Diabetes during pregnancy and method of birth: a population study of women giving birth in New South Wales, Australia

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Certificate of original authorship

I, Reem Samir Zeki declare that this thesis, is submitted in fulfilment of the requirements for the award of Doctor of Philosophy in the Faculty of Health at the University of Technology Sydney.

This thesis is wholly my own work unless otherwise referenced or acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis.

This document has not been submitted for qualifications at any other academic institution.

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To my great family, I dedicate this thesis.

Format of the thesis

This PhD thesis is in a compilation format. Each of four studies is reported in a thesis chapter. Chapters 4 and 5 have been published, and Chapter 6 has been resubmitted with revision and I am awaiting the decision. The fourth manuscript, Chapter 7, is currently being prepared for publication. The next section provides the publication details of Chapters 4, 5 and 6.

Published works by the author incorporated into the thesis

Study one (Chapter 4): Zeki, R., Oats, J.J.N., Wang, A.Y., Li, Z., Homer, C.S.E. & Sullivan, E.A. 2018, 'Cesarean section and diabetes during pregnancy: An NSW population study using the Robson classification', *Journal of Obstetrics and Gynaecology Research*, vol. 44, no. 5, pp. 890-8.

Study two (Chapter 5): Zeki, R., Wang, A.Y., Lui, K., Li, Z., Oats, J.J.N., Homer, C.S.E. & Sullivan, E.A. 2018, 'Neonatal outcomes of live-born term singletons in vertex presentation born to mothers with diabetes during pregnancy by mode of birth: a New South Wales population-based retrospective cohort study', *BMJ Paediatrics Open*, vol. 2, no. 1.p. e000224.

Study three (Chapter 6): Zeki, R., Li, Z., Wang, A.Y., Homer, C.S.E., Oats, J.J.N., Marshall, D., Sullivan, E.A. Obstetric anal sphincter injuries among women with gestational diabetes and women without gestational diabetes: a NSW population-based cohort study, *The Australian and New Zealand Journal of Obstetrics and Gynaecology*, submitted on 21st January 2018, accepted on 2nd December 2018 and published online on 17 February 2019.

Statement of contributions to jointly authored works contained in the thesis

Chapters 4, 5 and 6 have been submitted for publication in peer-reviewed journals. For each of these manuscripts, I have been responsible for deciding the research question, conducting the statistical analysis and drafting the manuscript.

During this process I have received support from my principal supervisor Distinguished Professor Elizabeth Sullivan and my co-supervisors Distinguished Professor Caroline Homer, Associate Professor Alex Wang and Professor Jeremy Oats (University of Melbourne). Additional assistance in statistical analysis interpretation of the data and review of the manuscripts was done by Zhuoyang Li.

For Chapter 5, Professor Kei Lui provided his clinical opinion in the interpretation of the data. For Chapter 6, Dr Drew Marshall provide his clinical opinion in the interpretation of the data.

I take responsibility for the accuracy of the results presented in these manuscripts.

Abbreviations

ACOG	American College of Obstetricians and Gynecologists
ADA	American Diabetes Association
ADIPS	Australasian Diabetes in Pregnancy Society
AIHW	Australian Institute of Health and Welfare
AOR	adjusted odds ratio
APDC	Admitted Patient Data Collection
BMI	body mass index
CEMACH	Confidential Enquiry into Maternal and Child Health
CHeReL	Centre for Health Record Linkage
CI	confidence interval
CS	caesarean section
EPDS	Edinburgh Postnatal Depression Scale
GCT	glucose challenge test
GDM	gestational diabetes mellitus
HAPO	Hyperglycemia and Adverse Pregnancy Outcome
IADPSG	International Association of Diabetes in Pregnancy Study Group
ICU	intensive care unit
LGA	large for gestational age
NICE	National Institute for Health and Care Excellence
NICU	neonatal intensive care unit
NSW	New South Wales
OASI	obstetric anal sphincter injury
OGTT	oral glucose tolerance test

PDC	Perinatal Data Collection
PPH	post-partum haemorrhage
RR	relative risk
SCN	special care nursery
SGA	small for gestational age
TSV	term singleton in vertex presentation
UK	United Kingdom
USA	United States of America
WA	Western Australia
WHO	World Health Organisation

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Abstract

Background and aims

Diabetes during pregnancy – including pre-existing diabetes and gestational diabetes mellitus (GDM) – is an increasing public health problem worldwide. The objective of this thesis is to investigate the association between method of birth and the perinatal outcomes of women with diabetes during pregnancy. It aims to:

- identify the main contributors to caesarean section amongst women with diabetes using the Robson classification for caesarean section
- determine neonatal outcomes for babies born to women with diabetes by method of birth
- compare the rate of obstetric anal sphincter injuries (OASIs) for women with and without GDM and investigate the association between combining episiotomy with method of birth and the risk of OASIs
- compare the perinatal outcomes for women giving birth with diabetes by public and private hospital sector.

