

2016

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This article was originally published as:

Jeffery, T., Petersen, R., & Quinlivan, J. (2016). Does cardiotocography have a role in the antenatal management of pregnancy complicated by gestational diabetes mellitus?. *Australian and New Zealand Journal of Obstetrics and Gynaecology*, 56 (4), 358-363.

Original article available here:

<http://onlinelibrary.wiley.com/doi/10.1111/ajo.12487/epdf>

This article is posted on ResearchOnline@ND at
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This is the peer reviewed version of the following article:

Jeffery, T., Petersen, R., and Quinlivan, J. (2016). Does cardiotocography have a role in the antenatal management of pregnancy complicated by gestational diabetes mellitus? *Australian and New Zealand Journal of Obstetrics and Gynaecology*, 56(4): 358-363. doi: 10.1111/ajo.12487

This article has been published in final form at: -

<http://onlinelibrary.wiley.com/doi/10.1111/ajo.12487/epdf>

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Title

Does cardiotocography (CTG) have a role in the antenatal management of pregnancy complicated by gestational diabetes mellitus (GDM)?

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Short title: CTGs and gestational diabetes

Keywords:

Gestational diabetes mellitus, Pregnancy, Cohort study, Cardiotocography,
number needed to treat.

Word count

Manuscript 3370

Abstract 179

Abstract

Background: Controversy surrounds the role of fetal cardiotocography (CTG) in the antenatal management of pregnancy complicated with gestational diabetes mellitus (GDM).

Aim: The aim was to investigate whether antenatal CTG aids the management in pregnancy complicated by GDM.

Materials and Methods: A prospective audit of 1404 consecutive antenatal CTGs in women diagnosed with GDM. Outcomes for all CTGs were audited to determine if the CTGs altered pregnancy management.

Results: In women requiring combination therapy (diet and medication), 43 CTGs were required to change management of a pregnancy. In women managed by diet alone with a secondary pregnancy complication, 161 CTGs were required to change management. In women managed by diet alone with no secondary pregnancy complication, CTGs did not change management.

Conclusions: Antenatal CTGs are not recommended in women with GDM managed by diet alone with no secondary pregnancy complication. Antenatal CTGs are recommended in women with GDM who require combination therapy (diet and medication). The role of CTG in women managed by diet alone with a secondary pregnancy complication should be based upon the nature of the complication.

Introduction

Gestational diabetes mellitus (GDM) is a common condition characterised by glucose intolerance first diagnosed during pregnancy.^{1,2} The prevalence of GDM in Australia was estimated at 4.6% in 2006.³ This is lower than the more recent 5.2%, reported by a large scale Australian study, suggesting that the prevalence of GDM is rising.⁴ . GDM pregnancies have an increased risk of a number of maternal and fetal complications including gestational hypertension, pre-eclampsia, caesarean delivery, development of type 2 diabetes postpartum, fetal macrosomia, birth trauma and shoulder dystocia.^{5,6} The risk of maternal and fetal complications is higher in GDM pregnancies with poor glycemic control.^{5,6} As a result, hypoglycemic medications including Insulin and Metformin can be instituted in GDM pregnancies which are unable to achieve glycemic targets with diet and exercise, to help optimise glycemic levels.^{4,7} GDM pregnancies requiring hypoglycaemic therapy are therefore at higher risk of potential complications compared to diet controlled GDM, due to poorer initial glycemic control.^{4,7}

Antenatal fetal surveillance is routinely performed in pregnancies complicated by GDM.⁸ Common surveillance methods include ultrasonography and cardiotocography (CTG) monitoring.^{8,9} In particular, CTG monitoring plays a role in detecting pregnancies at risk of stillbirth, allowing for prompt further testing and intervention.^{10,11}

The fetal heart rate is determined by a balance of sympathetic and parasympathetic stimulation of the sinoatrial node.¹² This balance is mediated through a number of neurotransmitters including catecholamines.¹² Therefore,

