The effect of an evidence based bowel protocol on time taken to return to normal bowel function in post operative total hip and total knee replacement patients

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Chapter 6 - Discussion

The following discussion will present and explore the relevance of the major findings from this study in relation to methodological, theoretical and clinical issues. This will be followed by a discussion about the strengths and limitations of the study. The final chapter will present the conclusions from this study in addition to implications and recommendations for nursing practice, education and future research.

The principal hypothesis developed and tested in this study was that patients who undergo a knee or hip replacement and are treated with the Murdoch Bowel Protocol® (the Protocol) will experience a statistically significant reduction in time taken to return to normal bowel function compared with patients who receive standard post operative bowel management. The purpose of this study was to test the effect of the Protocol on time taken to return to normal bowel function in post major joint replacement patients. The study also sought to determine whether differences in age; gender; length of pre-operative fasting, anaesthetic type or operation type influenced the time taken to return to normal bowel function post-operatively.

Total hip and total knee replacement surgeries are two of the most commonly performed elective orthopaedic procedures in Australia with over 80,000 performed in 2011 (Australian Orthopaedic Association, 2012). The number of these procedures is increasing annually having risen 7.9% from 2009 to 2010 (Australian Orthopaedic Association, 2011). Of these, over 60% were undertaken in private hospitals. It could be argued that the public hospital cohort may represent a different patient demographic but not all patients undergoing this procedure in a public hospital represent a particular socio-economic demographic or are considered ‘high risk’ due to multiple
co-morbidities which once necessitated public hospital admission. Many private hospitals house high-dependency or intensive care units enabling them to care for patients with complex medical needs. Clinical trials are often undertaken across both public and private hospitals with recruitment not differentiating between cohorts on the basis of this alone. Of interest, the Protocol has been requested for use across multiple public hospitals in both Australia and New Zealand suggesting the problems experienced at the researcher’s hospital are similar to those experienced in public hospitals.

The study originated after several clinical incidents and a clinical audit at the researcher’s hospital showed considerable room for improvement in relation to post operative bowel management in the surgical orthopaedic patient cohort. Discussions with colleagues at other hospitals both within Western Australia and interstate revealed that the problems we experienced were not unique to us and were widespread. Despite the large volume of literature acknowledging these patients were at high risk for developing severe post operative constipation due to multiple factors including the administration of opioid analgesia, no robust evidence existed about how to best manage the problem. The lack of evidence and clinical guidelines meant that patients were often treated in an ad hoc manner dependent on the experience and preference of both their nursing and medical staff. The development and testing of the Protocol was a logical step to provide the evidence needed to assist nurses to provide care for what is a basic but poorly managed aspect of clinical care. A follow-up clinical audit conducted at the researcher’s hospital one year after implementation of the Protocol revealed significantly improved results and positive responses from both medical and nursing staff and patients. This success saw multiple other hospitals, both public and private across both Australia and New Zealand request use of the Protocol, with one orthopaedic surgeon requesting its use at multiple Perth hospitals.
at which he worked. Whilst happy for the Protocol to be used it was important to emphasise that no formal evaluation of the protocol had been conducted hence the urgent need for a robust assessment of the intervention.

The theoretical framework for this study was based on the Neuman Systems Model and was considered the most appropriate framework to guide this study. Its emphasis is on the patient and his/her response to various stressors in the environment, stressors which the nurse must identify and remediate. In addition, primary, secondary and tertiary prevention strategies are key components of the framework and are particularly relevant in the context of this Protocol.

**Summary of Findings**

**Comparison of complete and incomplete cases.**

As previously discussed, soon after data collection began at the largest intervention hospital it was noted that a significant amount of critical data was missing for the first 51 patients recruited. The large amount of missing data meant these incomplete cases were not suitable for inclusion into the study and recruitment recommenced after remedial measures had been implemented. To demonstrate that all cases were drawn from the same population the 51 incomplete cases were compared with the 331 complete cases. No statistically significant differences were found in any of the baseline variables confirming no difference between these groups. Subsequent analysis was conducted on completed cases only.

