>57.70%</td>
</tr>
<tr>
<td></td>
<td>Bhakta, 2014</td>
<td>Toledo, Ohio</td>
<td>NPRS-10 ≥ 4 (289)</td>
<td>40.00%</td>
<td>57.70%</td>
</tr>
<tr>
<td>Willingness to use acupuncture</td>
<td>Zhang, 2014</td>
<td>Melbourne, Australia</td>
<td>Pain and consent to acupuncture (200)</td>
<td>69.00%</td>
<td>68.90%</td>
</tr>
<tr>
<td></td>
<td>Burns, 2018</td>
<td>Milwaukee, Wisconsin</td>
<td>Triage severity 2–5 (706)</td>
<td>53.70%</td>
<td>68.90%</td>
</tr>
<tr>
<td></td>
<td>Reinstein, 2017</td>
<td>Minneapolis, Minnesota</td>
<td>Pain and anxiety (279)</td>
<td>89.00%</td>
<td>68.90%</td>
</tr>
<tr>
<td>Women’s willingness to use acupuncture</td>
<td>Zhang, 2014</td>
<td>Melbourne, Australia</td>
<td>Pain and consent to acupuncture (200)</td>
<td>Women more likely than men compared with controls</td>
<td>Acupuncture: borderline significance; non-pharmacological: significant association</td>
</tr>
<tr>
<td>Concerns about addiction</td>
<td>Conrardy, 2016</td>
<td>Chicago, Illinois</td>
<td>Discharged with oral opioids (274)</td>
<td>58.70%</td>
<td>21.40%</td>
</tr>
<tr>
<td>Adverse event rate</td>
<td>Fry, 2002</td>
<td>Sydney, Australia</td>
<td>Severe pain NPRS-10: 8.5 (349)</td>
<td>4.2% (objective: altered vital signs)</td>
<td>19.9% (subjective: nausea, dysphoria, vomiting)</td>
</tr>
</tbody>
</table>

Note: ED: emergency department; NPRS-10: numerical pain rating scale our of 10.
Section D

Outline

This section assesses the strengths and weaknesses of the following article: Jan A. Lessons learned in teaching battlefield (ear) acupuncture to emergency medicine clinicians. *Med. Acupunct.* 2020; **32**(5): 253–262.

In attempting to review this article critically, there is immediate difficulty in categorising it. From the preceding sections in this chapter, the reader will realise the number of tools available for assessing the quality and strength of research papers. However, this study differed from typical RCTs, observational studies, systematic reviews or narrative reviews, and consequently, there were no established tools available to assess it.

This manuscript takes on many aspects and includes being a chapter of a thesis, an article on lessons learned with pearls and pitfalls, a BFA description, or even a narrative review. Besides having diversity in its categorisation, it also aims to capture a varied audience. This article was aimed at several groups, including BFA instructors, acupuncturists, emergency physicians and other non-acupuncturist clinicians interested in BFA and associated acupuncture techniques. Therefore, I used a range of dimensions to evaluate this manuscript, including whether it answered any of the research questions in this thesis, its ability to assist instructors or inform curriculum development for future BFA courses, its ability to inform instructors about the nuances of applying BFA in the ED environment, whether it follows the principle of lessons learned and whether it was simple and engaging.

**Answering the research questions**

- Did the article provide useful information on training requirements for ED acupuncture?
- Is BFA teachable to emergency clinicians in a short 4-hour course?

The article demonstrates that BFA is teachable in 4 hours and provides many tips on how to do so. This argument is based on course participant feedback on satisfaction (rated 5.6/6 on the Likert scale) and their perceived competency in performing BFA by myself and faculty. It also refers to the successful and popular 4-hour courses offered in the US.

On the negative side, the article provides no data from high-quality research (see the NHMRC quality of evidence criteria in Chapter 1) on post-training BFA competency. This question would
be best answered using an RCT in which providers are randomised to one of two groups—basically trained and formally trained (qualified acupuncturists)—and that is sufficiently powered to reliably measure pain reduction and the secondary outcomes of patient satisfaction and adverse effects (particularly minor). This topic has been researched by Witt et al. for patients with chronic pain, and results were not in favour of more extended training. A lower-quality study could investigate a standard of competency of students following the course. Assessments measures might include patient selection, point location, dexterity with needle insertion and patient feedback (satisfaction and pain score reduction). Evidence aside, these suggested assessments could become a list of items for the instructor to evaluate at 6 weeks following the completion of the course to ascertain teaching and candidate competency.

- What is the minimum body acupuncture training required for practitioners to be safe and competent?

The article provides some limited evidence for the training requirements of ED clinicians performing body acupuncture. Evidence was based on participant feedback, faculty impressions and opinions of experts from other health sectors.

**Manuscript objectives**

- Does the manuscript assist instructors or inform curriculum development of future BFA courses?

This is the first paper in the global literature on how to teach BFA. It includes a range of teaching methods as well as pearls and pitfalls from my teaching experience. There have been at least 30 BFA publications to date, with four articles specifically describing the technique. The remaining articles include RCTs, observational studies, qualitative reviews, case reports, letters and articles on logistic hurdles in the military, provider and patient feedback and BFA history.

- Does the manuscript teach non-emergency medicine instructors the nuances of applying BFA in the ED setting?

Being an emergency physician, educator, researcher and acupuncturist makes me somewhat unusual. Therefore, the strength of this paper lies in the cross-pollination of skills. It introduces new ways of teaching, including infotainment, blended learning and problem-based learning, and provides in-depth EBM knowledge into the acupuncture domain. Further, instructors need to understand the clinical presentations and peculiar SAC deficits encountered by emergency
physicians. The ED environment also encompasses certain characteristics, including chaos and the need for hypervigilance to avoid errors (e.g. needle counting and taping needles securely) that non-emergency physician instructors would need to understand. The article has two quick reference tables, one to avoid adverse effects and the other on clinical indications.

- Does the manuscript assist emergency clinicians and novice acupuncturists in discovering more about the nuances of the technique?

A large proportion of my readership would be emergency clinicians who have attended the course or are interested in ED acupuncture. Therefore, with that audience in mind, it was important to include both basic and advanced skills and knowledge. Similarly, regarding the cross-pollination factor raised above, information on therapeutic touch, care, and compassion had to be carried from the acupuncture milieu to emergency medicine. This cross-pollination is of potential benefit to emergency physicians on the verge of burnout. Relearning the art of caring and bedside manner may help reduce the depersonalisation that accompanies their challenging work.70,71

**Does it follow the principles of lessons learned?**

‘Lessons learned’ is a process often used in industry projects to develop products and skills or a combination of the two.72 It is a process that identifies personnel, skills, knowledge, administration and resources, documenting and analysing these into categories such as what went well and what needs improvement. This information is stored in a form that is readily retrievable for further use on subsequent projects.72 In this case, the project was the teaching of BFA to be applied in the ED setting. It identified the personnel (i.e. who was trained and who should teach), the skills needed to treat real patients, theoretical knowledge and patient selection and resources such as needles and specialised tapes. Administrative hurdles are also discussed. From the perspective of lessons learned, this manuscript was successful.

**Simple and engaging**

- Was the manuscript simple to read? Were there too many concepts?