CTG tracings can reflect underlying fetal pathology or a physiological response to fetal distress.^{12,13} A number of conditions are associated with abnormal CTG tracings. Causes of particular concern include: cord compression or prolapse, chorioamnionitis, fetal hypoxia and maternal hypovolemia.^{12,13} Specific CTG findings that suggest fetal hypoxia and acidosis include: reduced baseline variability, the absence of accelerations and the development of late decelerations.¹⁴

Whilst a reactive CTG represents a well oxygenated central nervous system and fetal wellbeing, abnormal CTGs can occur in the absence of underlying pathology.¹³ For example, early decelerations often represent compression of the fetal head in response to normal maternal contractions.^{12,13} In the case of GDM pregnancies, it is important to note that an abnormal CTG may not occur as a result of GDM itself. Rather, CTG changes in GDM pregnancies will often result from associated secondary complications such as hypertension or intra uterine growth restriction.

There is a lack of consensus on the frequency and commencement gestation of CTG monitoring in GDM pregnancies.^{15,16} Current Australian and International guidelines recommend the frequency of CTG monitoring should be guided by the presence of other pregnancy complications.^{15,16} The Australasian Diabetes in Pregnancy (ADIPS) Testing and Diagnosis Guidelines do not specify recommendations for the commencement or frequency of CTG monitoring in GDM pregnancies.⁸ Furthermore, the latest Australasian GDM management guidelines written in 1998 suggest that while CTG surveillance is commonly undertaken from 36 weeks gestation, there is no evidence to suggest

that this affects fetal outcomes in uncomplicated GDM.¹⁵ This is further supported by International guidelines which assert that current data is insufficient to determine if CTG monitoring is of any benefit in well controlled GDM pregnancies.¹⁶

There is limited research exploring the effectiveness and necessity of CTG monitoring in GDM pregnancies.^{15,16} A literature search using terms “gestational diabetes mellitus”, “gestational diabetes”, “diabetes”, “pregnancy”, “CTG”, “management” and “adverse” in multiple combinations revealed 43 relevant abstracts, and on review, only one study that specifically examined the effectiveness of CTG monitoring in predicting adverse events in GDM pregnancies. This 1995 observational study by Kjos in the United States evaluated the effectiveness of twice-weekly CTGs and amniotic fluid index on predicting fetal distress requiring caesarean section in GDM pregnancies.¹¹ 3671 deliveries complicated by either gestational diabetes or pre-existing diabetes were included in the study. Of these women, 2134 underwent regular ante-partum surveillance.¹¹ Non-reactivity during CTG was associated with increased fetal distress (OR 3.6, 95% CI: 2.14 – 6.06).¹¹ The presence of decelerations on CTG was also associated with increased fetal distress (OR 3.6, 95% CI: 2.14 – 6.06).¹¹

While this study had a substantial sample size, there were some limitations.¹¹ In particular, the study included women with both GDM and pre-existing type 1 or type 2 diabetes.¹¹ Additionally, GDM pregnancies managed by diet alone and without secondary complications received ante-partum surveillance at a significantly later gestational age (38.9 ± 0.2 weeks, $p < 0.0001$)

and received fewer tests (3.2 ± 0.2 weeks, $p < 0.0001$) than other groups in the study.¹¹ Therefore, it is not known if GDM pregnancies received the same benefit of routine CTG monitoring as type 1 and 2 diabetic pregnancies.

In the absence of research, there is debate regarding the necessity of CTG monitoring in GDM pregnancies without secondary pregnancy complication.¹⁷⁻¹⁹ Landon and Vickers, suggest that: "In well controlled normotensive GDM pregnancies with normal fetal growth, it is probably true that no tests for fetal well-being are required".¹⁷ An article by Loomis also emphasised the lack of evidence for or against fetal surveillance for women with uncomplicated GDM.¹⁸

Further information is required to refine antenatal management in pregnancy complicated by GDM.¹⁷⁻¹⁹ In particular, data are required on the efficacy and cost-effectiveness of CTGs in aiding management in the various GDM subgroups.¹⁷⁻¹⁹

Therefore the aim of this study was to determine the number of CTGs required to effect change in clinical management in women with a GDM pregnancy. Our primary hypothesis was that CTG monitoring would not add value in the setting of women with a GDM pregnancy managed by diet alone with no secondary complication.