Materials and method

Four population-based studies were conducted using the New South Wales (NSW) Perinatal Data Collection. The study population comprised 1,103,380 women who gave birth in NSW between 2002 and 2013 and their babies. Of these women 7,200 (0.7%) had pre-existing diabetes, 57,822 (5.2%) had GDM and 1,038,358 (94.1%) had no diabetes. Women were stratified by onset of labour, method of birth, and birthweight. Neonatal outcomes included perinatal death, five minutes Apgar score, admission to

neonatal intensive care and/or special care nursery and neonatal resuscitation. The primary maternal outcome was OASI.

Results

The total caesarean section rate was higher among women with pre-existing diabetes (53.6%) and women with GDM (36.8%) compared to women without diabetes (28.5%). Robson group five (multiparity with a history of caesarean section) was the main predictor of the total caesarean section rates in all women. Of the 39,625 women with diabetes who laboured, 32.1% had instrumental or caesarean births that were associated with poorer outcomes. Women with GDM who had an instrumental vaginal birth and gave birth to babies with birthweights ≥4000g had a significant increase in the odds of OASIs compared to women without diabetes. Combining episiotomy and forceps was a protective factor on OASIs. Similar proportions of no labour caesarean section were observed among women with pre-existing diabetes in private and public hospitals. Proportions of induction of labour were similar among women with GDM in private and public hospitals.

Conclusion

The Robson classification can be used to benchmark and monitor method of birth for women with diabetes. Information, education and counselling on the risks and complications associated with different methods of birth, should routinely be provided for women with diabetes antenatally.

Chapter 1: Introduction to this PhD thesis

1.1 Background

Diabetes during pregnancy, including pre-existing diabetes and gestational diabetes mellitus (GDM), is an increasing problem worldwide (Hunt & Schuller 2007). Pre-existing diabetes includes both type 1 and type 2 diabetes (American Diabetes Association (ADA) 2014). GDM is glucose intolerance that is diagnosed for the first time during pregnancy (ADA 2014; Nankervis et al. 2013).

The increase in the prevalence of diabetes during pregnancy parallels the increase of both type 1 and type 2 diabetes and the rise in obesity in the general population (Agarwal et al. 2018; ADA 2018; Australian Institute of Health and Welfare (AIHW) 2018). For example, there was a three-fold increase in the prevalence of diabetes among the Australian general population between 1989-1990 and 2014-2015, with 1.5% of women aged 18 to 44 years reported as having either type 1 or type 2 diabetes (AIHW 2018). Of women who gave birth in Australia in 2015, 1.1% had pre-existing diabetes and 9.4% had GDM (AIHW 2017a).

Several comorbidities and adverse outcomes are associated with diabetes during pregnancy, with both mothers and babies being affected. These morbidities and adverse outcomes include congenital malformations, preterm birth, pre-eclampsia, fetal macrosomia, shoulder dystocia, birth trauma, and perinatal mortality (stillbirth, neonatal mortality). These complications are more common in women with pre-existing diabetes and their babies than in women with GDM (ADA 2018; National Institute for Health and Clinical Excellence (NICE) 2015).

Women with diabetes during pregnancy have a higher rate of birth interventions such as caesarean section and induction of labour than women without diabetes (Shand et al. 2008). This may reflect the lack of agreement in national and professional society guidelines around the recommended method of birth for women with diabetes, the paucity of strong evidence, and a lack of practice consensus. Between 2005 to 2007, more than half (59.2%) of women with pre-existing diabetes and 40.1% of women with GDM who gave birth in Australia did so by caesarean section compared to 30.0% of women without diabetes (AIHW 2010).

Several factors contribute to inconsistency in management guidelines for method of birth for women with diabetes during pregnancy, including the different screening and diagnosis criteria for GDM and the heterogeneity of outcome definitions. In addition to the lack of the strong evidence, other factors can influence decisions around method of birth, including institutional factors, maternal socio-demographic factors, and obstetric characteristics.