The reviewers’ initial criticism of the article was that it was confusing, with multiple references to BFA and body acupuncture. It was criticised for attempting to navigate concepts on intuitive or emotional learning and overcoming bias towards acupuncture. These topics were subsequently removed. It now simply urges instructors to adopt new educational advancements,
negotiate administrative hurdles and tailor the course specifically for emergency clinicians. The manuscript presents simple tables and figures on silicone ear simulation, points to be needled, a mnemonic to remember contraindications, adverse effects (and how to avoid them in the ED) and a summary of BFA trials to date.

- Was the format engaging?

The paper was written with multiple audiences in mind, ranging from non-academics to academics, acupuncturists to non-acupuncturists, emergency clinicians to non-emergency clinicians and teachers to students. So, while this paper has a formal academic layout (including background, objectives and conclusions), it also contains non-academic features. There is a shift towards conversational prose and the use of the first person. The abstract differs from those of typical scientific papers by discussing the main points rather than methods and results. I deliberately deleted potentially boring feedback results to produce a more engaging piece of writing.

**Journal word limit**

There was no word limit for this publication.

**Citations and impact**

Given the recency of this publication, no comments can be made on these parameters.

**Conclusion**

This is the first paper on how to teach ED acupuncture. The manuscript is a hybrid of various genres, including a narrative review, lessons learned, pearls and pitfalls and expert opinion. The article is difficult to compare against a standard, but it was assessed as successfully engaging a range of readers by using a straightforward prose style with many supplementary figures and tables. Further, it accomplished its objective of informing readers about modern ED teaching methods, research skills, the evidence for BFA and the subtleties of using BFA in the ED environment. Its major weakness is that it lacks high-quality evidence to answer the thesis research question, ‘Is acupuncture teachable in a basic format?’. While limited data were obtained on participant and provider satisfaction, the paper lacks data on post-training BFA and body acupuncture competency.
Section E

Outline

This section assesses the strengths and weaknesses of the randomised controlled trial: Jan AL, Aldridge ES, Rogers IR, Visser EJ, Bulsara MK, Hince DA, Suen LK, Woosey MV. Battlefield acupuncture added no benefit as an adjunct analgesic in emergency department for abdominal, low back or limb trauma pain. Emerg. Med. Australas. 2020 [advance online publication].

First, the importance and limitations of the study are discussed. Next, the study is evaluated and compared with the three most recent ED acupuncture trials using tools recommended by NHMRC. To assess methodological quality, NHMRC recommends using Cochrane RoB and the SIGN checklist. For reporting standards, NHMRC recommends the CONSORT checklist, which also has an acupuncture extension (STRICTA). The trial's value from the patient perspective is also worthwhile as the ultimate purpose of this research is to benefit patients. Hence, the EUPATI checklist is also used.

The three most recent RCTs on ED acupuncture are:


Importance

Our study was important to continue the search for non-pharmacological solutions to the opioid crisis. Further, results on the efficacy of BFA as an adjunct for acute pain in the postoperative setting have been mixed (see Table 5.2). Finally, we needed to address and
improve upon concerns about the quality of recent ED acupuncture studies.⁸⁰–⁸² Therefore a further quality BFA RCT would provide additional much-needed information.

Limitations

Blinding was incomplete and hence a limitation of this study. Nevertheless, within an acupuncture study's confines, a believable sham was provided for the patients, and assessors, data analysts, and treating clinicians were all blinded. The use of a convenience sample was a stated limitation and is discussed henceforth.

Methodological quality

Cochrane Risk of Bias 2

This section evaluates our trial against two comparators using the Cochrane RoB 2 guidelines.⁷³ Comments are listed below under the corresponding RoB 2 numbered criteria.

Sections 3.1 and 3.2: Randomisation

Our study had a low risk of randomisation bias because subjects were block randomised utilising specialised software (that enables external review) and opaque sealed envelopes. However, we did use convenience sampling based on investigator availability, which predominantly excluded night shift hours. Comparator studies describe adequate methods of randomisation. However, Fox et al.⁷⁸ did not use a random number generator and shuffled the envelopes, while Beltaief et al.⁷⁹ failed to stipulate whether randomisation envelopes were opaque. The study by Cohen et al.⁵¹ was the only comparator that stated the use of a convenience sample — a typical method employed in RCTs.⁸³ Therefore, our trial had a low risk of randomisation bias, while comparator studies had some minor concerns regarding this parameter.

Section 4: Deviations from the protocol

This section discusses bias arising from additional interventions, effect of interest, blinding and intention to treat.

Section 4.1: Additional interventions and effect of investigator interest

Our study used a fixed acupuncture protocol, unlike the other three studies. Having a flexible protocol would enable the acupuncturist to allocate more time and interest to achieve pain relief in the intervention arm. However, in clinical practice, acupuncture prescriptions vary according
to individual TCM diagnoses within a specific Western medical diagnosis.\textsuperscript{84} It is also usual practice to modify the prescription according to patient response.\textsuperscript{84} Fixed protocols apply to the trial environment to minimise treatment variations.\textsuperscript{84} The RoB tool searches for deviations from the predefined trial intervention protocol. The comparator RCTs pre-established their flexible acupuncture protocols, thus should not necessarily be marked down on this Cochrane criterion. A possible criticism of our trial was that SAC was at the discretion of the medical investigator or treating doctor. However, this variation would not alter investigator interest nor favour the acupuncture intervention.

\textit{Section 4.3: Blinding}

Our study reduced blinding bias to a minimum by including a sham group and blinding assessors and data analysts. Because the terminology for single, double and triple blinding is confusing, I have elected to describe each blinding component where relevant.\textsuperscript{85}

In acupuncture studies, patient blinding is possible using sham treatment strategies. Choices include placebo needles (e.g. Park or Streitberg) that can disguise needle penetration.\textsuperscript{86} However, studies have shown that placebo needles improve pain above usual care,\textsuperscript{87} implying that touch, acupressure or interest play some role in the therapeutic effect. Further, with sham acupuncture, blinding efficacy is mostly unsuccessful. Patients are more likely to predict their trial group allocation.\textsuperscript{89} We reduced the risk of patient blinding bias (stated in Table A7-6 as ‘some concerns only’) by including a sophisticated sham control. The anecdotal feedback from investigators was that most patients verbally or non-verbally gave the impression that they perceived our sham (piezoelectric device) as real. However, this would have been better ascertained using formal feedback. Nevertheless, the use of a sham acupuncture device was an improvement over comparative studies, and we recommend future trials to consider using this novel sham technique.

In our study, treating physicians and nurses but not trial investigators were blinded. Practitioner blinding is possible in acupuncture trials and has been achieved in two RCTs in which acupuncture-naive paramedics administered ear acupressure.\textsuperscript{90,91} However, for more complex acupuncture applications, knowledge of acupuncture is required, which precludes practitioner blinding. A fourth category of blinding may need to be applied to ED acupuncture studies involving treating physicians and nurses. These healthcare workers are usually separate from the acupuncturist and should be blinded. It is unclear from the study by Cohen et al.\textsuperscript{51} whether
the treating staff were blinded, but it is unlikely given that body acupuncture is easily recognised. In our study, the treating physicians and nurses remained unaware of patient allocation, and our protocol required the investigator to not be involved in patients’ ongoing analgesia care. Again, the blinding of treating clinicians made our study superior to all comparator studies.