**Baseline comparison of variables.**

A comparison of baseline variables was undertaken between the control \((n = 171)\) and intervention \((n = 160)\) groups. Statistically significant results were found in three variables; hours of pre-operative fasting; type of
anaesthetic and gender. As 155 of the 160 intervention patients were recruited from a single hospital site it is likely that both the length of pre-operative fasting and anaesthetic type reflect hospital policy and/or procedure or doctors’ preferences. As discussed in the literature review, the evidence surrounding the importance of adequate hydration remains conflicted yet despite this it remains a mainstay of constipation prophylaxis and treatment. For this reason it was analysed in this study. Pre-operative fasting times were found to differ markedly across all participating hospitals with a medians ranging from four to 15 hours with the mean fasting time for control hospitals 10.03 hours (SD 4.3) vs a mean fasting time of 8.77 hours (SD 3.2) for intervention hospitals. As patients generally only commence intravenous fluids on induction of anaesthesia these rates were considered particularly high. The Australian and New Zealand College of Anaesthetists fasting guidelines recommend that healthy adults having an elective procedure take limited solid food up to six hours prior to anaesthesia and clear fluids totalling not more than 200 mls per hour up to two hours prior to anaesthesia (Australian and New Zealand College of Anaesthetists, n.d.). The effect of hydration on the main outcome measure was analysed using the generalised linear model and is reported later in this chapter.

Regional anaesthesia is the most commonly performed anaesthetic type at control hospitals with general anaesthesia most commonly performed at intervention hospitals. Similar numbers of patients received combined regional and general anaesthesia at both hospital groups. Gender differences between hospital groups are harder to explain. Significantly higher numbers of male patients were operated on at control hospitals and significantly higher numbers of female patients were operated on at intervention hospitals. No plausible explanation can be offered for these differences in gender frequency.
Effect of possible confounding post-operative variables.

A comparison of two possible confounding post-operative variables was undertaken; post-operative day first mobilised and length of inpatient stay. Days to normal bowel function was the main outcome measure for this study and was also analysed here. All three results were found to be highly statistically significant between control and intervention groups. Whilst post-operative day to first mobilisation was found to be statistically significant between groups it was not considered clinically significant as the median day to first mobilisation was day one for both hospital groups. The length of stay was also found to be highly statistically different between groups with control patients staying on average 4.96 days (median five days) compared with intervention patients who stayed an average of 7.07 days (median seven days). Several factors may account for this including doctor preference or hospital policy and procedural differences. It is possible that a shorter length of stay may have contributed to less pain and self-management education of patients leading to higher analgesia use post discharge. This outcome however was not measured. As 155 of 160 intervention patients were recruited from a single hospital, these site specific differences could have a significant impact on the intervention group outcomes. Of note, anecdotal reports confirm that none of the patients at intervention hospitals required prolonged length of stay for the management of post operative constipation. Days to normal bowel function was the main outcome measure for this study. The differences between groups was highly statistically significant with the control group reporting a longer time to normal bowel function compared with the intervention group ($p = 0.000$).

A comparison of days to normal between groups.

Days to normal bowel function was tabulated cumulatively across groups to compare differences. Days one to three were grouped together as most post-
operative patients do not experience a bowel motion prior to this time. Days four to seven were tabled individually as this is when most change occurred between control and intervention groups. As most intervention patients had returned to normal bowel function by day seven (93.9%) days 8-14 were grouped together. By day 14, 99.5% of intervention patients had returned to normal bowel function compared with only 75.2% of control patients. Those patients who had not returned to normal bowel function by day 14 were collectively grouped together as 15+ days. Of note, the comparative results showed that by day five (median length of stay for the control hospitals) only 28.2% of control patients had returned to normal bowel function vs 68.2% in the intervention group, with this figure increasing to 42.3% in the control group and 93.9% in the intervention group by day seven. As post-operative joint replacement management follows a very similar care path it is highly likely that these significant differences are due to the intervention protocol.

**Post discharge comparison of variables.**

Analysis of multiple post discharge variables was undertaken between groups. The use and type of analgesia taken as well as laxative use were analysed as was the incidence of constipation post discharge. The vast majority of patients from both groups continued to take analgesia after discharge with opiates taken by 84% of those in the control group and 82% of those in the intervention group. Paracetamol was also commonly used with 91.8% of control patients and 79.4% of intervention patients reporting having taken it since discharge. The use of non-steroidal anti-inflammatory drugs (NSAID) was minimal and likely due to the suggestion they may inhibit bone healing.

Laxative use was compared across groups with 44% of those in control groups taking laxatives after discharge compared with 40% in the
intervention group. It is important to note that the Protocol did not continue after discharge although some patients did confirm they continued using Movicol® after discharge. This is particularly relevant when considering the majority of patients were discharged on opioid analgesia.