Most of the literature on method of birth for women with diabetes during pregnancy are small hospital-based studies (Acker, Sachs & Friedman 1985; Das et al. 2009; Langer et al. 1991; Kolderup, Laros Jr & Musci 1997; Ecker et al. 1997; Conway & Langer 1998) that have a narrow focus on shoulder dystocia and birth trauma such as brachial plexus injury as their outcomes (Langer et al. 1991; Nesbitt, Gilbert & Herrchen 1998; Athukorala et al. 2007; Gherman et al. 1997; Kolderup, Laros Jr & Musci 1997; Rouse et al. 1996; Ecker et al. 1997; Conway & Langer 1998). Large population-based studies are needed which focus on other perinatal outcomes, including baby and maternal outcomes by method of birth.

1.2 Objectives

The main aim of this doctoral research was to investigate the association between method of birth and perinatal outcomes of women with diabetes during pregnancy and their babies. This includes investigating the impact of socio-demographic and obstetric factors and other health service factors on method of birth and outcomes.

Four population-based studies were conducted to meet this aim. To demonstrate pictorially the nature of each study, relevant summary diagrams are attached as Figures 1.1, 1.2, 1.3, and 1.4. These diagrams do not appear in the published articles. A fifth summary diagram (Figure 1.5) encapsulates the connectedness of the four studies.

Study one: This study aimed to identify the main contributors to caesarean section among women with diabetes and without diabetes during pregnancy using the Robson classification (Robson 2001) and to compare within each Robson classification group the caesarean section rates between women with diabetes (pre-existing and GDM) during pregnancy and those without. The Robson classification for caesarean section is a prospective classification based on women's obstetric characteristics (Robson 2001). See Figure 1.1.