Section 4.4: Intention to treat

Intention to treat was included as part of the group analysis in both our and Cohen et al.’s study.\textsuperscript{51} Intention to treat may have been an issue in Fox et al.’s RCT given that the dropout rate in the intervention group was > 20% and analysis was conducted on the reduced group size rather than on the randomised allocation number.\textsuperscript{78} Beltaief et al. did not report on whether they used intention to treat. However, withdrawal was low—four of 119 participants in total and three of 57 in the acupuncture group—thus its impact is likely to be negligible.\textsuperscript{79} Therefore, our study and that by Cohen et al.\textsuperscript{51} were superior to the other two studies for this criterion.

Section 5: Incomplete data

In our study, there were three dropouts from the intervention group, equating to 10% of participants. A dropout percentage of more than 20% is considered significant.\textsuperscript{92} Significant concerns were raised for the study by Fox et al.,\textsuperscript{78} in which four of 15 participants (27%) withdrew in the early phases of the study, and only 11 were analysed rather than 15. In the study by Cohen et al.,\textsuperscript{51} approximately 18% were lost in the second-day follow-up, which creates some concern. Beltaief et al.\textsuperscript{79} had the lowest dropout rate. Therefore, while not being the top performer, our study had a low risk of bias in this category.

Section 6: Outcome measurement bias

A significant source of bias concerning the compared RCTs is assessor blinding. This potential source of bias was not an issue in our study or that by Cohen et al.,\textsuperscript{51} but both Fox et al.\textsuperscript{78} and Beltaief et al.\textsuperscript{79} did not blind assessors.

Section 7: Selective reporting

In both our RCT and that by Cohen et al.,\textsuperscript{51} the published outcomes were equivalent to the preregistered protocols. Fox et al.\textsuperscript{78} displayed reporting bias, with an alteration of the primary outcome from the predetermined outcomes at trial registration. Initially, the primary outcome
was a functional ‘get up and go’ test, but this was changed to pain scores following trial registration. Beltaief et al.\(^7\) registered their trial following the study's completion, potentially enabling alteration of reported outcomes. Therefore, both our research and that by Cohen et al.\(^5\) had reduced bias on this criterion.

Summary of strengths and weaknesses using Cochrane RoB 2

Compared with the other studies, our study had the lowest overall bias based on Cochrane RoB 2, representing a significant strength. This was primarily attributable to our use of a sophisticated sham and blinding at multiple levels. Blinding was applied to the sham group, treating healthcare workers, assessors and analysts. The intervention was strictly standardised with adherence to a predetermined protocol, and data were subject to intention to treat analysis.

The major weakness of the study was that investigators and patients were not blinded, which is mostly not achievable in acupuncture studies with complex acupuncture prescriptions.

Table A7-6 summarises the risk of bias of our and comparator studies using the Cochrane RoB 2 tool.
Table A7-6: Cochrane Risk of Bias 2: Comparison of Recent Trials on Emergency Department Acupuncture

<table>
<thead>
<tr>
<th>Lead author, year</th>
<th>3.1 Randomisation</th>
<th>3.2 Allocation concealment</th>
<th>4.1, 4.2 Non-protocol interventions and interest</th>
<th>4.3 Patient blinding</th>
<th>4.3 Practitioner blinding</th>
<th>4.4 Intention to treat</th>
<th>5 Incomplete outcome data</th>
<th>6 Outcome measurement, inc. blinding of assessors</th>
<th>7 Selective reporting</th>
<th>Summary of bias risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fox, 2018</td>
<td>L</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>S</td>
<td>L</td>
<td>L</td>
</tr>
<tr>
<td>Beltaief, 2018</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>H</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>H</td>
<td>S</td>
<td>H</td>
</tr>
<tr>
<td>Cohen, 2017</td>
<td>L</td>
<td>S</td>
<td>S</td>
<td>H</td>
<td>H</td>
<td>S</td>
<td>L</td>
<td>S</td>
<td>H</td>
<td>H</td>
</tr>
</tbody>
</table>

Note: L: low risk of bias; S: some concern of bias; H: high risk of bias.
SIGN checklist

The SIGN checklist assesses multiple dimensions of trial quality. Many of its criteria overlap those of Cochrane RoB 2 and CONSORT 2010/STRICTA. Our study performed well across the range of SIGN parameters. SIGN parameters that differ from those of RoB 2 and CONSORT 2010/STRICTA guidelines are discussed below (see Table A7-7). The numbers in parentheses in the text below correspond to the numbers in Table A7-7.

Both our study and that of Cohen et al. had a focused research question linked to the primary and secondary outcomes (1.1). In the study by Fox et al., there is confusion whether the primary outcome is the ‘get up and go’ test, pain score difference, leg pain or range of movement. There was a change in the primary outcome between trial registration and publication. Nevertheless, given that this was an exploratory pilot feasibility study, it was appropriate to include various outcomes. Beltaief et al. registered their study following completion and had an atypical composite primary outcome, namely durable and rapid analgesia. This outcome contrasts with their initial trial registration, which stated pain score change as the primary outcome.

Our study used a 30% reduction in NPRS pain score at 30 and 60 minutes and compared acupuncture as an adjunct to SAC versus SAC alone as a secondary outcome based on NNT. Given the lack of statistically significant difference in pain scores, NNT could not be estimated. Rather than changing their primary outcome, Beltaief et al. should have used a 30% or 50% pain score reduction at 30 and 60 minutes, which are acceptable outcome measures in pain research.

Blinding is again an issue affecting the assessment of multiple criteria. It is difficult to ensure that treatment in the acupuncture groups will be equivalent when these patients can be identified by treating physicians and nurses. Our study again scored better because of this (1.6). All studies were relevant to common painful conditions presenting to the ED (2.3). Cohen et al.’s research was the only multisite study with high participant numbers, but insufficient information is provided to ascertain differences between sites (1.10).

SIGN overall assessment summary (2.4)

The SIGN overall assessment summary determines whether the researchers’ conclusions are valid. Based on SIGN, valid conclusions can only be drawn from our study and that by Cohen et al.
### Table A7-7. SIGN Assessment Tool for Randomised Trials Applied to the Four Most Recent ED Acupuncture Studies