When telephoned approximately one week after discharge patients were asked if they had experienced constipation since leaving hospital. In the control group 57% of patients and 31% of intervention patients reported constipation after discharge which was a highly statistically significant result. Whilst this measure was subjective and self-reported by patients (not using the Bristol Stool Chart) the difference is so significant it likely reflects the effect of the intervention protocol administered whilst an inpatient. Despite this positive result for the intervention group, 31% represents a high proportion of patients experiencing constipation post discharge. This outcome supports the introduction of targeted information for patients and their carers about the ongoing risk of constipation associated with opioid usage after discharge.

Variables associated with normal bowel function by day five.

Logistic regression was used to model six independent variables: age; gender; group (control or intervention); length of pre-operative fasting; anaesthetic type (general, regional and general + regional) and length of stay on the dependent binary variable, normal bowel function by day five. Overall three variables were found to be statistically significant: allocated group (control or intervention); regional + general anaesthetic and length of stay. A significant predictor of days to normal bowel function at discharge was being in the intervention group. Results indicated that patients in the intervention group were seven times more likely to have returned to normal bowel function by day five compared with patients recruited to the control
groups. Those patients who received combined general plus regional anaesthesia were almost two and a half times more likely to have returned to normal bowel function at day five than those who received a general anaesthetic. It is possible the combined anaesthetic resulted in a reduced dosage of anaesthetic agents and/or a reduced need for post operative analgesia. These variables may have contributed to a faster return to normal bowel function however their inclusion was beyond the scope of this study and should be evaluated in future research. Length of hospital stay was also significant finding; for every extra day a patient stayed in hospital they were ~20% less likely to have returned to normal bowel function by day five.

**Variables affecting days to normal bowel function.**

The generalised linear model (GLM) was used to assess the impact of the independent variables age; gender; group (control or intervention); length of pre-operative fasting; anaesthetic type; operation type and length of stay on the dependent continuous variable, days to normal bowel function. Of note, gender, age, and length of pre-operative fasting were not found to influence days to normal bowel function. Four statistically significant results were found. Of note, those in the intervention group took an average of *six days less* than those in the control groups to return to normal bowel function; each extra inpatient day meant an extra half a day to return to normal bowel function; and those who had a TKR took 1.24 days longer to return to normal bowel function than those who underwent THR. When compared with general anaesthesia (GA) patients who underwent combined regional and GA took on average *two days less* to return to normal bowel function.

**Summary of Study Findings**

Data were collected over three time periods: at pre-admission; during hospitalisation and at telephone follow-up approximately one week after
discharge. Those patients who had not returned to normal bowel function at the time of the first post-discharge telephone call were telephoned again approximately one week later. Multiple variables were evaluated to assess their relationship to the dependent variable, time taken to return to normal bowel function. Incomplete \((n = 51)\) and complete \((n = 331)\) cases were initially compared with none of the variables showing any differences hence all further analysis was conducted on complete cases only.

The recruitment of 155 of the 160 intervention cases from a single hospital resulted in statistically significant differences across some outcome measures which were most likely a result of hospital specific policies, procedural guidelines or clinician preferences. These were length of stay, anaesthetic type and day first mobilised although the latter was not considered clinically significant.

Of those intervention patients treated with the Protocol 68.2% had returned to normal bowel function by day five compared with 28.2% of those in the control group. By day seven these figures had increased to 93.4% compared with 42.3% respectively. Whilst there was no significant difference in the proportion of patients who took opioid analgesia post discharge there was a highly statistically significant difference in the numbers of patients who reported constipation during follow-up phone calls with 57.1% reporting this in the control group vs 31.2% in the intervention group. When all relevant variables were taken into account the allocation of patients from hospitals randomised into either control or intervention clusters was the most significant predictor of days to normal bowel function. Patients allocated to intervention hospitals were seven times more likely to have returned to normal bowel function by day five and took six days less to return to normal bowel function compared to those from control hospitals (mean 5.06 days in
intervention versus mean 10.64 days in control). Age, gender and length of pre-operative fasting were not found to be significant contributors to the outcome variable.

These results confirm the administration of opioids was the main contributing factor to the development of constipation in the post-operative orthopaedic patient cohort. They also demonstrate that administration of the Murdoch Bowel Protocol© resulted in a statistically significant reduction in time taken to return to normal bowel function in post operative major joint replacement patients and support the research hypothesis.