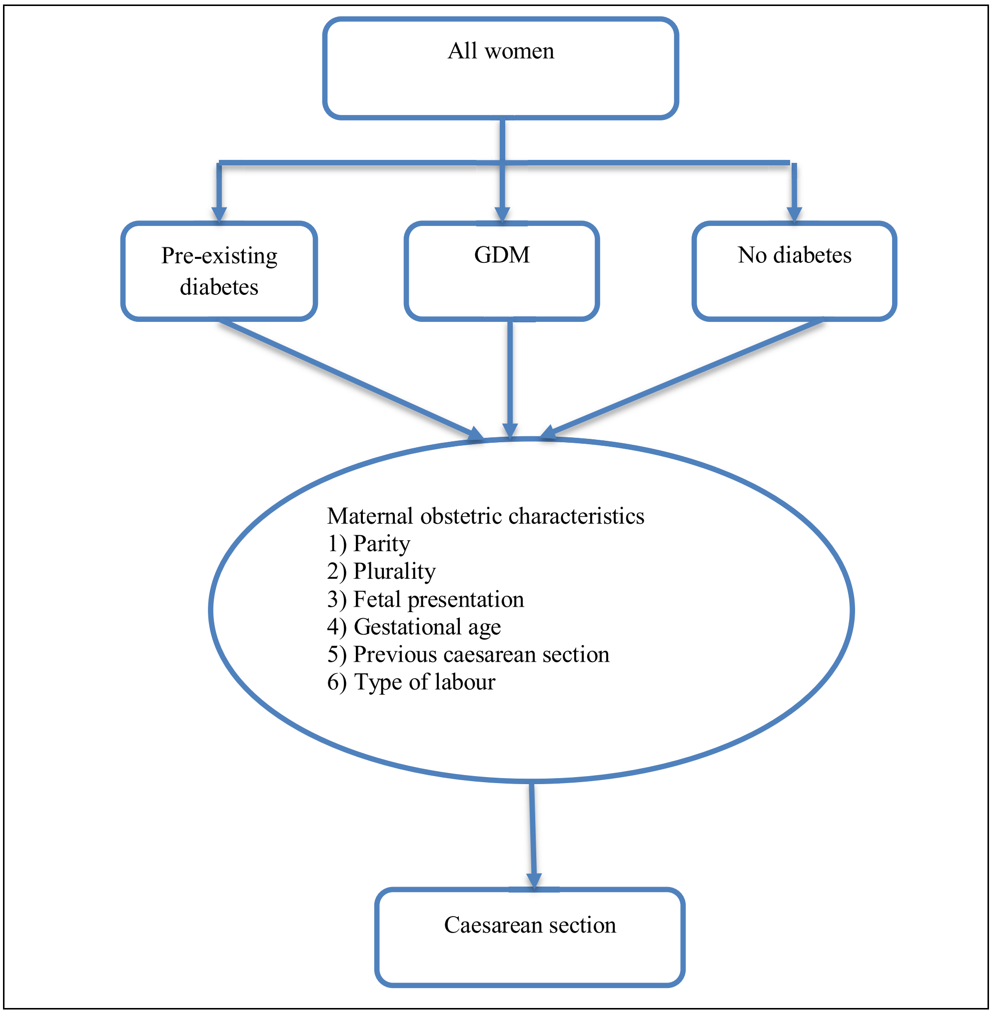

Figure 1.1: Caesarean section and diabetes during pregnancy: A New South Wales population study using the Robson classification

Study two: This study aimed to compare adverse neonatal outcomes for live-born term singletons in vertex presentation (TSV) born to mothers with diabetes during pregnancy (pre-existing and GDM) by mode of birth-stratified by birthweight. See Figure 1.2.

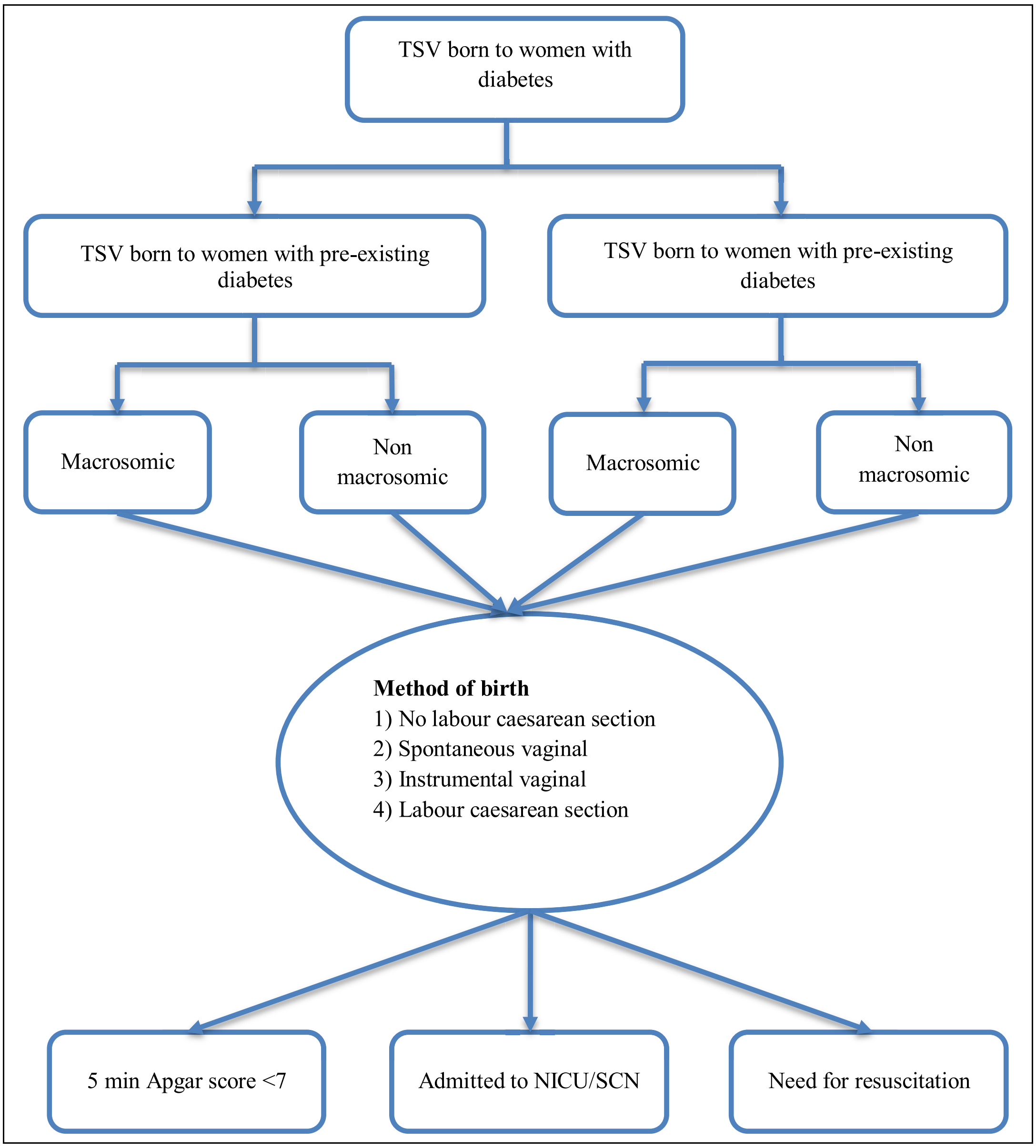

Figure 1.2: Neonatal outcomes of live-born term singletons in vertex presentation (TSV) born to mothers with diabetes during pregnancy by mode of birth: A New South Wales population-based retrospective cohort study