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question</td>
<td>✓</td>
<td>✕</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised</td>
<td>✓</td>
<td>✕</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used</td>
<td>✓</td>
<td>~</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>1.4 The design keeps subjects and investigators ‘blind’ about treatment allocation</td>
<td>~</td>
<td>✕</td>
<td>✕</td>
<td>✓</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation</td>
<td>✓</td>
<td>~</td>
<td>~</td>
<td>~</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>AP + SAC: 10%, Sham + SAC: 10%, SAC: 0%</td>
<td>AP + SAC: 27%, SAC: 7%</td>
<td>AP: 5%, SAC: 2%</td>
<td>AP: T1: &lt; 2%, T48: 18%, AP + SAC: T1: 0%, T48: 20%, SAC: T1: 4%, T48: 23%</td>
</tr>
<tr>
<td>1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)</td>
<td>✓</td>
<td>✕</td>
<td>✕</td>
<td>✓</td>
</tr>
<tr>
<td>1.10 Where the study is carried out at more than one site, results are comparable for all sites</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>~</td>
</tr>
<tr>
<td>2.1 How well was the study done to minimise bias?</td>
<td>✓</td>
<td>✕</td>
<td>✕</td>
<td>✓</td>
</tr>
<tr>
<td>2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>✓</td>
<td>✕</td>
<td>✕</td>
<td>✓</td>
</tr>
<tr>
<td>2.3 Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2.4 Summary of authors’ conclusions</td>
<td>No difference for acupuncture as an adjunct</td>
<td>BFA feasible</td>
<td>Analgesic effect of acupuncture better and quicker</td>
<td>Non-inferiority of acupuncture</td>
</tr>
<tr>
<td>My summary assessment</td>
<td>Valid conclusion</td>
<td>Pilot study only, altered outcomes</td>
<td>No blinding, post-study trial registration</td>
<td>No blinding, no sham, uncertain physician blinding; valid conclusion</td>
</tr>
</tbody>
</table>

Note: Shaded rows signify parameters not covered by Cochrane Risk of Bias 2. ED: emergency department; SIGN: Scottish Intercollegiate Guidelines Network; AP: acupuncture; SAC: standard analgesia care; T1: 1 hour; T48: 48 hours; ~: partial completion.
**CONSORT 2010**

Our study outscored the other three RCTs by only having one incomplete item in the CONSORT 2010 standards checklist (see Table A7-8). Our trial did not include the term ‘randomised trial’ in the title (section 1a.). Although theirs was a pilot study, Fox et al.\(^7\) did not comment on their power calculations (section 7a), statistical methods (section 12a) or specific objectives (section 2b). Beltaief et al.\(^7\) did not report their concealment methods (section 9), blinding (section 11a) or calculation of sample size (section 7a). Cohen et al.\(^5\) did not describe allocation concealment (section 9), whether the treating physicians were blinded (section 11a) and the numbers analysed on final follow-up (section 16).

**STRICTA checklist**

Based on the STRICTA checklist,\(^7\) our study outperformed the comparators (see Table A7-9). Many of the checklist items are geared towards body acupuncture and multiple sessions, making this assessment of a single session of ED ear acupuncture problematic. Most of the deficiencies of the comparator studies centred on their flexible acupuncture protocols and failure to describe variations in prescriptions. Beltaief et al.\(^7\) and Cohen et al.\(^5\) both provided STRICTA reporting tables in their appendices, enabling a more straightforward assessment compared with providing textual information in the paper, as in our publication.
Table A7-8: CONSORT 2010: Performance of Recent Studies on ED Acupuncture

<table>
<thead>
<tr>
<th>CONSORT criteria</th>
<th>Jan et al., 2020</th>
<th>Fox et al., 2018&lt;sup&gt;8&lt;/sup&gt;</th>
<th>Beltaief et al., 2018&lt;sup&gt;9&lt;/sup&gt;</th>
<th>Cohen et al., 2017&lt;sup&gt;11&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a ‘Randomised trial’ in title</td>
<td>✗</td>
<td>✗</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>1b Structured abstract</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2a Scientific background</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2b Specific objectives</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>3a Trial design</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>4a Eligibility</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>4b Setting and location</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>5 Description of intervention</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>6a Primary and secondary outcomes</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>7a Calculation of sample size</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>8a/8b Randomisation method</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>9 Concealment method</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>10 Who implemented</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>11a Blinding</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>12a Statistical methods</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>12b Statistical additional analyses</td>
<td>✓</td>
<td>N/A</td>
<td>N/A</td>
<td>✓</td>
</tr>
<tr>
<td>13a Results—flow chart</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>14a Recruitment period</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>15 Baseline data</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>16 Numbers analysed</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>~</td>
</tr>
<tr>
<td>17a Primary and secondary outcomes</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>18 Ancillary analyses</td>
<td>✓</td>
<td>N/A</td>
<td>N/A</td>
<td>✓</td>
</tr>
<tr>
<td>19 Harms</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>20 Limitations</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>21 Generalisability</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>22 Interpretation</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>23 Trial registration</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>24 Trial protocol</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>25 Funding</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Note: Categories that are not relevant to the above studies have been excluded. ED: emergency department; CONSORT: Consolidated Standards of Reporting Trials; N/A: not applicable.
### Table A7-9: STRICTA: Performance of Recent Studies on Emergency Department Acupuncture

<table>
<thead>
<tr>
<th>Item</th>
<th>Detail</th>
<th>Jan et al., 2020</th>
<th>Fox et al., 2018</th>
<th>Beltaief et al., 2018</th>
<th>Cohen et al., 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Acupuncture rationale</td>
<td>a) Style of acupuncture (e.g. TCM, Japanese, Korean, Western, Five Element, ear acupuncture)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b) Reason for treatment provided based on historical context, literature sources and/or consensus methods, with references where appropriate</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>c) Extent to which treatment was varied</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>2</td>
<td>Details of needling</td>
<td>a) Number of needle insertions per subject per session (mean and range where relevant)</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b) Names (or location if no standard name) of points used (uni-/bilateral)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>c) Depth of insertion based on a specified unit of measurement or on a particular tissue level</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>d) Response sought (e.g. de qi or muscle twitch response)</td>
<td>N/A</td>
<td>N/A</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>e) Needle stimulation (e.g. manual, electrical)</td>
<td>N/A</td>
<td>N/A</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>f) Needle retention time</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>g) Needle type (diameter, length and manufacturer or material)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>3</td>
<td>Treatment regimen</td>
<td>a) Number of treatment sessions</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b) Frequency and duration of treatment sessions</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>4</td>
<td>Other components of treatment</td>
<td>a) Details of other interventions administered to the acupuncture group (e.g. moxibustion, cupping, herbs, exercises, lifestyle advice)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b) Setting and context of treatment, including instructions to practitioners and information and explanations to patients</td>
<td>✓</td>
<td>~</td>
<td>~</td>
</tr>
<tr>
<td>5</td>
<td>Practitioner background</td>
<td>Description of participating acupuncturists (qualification or professional affiliation, years in acupuncture practice, other relevant experience)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>6</td>
<td>Control or comparator interventions</td>
<td>a) Rationale for the control or comparator in the context of the research question, with sources that justify this choice</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b) Precise description of the control or comparator. If sham acupuncture or any other type of acupuncture-like control is used, provide details as for Items 1 to 3 above</td>
<td>✓</td>
<td>~</td>
<td>✓</td>
</tr>
</tbody>
</table>

Categories that are not relevant to the above studies have been excluded. STRICTA: Standards for Reporting Interventions in Clinical Trials of Acupuncture; ~: partial completion.
EUPATI assigns a value based on four criteria from the patient perspective: aspects of trial design, relevant endpoints, costings and consistency with prior research (see Table A7-10).77

**Trial design**

A strength of our study design was its pragmatism, with the simple addition of acupuncture or sham as an adjunct to SAC. This design ensured acceptance by ethics committees, patients and treating staff because acupuncture was merely an addition to what would have been administered. The use of a sophisticated sham and fixed acupuncture intervention to minimise bias made the study superior to its comparators, thus more acceptable by established trial standards.