Methods

Type of study and approvals

A prospective audit of all pregnancies diagnosed with GDM was undertaken. The Institutional Ethics Committee determined the project fulfilled

the criteria of an audit project as no intervention other than routine care in accordance with clinical protocols was being undertaken and regular auditing was already being undertaken. Therefore, the project was exempted from formal ethics committee approval.

Patient population

All pregnant women greater than 20 weeks gestation referred for public maternity care who resided within the referral postcodes of the Joondalup Health Campus within the North Metropolitan Health Service of Western Australia between 1 January 2012 to 30 June 2014 were included in the audit. Women with a history of pre-existing Diabetes Mellitus (type 1 or 2) were specifically excluded.

Diagnosis of GDM

All women had an OGTT between 24-30 weeks gestation in accordance with the existing clinical guideline.²⁰⁻²³ Women were included in the CTG audit if their OGTT results were consistent with a diagnosis of GDM in accordance with IADPSG 2010 diagnostic criteria.²⁰⁻²³

Antenatal care protocols

All women diagnosed with GDM across the audit period received clinical care according to the hospital guideline. Management involved an initial consultation with a diabetic educator, dietician and obstetric doctor (registrar or consultant). Patients commenced self-monitoring of blood sugar levels and adopted a diabetic diet. A review visit two weeks later determined if medication, in addition to diet, was required to achieve target blood sugar levels of <5.5 mmol/L (fasting) and <7.0 mmol/L (2 h postprandial).²⁰

As part of the hospital guideline, women with a GDM pregnancy managed by diet alone underwent ultrasound examinations (US) at 32 and 36 weeks gestation and cardiotocography (CTG) at 36, 37, 38 and 39 weeks gestation. They were offered induction of labour at 40 weeks gestation.

Women with a GDM pregnancy managed with combination therapy (diet and medication) commenced CTGs from 34 weeks and had an additional US at 34 weeks. These women were offered induction of labour at 38 weeks.

Women with a GDM pregnancy with a secondary pregnancy complication (for example: fetal macrosomia, antepartum haemorrhage, hypertension, polyhydramnios) had an individualized management plan of CTG and US and were offered delivery as directed by the attending specialist.

Recording the outcome of CTGs

The attending midwife recorded the outcome of each CTG. The attending obstetric registrar also reviewed the CTG to ensure there was concordance in the interpretation of outcome. Where there was discordance in outcome or the CTG was recorded as being abnormal, the case was discussed with the attending consultant who reviewed the woman and CTG to make a decision on management.

All staff (attending midwives, registrars and consultants) had successfully completed the RANZCOG Fetal Surveillance Education Program (<http://www.fsep.edu.au>) and achieved a pass mark in excess of 70% during the audit period.

CTGs were recorded as reactive non stress test (RNST) or non reactive

non stress (NRNST) in accordance with established criteria.²⁴

NRNST were further categorized as an abnormal CTG if the attending staff member noted a feature of concern such as a deceleration, baseline rate abnormality (bradycardia or tachycardia) or baseline variability abnormality (sinusoidal pattern, reduced or increased variability).

Follow up of CTGs

Patients with a RNST CTG were discharged with advice to attend the antenatal clinic at their next scheduled appointment.

Patients with a NRNST CTG were encouraged to have a meal, go for a walk and return for a repeat CTG within a few hours. Vibroacoustic stimulation was occasionally applied. If the repeat CTG was a RNST women were discharged with advice to attend the antenatal clinic at their next scheduled appointment. If the repeat CTG was a NRNST, a biophysical profile ultrasound (BPP) was requested. This generated a total score out of 10 (including the CTG). A score of 8 or 10 was deemed normal and women were discharged with advice to attend the antenatal clinic at their next scheduled appointment. An overall score of 6 was deemed borderline and required consultant review and possible delivery. An overall score of 4 or less was deemed abnormal and required consultant review and delivery.