Study Three: This study aimed to compare the rates of obstetric anal sphincter injuries (OASIs) between women who had GDM and women who did not have diabetes by birthweight and method of birth. The second aim of the study was to investigate the association between episiotomy and no episiotomy by specific method of birth (e.g. episiotomy and non-instrumental vaginal birth vs non-instrumental vaginal birth; episiotomy and instrumental vaginal birth vs instrumental vaginal birth, episiotomy and prelabour caesarean section vs prelabour caesarean section, and episiotomy and intrapartum caesarean section vs intrapartum caesarean section) and the risk of OASIs for women who had GDM and those who did not have GDM. See Figure 1.3.

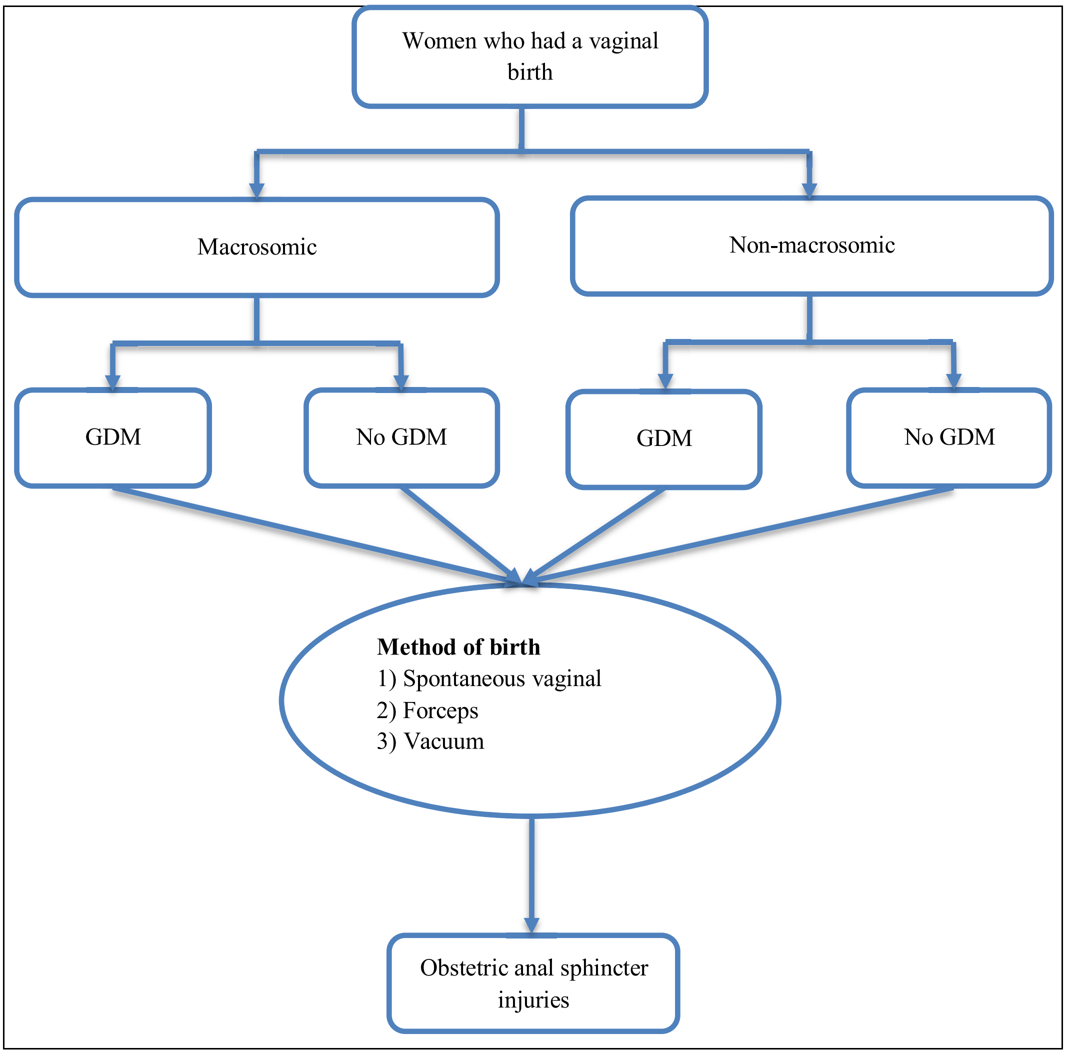

Figure 1.3: Obstetric anal sphincter injuries among women with gestational diabetes and women without gestational diabetes: a NSW population-based cohort study