There were some areas for improvement in retrospect. One weakness of our pragmatic design was that opioids were prescribed to more than half the patients prior to the acupuncture intervention, which may have negated the benefit of the acupuncture. Similarly, in the study by Cohen et al., opioids such as tramadol and dextropropoxyphene were included in the initial pre-parenteral opioid rescue regime. Both patients and clinicians are seeking to reduce the use and consequent harm of opioids.42,94 A potentially better clinical question for future researchers is whether acupuncture in addition to simple analgesia (not opioids) provides equivalent or superior analgesia.

Future trials could be improved by carefully considering the acute pain condition treated in the ED. The selection of three pain conditions commonly seen in our ED was based on a prior survey to enable the successful recruitment of numbers (see Chapter 4). However, from a patient advocacy perspective, the ideal scenario would be to choose a condition with a high risk of opioid reuse. A primary motivator for using acupuncture as a pain relief modality is to offset the harm caused by opioids. Therefore, across all studies, appropriate conditions included low back pain (Jan et al., Fox et al., Cohen et al.), recurrent renal colic (Beltaief et al.) and migraine (Cohen et al.), while inappropriate conditions included abdominal pain, limb injuries (Jan et al.) and ankle sprains (Cohen et al.). Future trials should explore neck pain, degenerative joint pain (shoulder, hip, knee) and other forms of non-catastrophic headache, all of which are common conditions for opioid prescription for non-malignant pain.95
Relevant endpoints

We used a 2-hour endpoint in our trial. Each of the three comparators used a 1-hour endpoint, which is less likely to represent analgesia for the duration of the ED stay. However, Cohen et al.\textsuperscript{51} also included a 48-hour follow-up. While our study may have been more representative of the entire ED stay, following up on the second day may have provided additional information about patient satisfaction, opioid usage, functional outcomes and pain scores. Interestingly, Cohen et al.\textsuperscript{51} found that patient satisfaction for the acupuncture intervention improved post discharge.

Costings

A surprising finding in our trial was the low wholesale cost of analgesics purchased by the hospital compared with the retail price of specialised ear acupuncture needles. The cost of filiform needles is minimal, but specialised ear acupuncture needles are relatively expensive. However, the overall cost of opioids should not be based on a face value calculation. It is estimated that 12\% of ED patients that receive a take-home prescription or supply of opioids will go on to recurrent use.\textsuperscript{96} Taking recurrent users into account, the ultimate cost of opioids will be much higher and include loss of workdays, rehabilitation, treatment of adverse effects (e.g. constipation, endocrine changes, immune suppression, sleep apnoea, depression and immune suppression), overdose and death.\textsuperscript{97} Indirect costs include legal and criminal proceedings. Well-researched estimates in the US show that patients with opioid dependence or abuse cost an extra US$14,810 per year (2017) compared with patients without abuse or dependence.\textsuperscript{98} A cost–benefit analysis will likely need to wait until ED acupuncture trials definitively show a decline in both ED and take-home opioid use.

Consistency with previous research

BFA trials have shown mixed results for pain reduction (see Chapter 5, Table 2). With its more rigorous design, our trial provides substantial authority in terms of the validity of its conclusion over others. Given its large sample size and use of multiple sites, the study by Cohen et al.\textsuperscript{51} is also a standout authoritative trial. As the quality and design of future research improves, it is expected that more clarity can be gained about the effectiveness and cost-saving potential of acupuncture.
Summary of strengths and weaknesses using EUPATI criteria.

The strength of our trial included its pragmatism and rigour in minimising bias. The compared studies mostly included painful conditions with risk of ongoing opioid dependence. Future trials need to include pain conditions for which opioids are used as a rescue and that are associated with a high risk of opioid dependence. They should also use a fixed acupuncture prescription and a sophisticated sham. If resources permit, measures should be performed post discharge (as per Cohen et al.51). An investigation of the cost benefits of acupuncture will need to wait until studies consistently show opioid reduction. Mixed results and variation in BFA trials' quality prevent definitive conclusions about its efficacy for pain reduction.
Table A7-10: EUPATI Criteria Applied to the Four Most Recent ED Acupuncture Studies

<table>
<thead>
<tr>
<th>Author, year of publication</th>
<th>Trial design</th>
<th>Patient relevance</th>
<th>Relevant endpoints</th>
<th>Benefit versus costs</th>
<th>Context of prior results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan et al., 2020</td>
<td>Acupuncture and sham as an adjunct to SAC v. SAC only</td>
<td>ED</td>
<td>Up to 2 hours</td>
<td>No immediate benefit</td>
<td>BFA giving mixed results</td>
</tr>
<tr>
<td>Fox et al., 2018</td>
<td>Acupuncture as an adjunct to SAC v. SAC only</td>
<td>ED</td>
<td>1 hour</td>
<td>No immediate benefit</td>
<td>BFA giving mixed results</td>
</tr>
<tr>
<td>Beltaief et al., 2018</td>
<td>Acupuncture v. SAC</td>
<td>ED</td>
<td>Up to 1 hour</td>
<td>Filiform needles inexpensive</td>
<td>Consistent</td>
</tr>
<tr>
<td>Cohen et al., 2017</td>
<td>Acupuncture v. acupuncture as an adjunct to SAC v. SAC</td>
<td>ED</td>
<td>Hourly until discharge and then at Day 2</td>
<td>Filiform needles inexpensive</td>
<td>Consistent</td>
</tr>
</tbody>
</table>

Note: EUPATI: European Patients’ Academy on Therapeutic Innovation; ED: emergency department; SAC: standard analgesia care, BFA: battlefield acupuncture.
Word limit

It is noteworthy that the word limit for publications in *Emergency Medicine Australasia* (Jan et al. 2020) and *Medical Journal of Australia* (Cohen at al., 2017) are 2,500 words, while the *American Journal of Emergency Medicine* and the *Journal of Pain Research* has no word limit (Fox et al., 2018 and Betlaief et al., 2018). Therefore, despite the journal’s more restrictive word limitations, our trial performed well while meeting the CONSORT 2010/STRICTA standards of reporting.

Citations and impact

Given the recency of this publication, no comments can be made on these parameters.

Conclusion

Compared with three similar studies of the efficacy of acupuncture for acute pain management in the ED, our study scored the lowest for bias on the Cochrane RoB 2 tool through its use of a sophisticated sham intervention, fixed acupuncture protocol and blinding. Our publication also outscored comparators, with fewer deficiencies in reporting criteria (i.e. sample size, allocation concealment and those administering the acupuncture) based on the CONSORT/STRICTA standards. The SIGN checklist highlighted that a valid conclusion could be drawn from our trial. The EUPATI criteria highlighted our rigorous design to reduce bias. The addition of a rigorous trial on BFA to the literature is a step towards assessing the efficacy of this acupuncture modality, establishing the standards required and providing useful data for upcoming systematic reviews on the topic.