Comparing the Conceptual Framework with the Empirical Evidence
In this study the post operative major joint replacement patient was at the heart of the Neuman Systems Model. The flexible line of defence works to buffer intra, inter and extra personal stressors invading the patient’s normal line of defence (or usual wellness state). These stressors include the administration of an anaesthetic agent as well as opioid analgesia; an alteration to usual diet and fluid intake; a decrease in usual levels of mobility and the possibility of a lack of private bathroom facilities. As the normal line of defence is penetrated by the stressors listed above, a variance from usual wellness occurs and the flexible lines of resistance are activated. The flexible lines of resistance seek to stabilise the patient and return them equilibrium and good health with interventions best initiated either before or after these lines are penetrated.

Examples of primary prevention strategies which reduce or eliminate the identified risks include ensuring private toileting facilities, monitoring bowel habits to identify early signs of constipation, increasing dietary fibre and fluid intake and encouraging early mobilisation. Secondary prevention
strategies which can be implemented after the flexible lines of resistance have been penetrated include early identification of constipation and implementing the Murdoch Bowel Protocol©. Tertiary prevention strategies which aim to assist with reconstitution (the return of system stability following treatment for stressor reaction) include ensuring adequate discharge education about risk factors, early signs and management strategies for constipation for the patient and their carer (if applicable) and a recommendation that Movicol® be continued at home should symptoms of constipation reoccur. As most patients will continue taking opioid analgesia after discharge these strategies are particularly important.

Whilst the aim of management is a return to the patient’s normal state of wellness, reconstitution depends on the patient’s reaction which in itself is influenced by individual variables including time exposed to the stressors discussed above. As major joint replacement surgery aims to improve quality of live it is likely that with the nurses’ assistance, the patient will return to a higher level of wellness.

The empirical evidence gathered as a result of this study confirms the Murdoch Bowel Protocol© acts to expand the flexible line of defence providing greater protection to the patient and strengthening their normal line of defence. Should the normal line of defence be penetrated the Protocol strengthens the lines of resistance and helps return the patient to a state of equilibrium and good health.

Data Collection Issues
The collection of data at all participating hospitals was completed by registered and enrolled nursing staff. The primary nursing contact at each hospital was trained by the researcher although the Bristol Stool Chart was
completed at 1000 hrs daily by each patient’s attending nurse and based on a self-reported stool type by each patient. As previously discussed, during the data input stage it was noted that a significant amount of critical inpatient and follow-up data (i.e. recording of Bristol Stool Chart type for each inpatient day, Movicol® administration, and recording of return to normal bowel function post discharge) was either missing or incomplete from the first 51 patients recruited from the largest intervention hospital. It was felt that continuation would be unethical and would significantly compromise the rigor of the study. Hence the decision was made to suspend patient recruitment and further data collection until a strategy could be implemented to ensure more stringent data collection in accordance with the study protocol. Discussions with key stakeholders from that hospital confirmed that a registered nurse already employed on the orthopaedic ward of that hospital could be recruited to oversee complete and accurate data collection of all 155 recruited patients. The need for this was not envisaged prior to commencement of the study.

**Interrater Variability**
As previously discussed in the Methods chapter as patients were recruited across seven hospitals the issue of interrater variability needed to be addressed. Data were collected at three time points: pre-admission clinic; during the inpatient stay and post discharge by phone call. Initial training was carried out at each site but as all nursing staff were unable to be present at these education sessions a ‘Frequently Asked Questions’ sheet was distributed to all nursing staff working on every orthopaedic ward included in the study. This sheet detailed the background to the study, what information needed to be collected and how to record it. All sheets gave consistent information for either control or intervention hospitals.
One main contact and liaison nurse at each hospital was trained by the researcher and acted as a resource to answer questions to ensure a consistent approach to data collection. In addition the researcher was available by email and visited each hospital midway throughout the data collection phase to ensure that any questions or problems were addressed promptly and that data was entered correctly and consistently between sites. Traditional test-retest reliability was not used in this study due to the diverse geographical distribution of the hospitals and nurses recording patient self-reported information or transcribing data from fluid balance or observation charts. The measurement and recording of such data is a core component of basic nursing practice and as such it was not considered necessary to provide education in the act of transcribing information.