Study four: This study aimed to compare birth interventions and adverse maternal and neonatal outcomes between public and private hospitals for women with diabetes during pregnancy who gave birth to live-born term singletons. See Figure 1.4.

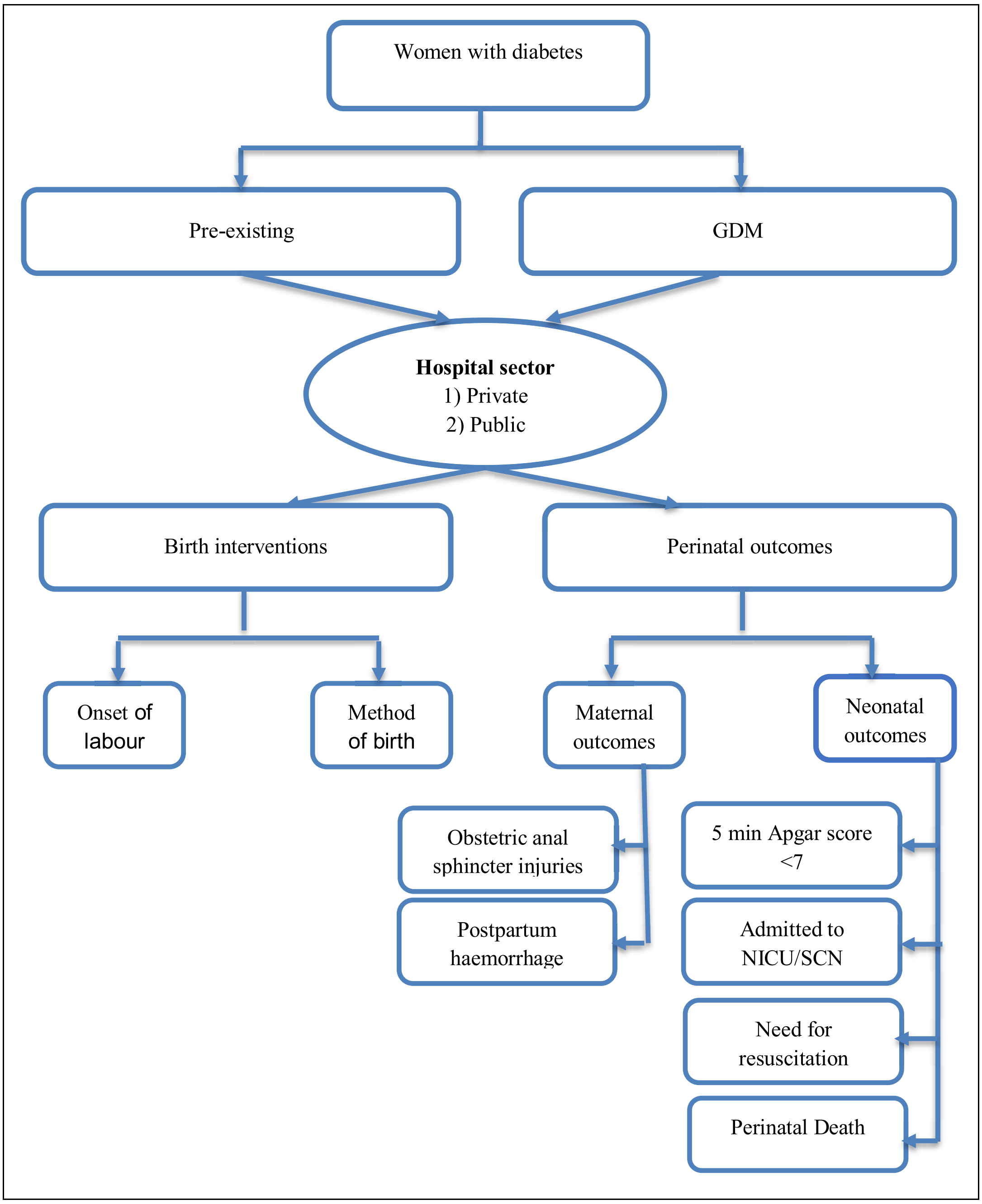

Figure 1.4: Birth intervention, maternal and neonatal outcomes for women with diabetes during pregnancy giving birth in public and private hospitals.