However, our study could have been strengthened by including a STRICTA table in the appendix and using simple analgesia with opioids only for pain rescue, with the chosen painful conditions all being associated with a higher risk of ongoing opioid dependence. The use of a larger sample size and multiple sites would have also added to its strengths. Post-discharge follow-up is a crucial patient-oriented measure. Future trials in this field should address these points to enable quality input to define the role of acupuncture in emergency medicine.
Chapter 7 Appendix References


Appendix 305


60. Kelly A-M. Patient satisfaction with pain management does not correlate with initial or discharge VAS pain score, verbal pain rating at discharge, or change in VAS score in the emergency department. J. Emerg. Med. 2000; 19(2): 113–6. doi.org/10.1016/S0736-4679(00)00219-5


Appendix to Chapter 7 - Section F

Conference presentation:

- Jan A. The role of acupuncture for acute pain in the emergency setting—a PhD thesis. Presented at: The AMAC WA End of Year Seminar; 2020 Nov 28; Perth, Australia.
Is there a role for acupuncture in acute pain in the emergency setting?

- What acutely painful conditions would you treat with acupuncture and why?
- Would you use a combination, i.e. acupuncture as an adjunct to parenteral or oral analgesia? Which medication and why?
- What acupuncture methods would you use?
Why do a PhD on the topic?

• An opportunity to contrast two paradigms (i.e. Western and Chinese Medicine) which are seemingly incompatible!
• Do this by subjecting a CM modality to the arbiter of WM ie EBM
• Pain is poorly managed – we need a new way of thinking about pain
Scientific reductionist model for pain reduction

Pain

- Musculoskeletal
- Spinal cord
- Personality

Healing

- Peripheral nerve
- Pain matrix
## What is the ideal analgesic?

<table>
<thead>
<tr>
<th>Stand-alone analgesic</th>
<th>Rapid onset, durable, wide range pain types &amp; patient populations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analgesic adjunct</td>
<td>Improves pain relief above other analgesics</td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td>Patients satisfied with modality and willing to use</td>
</tr>
<tr>
<td>Adverse effects</td>
<td>Low: mortality, significant and minor adverse effects</td>
</tr>
<tr>
<td>Opioid sparing</td>
<td>Reduces ED opioid administration, take home scripts and usage</td>
</tr>
<tr>
<td>Time</td>
<td>Application including pre and post administration time in short</td>
</tr>
<tr>
<td>Cost</td>
<td>Inexpensive in short term and long term savings</td>
</tr>
<tr>
<td>Training</td>
<td>Easy to learn by usual ED clinicians</td>
</tr>
</tbody>
</table>

## What are the problems with current standard analgesia care (SAC) that acupuncture might address?

<table>
<thead>
<tr>
<th>ED Analgesic weaknesses that acupuncture might address?</th>
<th>Current ED standard analysis care performance?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most ED analgesic armamentarium includes potent stand-alone analgesics. Acupuncture could find a role if effective as a stand-alone as an alternative to opioids or NSAIDs in at risk patients or those refusing analgesic medications?</td>
<td>Stand-alone analgesic</td>
</tr>
<tr>
<td>The ED uses analgesics as adjuncts which are largely effective. For acupuncture to find a role it would need to be effective as an adjunct analgesic for patients who have failed oral analgesics or to delay or avoid NSAIDs, opioids, steroid injections, pain procedures or surgery in patients at risk of adverse effects to these interventions?</td>
<td>Analgesic adjunct</td>
</tr>
<tr>
<td>Patient satisfaction is not associated with analgesic medications including opioids and improved satisfaction leads to better patient compliance and reduced litigation.</td>
<td>Patient satisfaction</td>
</tr>
<tr>
<td>Opioids, NSAIDs, steroid injections, pain procedures are modalities with definitive risks of adverse effects</td>
<td>Adverse effects</td>
</tr>
</tbody>
</table>

Appendix 314
What are the problems with current standard analgesia care (SAC) that acupuncture might address (cont.)?

<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioid sparing</td>
<td>ED clinicians and nurses are time poor and this contributes to less than ideal pain management.</td>
</tr>
<tr>
<td>Time</td>
<td>ED clinicians require more training on opioid sparing analgesic modalities.</td>
</tr>
<tr>
<td>Cost</td>
<td>ED analgesia while inexpensive in short term likely has long term costs on the community.</td>
</tr>
<tr>
<td>Training</td>
<td>ED clinicians require more training on opioid sparing analgesic modalities.</td>
</tr>
<tr>
<td>Health care costs are rising in EDs. Opioids while not necessarily costly in the ED have huge costs in the community later for rehabilitation, overall health care and legal costs.</td>
<td>ED clinicians require more training on opioid sparing analgesic modalities.</td>
</tr>
<tr>
<td>ED clinicians require more training on pain management for safer opioid usage and other pain reducing modalities.</td>
<td>ED clinicians require more training on opioid sparing analgesic modalities.</td>
</tr>
</tbody>
</table>

What about opioids?

<table>
<thead>
<tr>
<th>Type</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stand-alone analgesic</td>
<td>Rapid onset, durable, wide range pain types &amp; patient populations.</td>
</tr>
<tr>
<td>Analgesic adjunct</td>
<td>Improves pain relief above other analgesics.</td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td>Patients are not satisfied with modality most willing to use.</td>
</tr>
<tr>
<td>Adverse effects</td>
<td>High mortality, significant and minor adverse effects short and long term.</td>
</tr>
<tr>
<td>Opioid sparing</td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td>Administration time short, paperwork is long.</td>
</tr>
<tr>
<td>Cost</td>
<td>Expensive in short term and costly to community long term.</td>
</tr>
<tr>
<td>Training</td>
<td>Requires further training by usual ED clinicians.</td>
</tr>
</tbody>
</table>
How will we investigate it?

Methodology

• Decide on outcomes
• Grade evidence within outcomes
• Systematic review & meta-analysis all forms of acupuncture
• Systematic review & meta-analysis ear only
• Patient survey
• Teaching a basic course
• Clinical trial
• Further literature review
• Collation and synthesis
How do we decide on certainty of information?

GRADE

<table>
<thead>
<tr>
<th>Evidence</th>
<th>Certainty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systematic review</td>
<td>High</td>
</tr>
<tr>
<td>Good</td>
<td></td>
</tr>
<tr>
<td>Randomised trial</td>
<td>Moderate</td>
</tr>
<tr>
<td>Audit</td>
<td>Low</td>
</tr>
<tr>
<td>Observation study</td>
<td>Uncertain</td>
</tr>
<tr>
<td>Expert opinion</td>
<td>Low confidence</td>
</tr>
</tbody>
</table>

Problems with Standard Analgesia Care
Under-treatment of pain, adverse effects of analgesics, patient satisfaction, time issues, costs, & training requirements

Problems SAC matched to acupuncture outcomes
1st outcome: analgesic effectiveness, 2nd outcome: patient satisfaction, adverse effects, opioid sparing, administration time, cost, training time & applicability

Outcomes
- Systematic reviews and meta-analysis
- Randomised clinical trials
- Questionnaire and audit
- External literature: Other Systematic reviews, recent ED acupuncture RCTs, observational studies, expert opinions

Characteristics of outcome
- Confidence of recommendation based on quality of my research or external literature to rate characteristics of specified outcome