**Limitations and Strengths**

**Limitations.**

Limitations to this study were identified and are discussed below. This study was conducted in private hospitals across two Australian states. It could be argued the patient population differs between public and private hospitals, however that argument is not considered valid. Private hospitals regularly operate on patients with complex medical and surgical problems and with multiple co-morbidities. Many private hospitals have high-dependency or intensive care units and some have emergency departments. In addition, a lack of health insurance does not in itself reflect a patient’s demographic status and large clinical trials are routinely conducted across both public and private hospitals. Further, many hospitals both public and private have requested use of the Protocol confirming that post operative orthopaedic constipation is a problem experienced across all hospital sectors.
A further limitation is the recruitment of 155 of 160 intervention patients from a single hospital. Sample numbers were based on the proportion of major joint replacements conducted at each hospital each month. Hospitals which participated in this study ranged from a 70 bed regional hospital undertaking approximately five major joint replacements per month to a 548 bed metropolitan hospital undertaking approximately 120 major joint replacements per month. This wide variation in the number of operations performed accounted for the difference in patient recruitment numbers across the seven hospitals.

A potential limitation already discussed relates to the unusable data from the largest intervention hospital. This limitation was overcome by suspending the study and improving data collection strategies resulting in complete data for all complete cases. As described earlier, analysis between complete and incomplete cases revealed no differences confirming the non-inclusion of this data resulted in no bias.

**Strengths.**

The limitations of this study were balanced by considerable strengths. A well-controlled cluster randomised trial was used. This legitimate form of randomised controlled trial (RCT) methodology was chosen to avoid confusion for nursing staff should both control and intervention patients be recruited from a single hospital. In addition it was likely that contamination could occur due to patients wishing to be enrolled in the intervention arm of the study due to prior experience with post-operative constipation or the development of constipation whilst an inpatient. These important constraints were avoided by randomising hospitals as ‘clusters’ rather than randomising the patients within them. The use of clusters hospitals meant there was no risk of contamination.
A further strength was that the researcher was blind to data collection. This lack of personal involvement eliminated bias and preserved the integrity of the recorded data.

Anecdotal feedback was received from multiple patients at the intervention hospitals, all of which were positive. Comments included "love Movicol thank you"; "thought the protocol was fabulous"; "this is a great study, say thanks to the researcher for me"; "very happy with this new regime"; "Movicol was fantastic, better than last knee surgery" and "was type 1 after previous hip surgery, now type 4".

Application of the Murdoch Bowel Protocol© to Clinical Practice

This study has confirmed the Murdoch Bowel Protocol© is a simple, reliable and easy to use tool requiring no modifications to its current format. As such it can be considered the gold standard for the treatment of opioid induced constipation. Whilst the Protocol does suggest patient review by a dietician or continence nurse specialist if required, it is acknowledged that these resources may not be available at all hospitals. In these circumstances the patient should be reviewed by a more senior nurse with knowledge of bowel assessment and management.

The Protocol has been used at the researcher’s hospital since May 2010 and during this time clinical audit has been undertaken annually and confirms improvements across all outcome measures. Anecdotally patients have also reported increased satisfaction with bowel management. Further, there have been no episodes of increased lengths of stay for management of constipation and emergency department management of faecal impaction in this group has decreased significantly at the hospital. Given this hospital performs a large proportion of the total hip and knee replacement operations
undertaken in Western Australia, this is clinically significant result as it reflects the likely outcome of the whole cohort of major joint replacement patients. This study has shown highly statistically significant results for the main outcome measure demonstrating that management using the Murdoch Bowel Protocol© results in a significant reduction in time taken to return to normal bowel function in the post-operative major joint replacement cohort. Whilst the issue of opioid induced constipation is a significant concern for post operative orthopaedic patients, the safety and efficacy of the protocol means that its use can be extended to other patient groups also suffering from opioid induced constipation including paediatric populations. Despite its ability to cause severe constipation, opioid analgesia remains a mainstay for the management of moderate to severe pain both for inpatients and outpatients meaning that many patients suffer from unnecessary pain and discomfort. As an inert iso-osmotic laxative, non-scheduled, freely available over-the-counter and suitable for both adults and children, Movicol® has been proven to be a safe, efficacious and well-tolerated agent for the management of opioid induced constipation.

The use of Microlax® enemas was not examined in this study. Whilst intervention hospital Microlax® usage could be assessed, the ad hoc bowel management approach in control hospitals could not, meaning a comparison of usage was not possible.

**Summary of Chapter**

Despite the limitations of this study, the considerable strengths justify the valuable contribution of the Murdoch Bowel Protocol® to clinical practice in a basic but poorly managed aspect of patient care. This robust quantitative RCT with highly statistically significant results for the main outcome measure has provided the empirical evidence to support use of the Murdoch
Bowel Protocol® in all patients taking opioid analgesia, notwithstanding the need for replication of the study in other discreet populations e.g. paediatrics, oncology and maternity.