An abnormal CTG required consultant review and individualized management.

Outcome

The primary outcome was the number of CTGs performed to elicit a “definitive change in management” (DCM). A DCM was defined as a decision by

a consultant to change management from the plan that had been in place prior to the commencement of the CTG. A DCM may have involved a decision to deliver or to increase fetal surveillance.

The secondary outcome was the cost to the healthcare system. Of note, cost estimates included the staff time to conduct, review and document outcomes of the CTG in the patient record. It also included the need to repeat a CTG due to a NRNST, or order a BPP that was subsequently normal or borderline but did not result in a DCM.

Analysis of results

We assumed it would be clinically significant if a DCM arose every 50 CTGs. Assuming a dichotomous endpoint of a CTG resulting in a DCM (yes or no), alpha error of 0.05 and power of 80%, this could be reliably detected with a sample size of 188 CTGs.

We were interested in outcomes for three subgroups. These were:

- a) GDM pregnancy managed by diet alone;
- b) GDM pregnancy managed by combination therapy (diet and medication);
- c) GDM pregnancy with a secondary pregnancy complication

In order to have a sample size of 188 CTGs in each of these three subgroups, we audited 1400 consecutive CTGs prior to analysis.

Data were presented as number and percentage, and as number needed to treat (NNT) for each subgroup.

Costs were generated on award determinations of staff time and Medicare Australia rebates for CTG and BPP respectively. Infrastructure costs were not included in the model.

Results

The demographic and pregnancy outcomes of audited women are summarised in Table 1. Mean age was 31 years. Most women were parous and a quarter delivered by caesarean section. Blood loss and birth trauma rates were similar to the wider maternity cohort. Newborn birthweight (adjusted for fetal gender) was also consistent with the background maternity population although the incidence of birthweight adjusted for gestational age above the 90th centile was slightly increased at 12% instead of the predicted 10%. Despite normal Apgar and cord blood levels, the rate of admission to special care nursery was higher than the background rate at 12%.

The 357 women underwent a total of 1404 antenatal CTGs (3.9 per woman). Of these, 1179 were initial CTGs, of which 19% (N=225) were NRNST and were subsequently repeated to generate the total sample of 1404 CTGs. Of the 225 repeated CTGs, 28% remained NRNST (N=63) and the patient was referred for BPP. Overall, a total of 14 women had a DCM as a result of the CTG process. Of these, 8 were as a result of an abnormal CTG and 6 due to an abnormal BPP after two NRNST.

Of the 357 women with GDM, 262 (74%) were managed with diet alone, whereas 95 required combined therapy with diet and medication to achieve optimal glycaemic control (Metformin or Insulin).

Overall, 135 women (38%) were diagnosed with a secondary pregnancy complication. These complications were fetal macrosomia (N=58), hypertensive disease of pregnancy (N=33; pre-existing hypertension, pregnancy induced

hypertension or pre eclampsia), reduced fetal movements (N=18), antepartum haemorrhage (N=8), threatened preterm labour (N=8), polyhydramnios (N=6), and other (N=12). Reduced fetal movements were defined as less than 10 movements in a two hour period chosen by the mother as a period when her baby was usually active. Eight women had more than one secondary complication.

Figure 1 summarises the outcomes of the three subgroups (GDM requiring combination therapy, GDM managed by diet alone with a secondary pregnancy complication, and GDM managed by diet alone without a secondary pregnancy complication).

In the subgroup of 95 women with GDM requiring combination therapy, 475 CTGs were performed. A DCM occurred in 11 of these 95 women. The number of CTGs required to effect a DCM (NNT) was 43.

In the subgroup of 79 women with GDM managed by diet alone identified with a secondary pregnancy complication, 484 CTGs were performed. A DCM occurred in 3 of these 79 women. The number of CTGs required to effect a DCM (NNT) was 161.

In the subgroup of 183 women with GDM managed by diet alone without a secondary pregnancy complication, 445 CTGs were performed. A DCM did not occur. The minimum number of CTGs required to effect a DCM (NNT) was therefore more than 445.