Compare outcome to the ideal analgesic or analgesic alternative
- Compare single outcome or multiple outcomes of acupuncture to analgesic alternative

Appendix 317
<table>
<thead>
<tr>
<th>Outcomes for evaluating ED acupuncture</th>
<th>Quality of evidence (primary or secondary outcome)</th>
<th>Strength of recommendation</th>
<th>Compared with the Ideal analgesic</th>
<th>Compared with other analgesic</th>
<th>Importance</th>
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<tbody>
<tr>
<td>Pain reduction (stand-alone)</td>
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<td>High</td>
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<td>Pain reduction (adjunct)</td>
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<td>Satisfaction</td>
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<td>Adverse effects</td>
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<td>Opioid sparing</td>
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<td>Important</td>
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<td>Administration time</td>
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<td>Cost</td>
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<td>Low</td>
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<td>Training requirements</td>
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</tbody>
</table>

What was done

Appendix 318
Review article: Does acupuncture have a role in providing analgesia in the emergency setting? A systematic review and meta-analysis

Andrew L Jan, Emogene S Aldridge, Ian R Rogers, Eric J Visser, Max K Bulsara, Richard C Niemtzow


Does Ear Acupuncture Have a Role for Pain Relief in the Emergency Setting? A Systematic Review and Meta-Analysis

Andrew L Jan, MBBS, FACEM, BA, FAMAC, MPha, Emogene S Aldridge, BHlthSc, Ian R Rogers, MBBS, FACEM, Eric J Visser, MBBS, FANZCA, FFPMANZCA, Richard C Niemtzow, MD, PhD, MPH.
SHORT REPORT

Patient attitudes towards analgesia and their openness to non-pharmacological methods such as acupuncture in the emergency department

Andrew L JAN 1,2, Emogene S ALDRIDGE 2, Ian R ROGERS,1,2 Eric J VISSER,2 Max K BULSARA 4 and Dana A HINCE 3

Letters

Acupuncture for analgesia in the emergency department: a multicentre, randomised, equivalence and non-inferiority trial

TO THE EDITOR: We commend Cohen and colleagues 1 on their recently published study, which is the largest randomised controlled trial (RCT) of acupuncture in the analgesic effect of acupuncture is unlikely to be equal for all pain presentations in the emergency setting and, therefore, the conditions for which its role is most beneficial need to be delineated.

Andrew L Jan1
Ian Rogers1
Eric J Visser2
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2 University of Notre Dame Australia, Fremantle, WA.
drandrewjan@gmail.com

Appendix 320
Lessons Learned in Teaching Battlefield (Ear) Acupuncture to Emergency Medicine Clinicians

Andrew L. Jan

ORIGINAL RESEARCH

Battlefield acupuncture added no benefit as an adjunct analgesic in emergency department for abdominal, low back or limb trauma pain

Andrew L. Jan, Emogene S. Aldridge, Eric J. Visser, Ian R. Rogers, Dana A. Hince, Michael V. Woosey, Max K. Bulsara, and Lorna K. SuEN

1School of Medicine, The University of Notre Dame Australia, Fremantle, Western Australia, Australia; 2Emergency Department, St. John of God Murdoch Hospital, Perth, Western Australia, Australia; 3Chronic Pain Education and Research, The University of Notre Dame Australia, Fremantle, Western Australia, Australia; 4Department of Biostatistics, Institute for Health Research, The University of Notre Dame Australia, Fremantle, Western Australia, Australia; and 5School of Nursing, The Hong Kong Polytechnic University, Kowloon, Hong Kong
Mortality

My research
• SR: No deaths in trials to date, none BFA trial. Not powered to determine outcome.

External research
• Prospective observational study nearly ½ million patients – no deaths, average 8 treatments gives < 1 death in 3 million treatments. Reports world wide and estimate numbers of treatments 1 every billion. Large observational study probably best that will ever be done to ascertain this outcome. RCTs could not be powered to ascertain this outcome.

Outcome
• Acupuncture very low mortality

Grade
• despite this being an observational study in outpatient environment, I am confident in this determination.
• Ranked number 1 outcome. Pain is subjective, opioid crisis has led to this ranking

Significant adverse effects

(those requiring treatment)

My research
• SR: Incidence in trials 1%, found in literature 0.02-2%

External Literature
• Observation study of ½ million patients: 1/300,000

Outcome
• Acupuncture has low risk of serious adverse effects

GRADE
• Confident in outcome based on large observational study and consistency in secondary outcome results. High importance
Minor adverse effects –
Difficulties in definition (whether therapeutic (deqi) or an AE) and standardisation

My research
SR: incidence of 2.4% in RCTs (usually open ended questionnaire)
Survey: common comment for not willing is ‘fear / not liking needles’
RCT: 2/30 patients withdrew because of painful needles

External Literature
Incidence of minor side effects using a validated tool was approximately 25% above placebo*

Outcome
Acupuncture does have common minor adverse effects which are common which are enough for patients to refuse treatment
GRADE
Result likely to be true
Low ranking
Future
Laser (painless) acupuncture RCT in the ED for acute pain

*Chung AE related to acupuncture Clin J Pain 2015

Analgesic efficacy – Stand-alone

My research
• SR: Superior against sham and equivalent to SAC, Level one evidence NHMRC
• Weaknesses: high heterogeneity, variation in quality of included studies

External Literature
• 3 recent studies including large RCTs consistent. 2 have quality concerns
• Outpatient systematic review: chronic and acute pain, indirect evidence, range of quality

Outcome
• Effective as a stand-alone
GRADE
• High quality evidence, confident in outcome, ranking number 2

Appendix 323
Analgesic efficacy – as adjunct

My research
- SR: limited evidence 2 studies. 2 others not included in meta-analyses.
- RCT: no adjunctive benefit. Note majority used opioids.

External Literature
- 2 recent studies including large RCT consistent. 1 has quality concerns

Outcome
- Uncertain if effective as adjunct analgesic

GRADE
- Ranked number 2 with stand-alone, future research likely to impact

Future
- More RCTs adjunct to simple analgesia

Patient satisfaction

My research
- SR: All studies where measured (n=10) as secondary outcome favoured acupuncture
- Questionnaire: majority willing to use/continue
- RCT: no difference to SAC

External Literature
- Large RCT secondary outcome improvement post discharge

Outcome
- Acupuncture is a patient satisfying modality

GRADE
- All secondary outcomes show consistency more confident in result
- Difficult decision whether to rank above or below adverse effects. Ultimately without evidence to the contrary will follow Hippocratic oath which is first do no harm

Appendix 324
Opioid sparing

My research
- SR: secondary outcome: one study tested for opioid reduction and no difference to SAC
- RCT: secondary outcome no opioid sparing

External Literature
- One RCT since SR: no opioid reduction
- Indirect evidence: Post operative acupuncture does show opioid reduction including as primary outcome measure

Outcome
- Uncertain whether acupuncture reduces opioid usage in the ED

GRADE
Uncertain of result due to paucity of studies as a secondary outcome in ED and conflicting results in postoperative pain tested as primary outcome
Mid ranking: in reaction to opioid crisis

Future
Primary outcome measure in ED

Administration time

My research
- SR: where cited, both body and ear acupuncture take < 10 minutes to deliver
- RCT: BFA mean time = 7.8 mins

External Literature
- No further information

Outcome
- Acupuncture administration takes a significant amount of time compared with oral or parental administration.