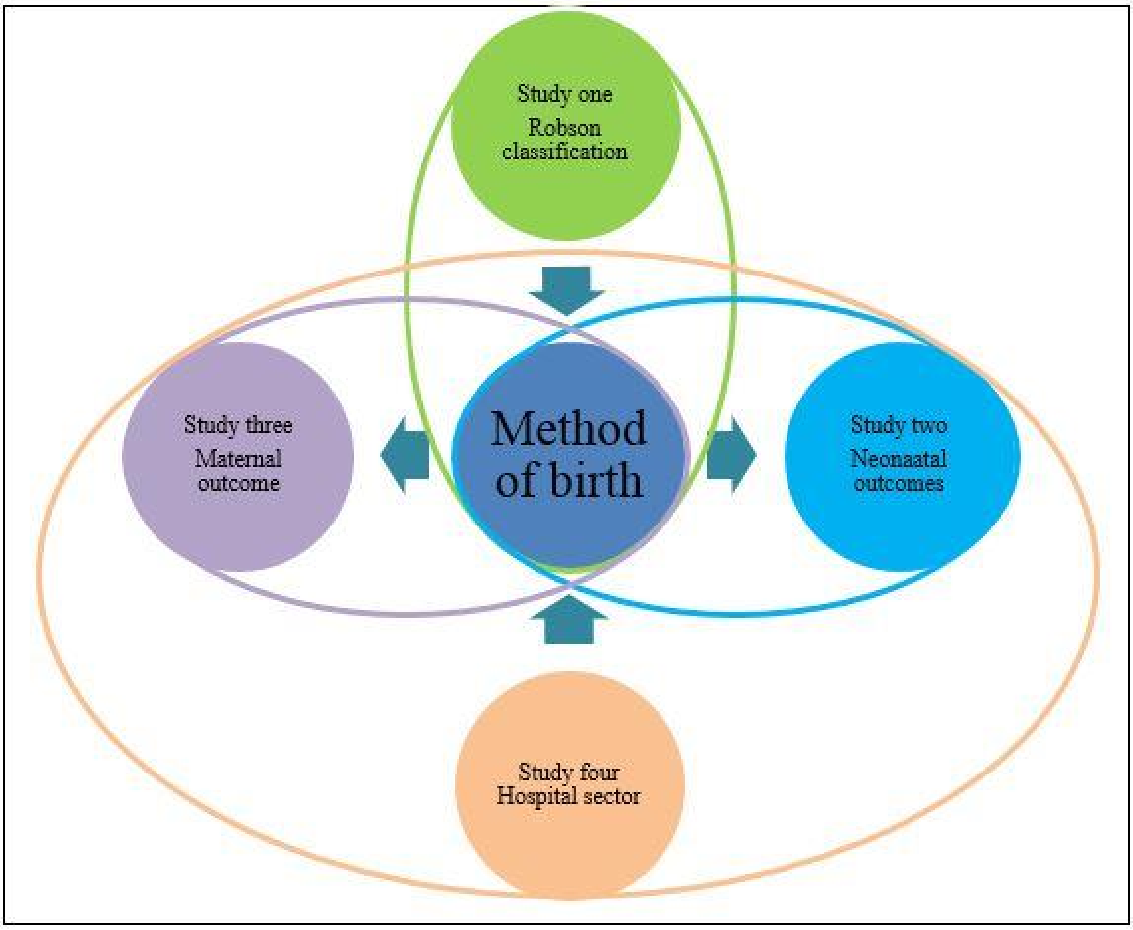

Figure 1.5: presents an overview of the relationship of the four studies included in this thesis.

1.3 Structure of this thesis

This thesis has eight chapters, each of which is briefly described here.

Chapter 1: Introduction

This chapter provides an introduction to the thesis, including background, rationale and objectives of this research.

Chapter 2: Background and literature review

This chapter provides the background to diabetes during pregnancy and examines the literature on method of birth for women with diabetes during pregnancy, outcomes of women with diabetes during pregnancy and their babies, as well as factors affecting the decision on method of birth for women with diabetes during pregnancy.