Table 2 summarises CTG-related costs in women with GDM. In the subgroup of 95 women with GDM requiring combination therapy, the cost per DCM was \$2,660. In the subgroup of women with GDM managed by diet alone

with a secondary pregnancy complication, the cost per DCM was \$8,063. In the subgroup of women with GDM managed by diet alone without a secondary pregnancy complication, the cost per DCM could not be calculated as there were no DCM. However, a total of \$21,280 was spent on the 183 women in this subgroup who underwent CTGs, ultrasounds and clinical reviews for no apparent clinical return.

Discussion

There were several key findings in this study. Firstly, CTG is a useful addition to the antenatal management of women with GDM who require combination therapy (diet and medication) to achieve fasting and postprandial glycaemic targets.²⁰ For every 43 CTGs, a DCM occurred in this subgroup of women. Our findings suggest that commencing CTG monitoring in GDM pregnancies requiring combination therapy from 36 weeks gestation is appropriate. .

In contrast, in the subgroup of women with GDM managed by diet alone without a secondary pregnancy complication, CTG was not found to be useful. After spending \$21,280 for 183 women to have CTGs, ultrasounds and clinical reviews, there was no apparent clinical return. Our results support the arguments regarding the lack of utility of universal CTG monitoring in GDM pregnancy managed by diet alone.¹⁷⁻¹⁹ Given one third of all CTGs in our study were performed in women in this subgroup, there is clear scope to rationalize hospital costs by refining clinical practice guidelines.

The cost of management of GDM pregnancy is subject of debate. The change in diagnostic criteria of GDM has resulted in rising prevalence in many centres, especially where rates of maternal obesity are high.^{20,21} Concern has been expressed that the cost and level of resources required to manage GDM outweigh the benefits.^{19,22,25} This has led to some countries deciding against adoption of the IADPSG 2010 criterion, in favour of higher glycaemic thresholds.²⁶ However, if the cost of managing GDM can be contained, and clinical practice guidelines restrict CTG antenatal surveillance to women with GDM pregnancy requiring combination therapy or with a secondary complication, then it may be possible to adopt IADPSG diagnostic criteria without straining obstetric services. This is important as women diagnosed with GDM have an increased lifetime risk of type 2 diabetes and other cardiovascular risk factors and the simple act of providing dietary counselling and diabetic education may help with chronic disease prevention and result in overall cost savings to the health system.^{27,28}

The role of CTGs in women with GDM managed by diet alone with a secondary pregnancy complication remains unclear. The NNT in our study was 161 at a cost of \$8,063. A number of sources have advocated for CTG monitoring if a secondary pregnancy complication is present in order to reduce fetal and maternal risks.^{6,10} More work is required to define the types of secondary complications that may benefit from CTG monitoring in order to refine management in this subgroup.

One limitation of this study is that our hospital clinical practice guideline offered delivery at 40 weeks. Therefore, the study is not able to comment on the

utility of antenatal CTGs for fetal surveillance in women with GDM pregnancy beyond 40 weeks. A second limitation is that the study sample was powered to detect the NNT to effect a DCM. It was not powered to detect fetal death in utero. We are therefore not able to comment on the efficacy of CTG to prevent fetal demise.

In conclusion, there is a lack of research exploring the effectiveness of antenatal surveillance using CTG in GDM pregnancy. Our findings suggest CTGs are a useful addition to the antenatal management of women with GDM requiring combination therapy (diet and medication). However, CTGs are not useful in the subgroup of women managed by diet alone without a secondary pregnancy complication. More research is required in the subgroup of women with GDM managed by diet alone with a secondary pregnancy complication.

Acknowledgements

We acknowledge research assistant Mrs Ronni Highet and research students Ms Danielle Lam and Dr Pooja Silbartie who contributed towards extraction of audit data. We also acknowledge Joondalup Health Campus for providing the GDM follow up clinical service during the audit period.

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Figure Legend

Figure 1: Number of CTGs to result in a “definitive change in management” (DCM) within the three categories.