GRADE
Certain of result due to consistency of reporting.
Low ranking

Future
Pre-post intervention study with a licensed acupuncturist and measure LOS and other logistic outcomes.
**Costing: direct costs of needles as consumables.**

This outcome is of limited utility as salaries, drugs, and further long-term costs (e.g., legal) are important measures needed to make an economic argument supporting the introduction of acupuncture in the ED.

**My research:**

SR: Filiform needles cheap, with BFA needles up to $5 USD per patient.

RCT: BFA needles as above, pharmaceutic analgesics cheaper wholesale a little over a dollar per patient.

**External Literature**

Nil to add.

**Outcome:** Acupuncture consumables are low cost but specialised ear needles are not cheaper than wholesale analgesics. Acupuncture consumables lower with purchase by hospitals.

**GRADE**

Secondary outcomes and consistent. Confident of outcome measurement.

**Low ranking**

**Future:** Cost savings possible with full time acupuncturist in large EDs. More informative research on long term community savings. May have to wait till ED acupuncture able to show opioid reduction short and long term.

---

**Training requirements:** Can ED clinicians be trained easily in basic acupuncture and be effective and safe?

**My research**

- SR: included trials used licensed acupuncturists, BFA used non-acupuncturists.
- RCT: 4 hour BFA training.
- Feedback from attendees: BFA felt competent, more time required for body acupuncture.

**External Literature**

- Physiotherapists in Australia require minimum 16 hours training in order to practice.
- In the USA over 7000 attendees completed the course.

**Outcome**

- BFA competency in 4 hours training, body acupuncture 16 hours sufficient.

**GRADE**

Certainty that BFA competency in 4 hours but uncertain if 16 hours is sufficient.

**Low ranking**

**Future**

Body acupuncture basic versus long training. Expert opinion: advisory (special interest group) colleges of emergency medicine and others.
Summation of Results

- Acupuncture has a very low mortality and significant adverse effect rate.
- It causes minor adverse symptoms which could be regarded by traditional acupuncturists as an essential component to enable therapeutic benefit.
- It is effective as a stand-alone analgesic but has uncertain effectiveness as an adjunct.
- Conditions favourable RCTs = recurrent painful musculoskeletal conditions, spinal pain, migraines, renal colic as well as trauma (limbs and ribs) and sore throats.

Summation of Results

- At this stage, unlike the postoperative setting, acupuncture has not shown to be opioid sparing in the ED.
- Acupuncture does takes time from busy ED clinicians to administer
- Acupuncture needles are low cost but are not currently cheaper than the wholesale price of analgesics.
- Some forms of acupuncture are easily learnt such as BFA, it remains unknown whether basic training similar to physiotherapists of 16 hours would be effective and safe.
### Indications

- **It is common practice to use opioids for patients who have failed simple analgesia or those with severe pain.**
- **There is a subset of these patients that are at risk of opioid recurrent use.**
  - **Non-catastrophic pain:** spinal ± radiculopathy, degenerative large joint disease, recurrent headaches, personalities at risk
  - Where NSAIDs, steroid injections, other procedures wish to be avoided.
  - Patients following multimodal pain assessment have mild to moderate pain.
  - Patient choice.

#### Comparison Table

<table>
<thead>
<tr>
<th>Ideal analgesic</th>
<th>Acupuncture</th>
<th>Opioid analgesic</th>
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</thead>
<tbody>
<tr>
<td><strong>Adverse effects</strong></td>
<td></td>
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<tr>
<td>Low: mortality, significant and minor adverse effects</td>
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<td></td>
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<tr>
<td>Low mortality, low significant but minor adverse effects</td>
<td></td>
<td></td>
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<tr>
<td>High mortality, significant and minor adverse effects short and long term</td>
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<tr>
<td><strong>Stand-alone analgesic</strong></td>
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<tr>
<td>Rapid onset, durable, wide range pain types &amp; patient populations</td>
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<td>Rapid onset, durable, wide range pain types &amp; patient populations</td>
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<tr>
<td>Rapid onset, durable, wide range pain types &amp; patient populations</td>
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<tr>
<td><strong>Analgesic adjunct</strong></td>
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<td>Improves pain relief above other analgesics</td>
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<tr>
<td>Uncertain whether pain relief occurs above other analgesics</td>
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<td></td>
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<tr>
<td>Improves pain relief above other analgesics</td>
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<tr>
<td><strong>Patient satisfaction</strong></td>
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<tr>
<td>Patients satisfied with modality and willing to use</td>
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<td></td>
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<tr>
<td>Patients are not satisfied with acupuncture &amp; most willing to use</td>
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<tr>
<td>Patients are not satisfied with modality and most willing to use</td>
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<tr>
<td><strong>Opioid sparing</strong></td>
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<tr>
<td>Reduces ED opioid administration, take home scripts and usage</td>
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<tr>
<td>Uncertain whether acupuncture reduces opioid usage in ED, take home scripts or post discharge usage</td>
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<tr>
<td>Requires further training by usual ED clinicians</td>
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<td><strong>Time</strong></td>
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<td>Administration time significant up to 10 minutes</td>
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<td>Administration time short, paperwork is long</td>
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<td><strong>Cost</strong></td>
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<td>Inexpensive in short term and long term savings</td>
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<tr>
<td>Versus acupuncture needles cheap, whole BFA needles more expensive than SAC</td>
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<tr>
<td>Inexpensive in short term and costly to community long term</td>
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<td><strong>Training</strong></td>
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<td>Easy to learn by usual ED clinicians</td>
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<tr>
<td>BFA Easy to learn by usual ED clinicians, at least 16 hours minimum training for body acupuncture</td>
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<tr>
<td>Requires further training by usual ED clinicians</td>
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</tbody>
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### Appendix

Appendix 328
Further studies

- In completion of this thesis just as many questions have been raised as answers. Some of the more important questions are:
  - Which is more effective, ear or body acupuncture? both?
  - Multimodal assessment of pain?
  - Acupuncture as adjunct to simple analgesia?
  - LLL acupuncture?
  - Satisfaction as primary outcome?
  - Opioid sparing as primary outcome?
  - Basic versus longer training?
  - Time and cost benefits of a full time acupuncturist in the ED?
Final Reflection

• Researchers postulate that a root cause of the opioid crisis was this letter to the editor based on a retrospective audit (Low grade evidence).
• Medicine as a business (e.g. Pharma Purdue) used this evidence to market oxycodone as non-addictive.
• Two lessons:
  • Don’t rely on low grade evidence.
  • There is more to Western Medicine than EBM! The ‘Art of medicine’, giving the doctor authority to independently make benevolent decisions.

Appendix

Addiction Rare in Patients Treated with Narcotics

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 29,464 hospitalized medical patients who were examined consecutively. Although there were 11,892 patients who received at least one narcotic preparation, there were only four cases of recognizable withdrawal symptoms, and addiction in patients who had no history of addiction. The addicted patients were analyzed separately. Of these, three were addicted to oxycodone, and one to hydrocodone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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