Chapter 3: Research methods

This chapter explains the methods used for this research.

Chapter 4: Study one

'Caesarean section and diabetes during pregnancy: A New South Wales population study using the Robson classification' identifies the main contributor to the caesarean section rate and compares caesarean section rates between women with diabetes and women without diabetes using Robson classification.

Chapter 5: Study two

'Neonatal outcomes of live-born term singletons in vertex presentation born to mothers with diabetes during pregnancy by mode of birth: a New South Wales population-based retrospective cohort study' compares the rates of adverse neonatal outcomes by method of birth for live-born term singleton in vertex presentation born to women with diabetes during pregnancy.

Chapter 6: Study three

'Obstetric anal sphincter injuries among women with gestational diabetes and women without gestational diabetes: A New South Wales population-based cohort study' compares the rates of OASI among women with and without GDM by method of birth and investigates the association between combine episiotomy with method of birth and the risk of OASIs.

Chapter 7: Study four

'Birth intervention, maternal and neonatal outcomes for women with diabetes during pregnancy giving birth in public and private hospitals' compares birth interventions and perinatal outcomes for women with diabetes who gave birth in private hospitals and those who gave birth in public hospitals.

Chapter 8: Discussion, conclusion and recommendations.

This chapter summarises the results of Chapters 4 to 7 and discusses these results in relation to published research. This chapter concludes the thesis and recommends future research.

1.4 Conclusion to the chapter

This chapter has introduced this PhD thesis. Chapter 2, the background and literature review, provides the background to diabetes during pregnancy and examines the literature on method of birth for women with diabetes during pregnancy. There will be some repetition of this literature in the four results chapters (Chapters 4 to 7) because each includes a literature review.

Chapter 2: Background and Literature Review

2.1 Background

2.1.1 Definitions and aetiology:

Diabetes is metabolic disorder characterised by hyperglycaemia resulted from a deficiency in insulin secretion or defect in insulin action or both (ADA 2014). Diabetes in pregnancy includes both pre-existing diabetes and gestational diabetes mellitus (GDM).

Pre-existing diabetes presents before pregnancy and continues after birth. It includes both type 1 and 2 diabetes (American College of Obstetricians Gynecologists (ACOG) 2005). Type 1 diabetes occurs early in life, mainly in children and young adults, and is characterised by an autoimmune process that destroys pancreatic beta cells leading to the need for insulin (ACOG 2005; ADA 2014; NICE 2015). Type 2 diabetes is more common than type 1 diabetes and is commonly diagnosed later in life; however, it is increasingly appearing in the younger population (Dabelea et al. 2014). Type 2 diabetes is characterised by insulin resistance, impairment in insulin release and hyperglycaemia (McIntyre et al. 2009).

GDM is defined as glucose intolerance that is diagnosed for the first time during pregnancy (ADA 2014; Nankervis et al. 2013). GDM may include hyperglycaemia induced by pregnancy or previously existing but undiagnosed hyperglycaemia (Nankervis et al. 2013). In normal pregnancies, women increase their insulin secretion to compensate for the insulin resistance of pregnancy. In women with GDM, however, hyperglycaemia occurs due to inadequate insulin supply for normal blood glucose regulation (Tieu et al. 2017).

In the majority of women, GDM resolves after pregnancy; however, women with a history of GDM are at a higher risk of developing type 1 and type 2 diabetes in the future (ADA 2014; Järvelä et al. 2006). In a hospital-based study conducted in Finland, Järvelä et al. (2006) found that of women with GDM who had given birth to singleton babies, 4.6% developed type 1 diabetes. This study identified several risk factors associated with developing type 1 diabetes after GDM, including age ≤ 30 years (odds ratio (OR) 3.93, 95% confidence interval (CI) (1.01-15.34)), and need for insulin (OR 16.33, 95% CI (2.98-89.57)) (Järvelä et al. 2006). Results from a meta-analysis conducted by Bellamy et al. (2009) showed that the relative risk of developing type 2 diabetes was 7.43, 95% CI (4.79-11.51) among women who had GDM compared to those without a history of GDM (Bellamy et al. 2009).

Factors associated with an increased the risk of developing type 2 diabetes after GDM include the use of insulin during pregnancy (Lee et al. 2007) and being an Indigenous Australian woman (Chamberlain et al. 2016). Other factors associated with an increased risk of developing diabetes after birth include being of an older age and developing hypertension after the index birth (Feig et al. 2008).

2.1.2 Screening and diagnosis of GDM

There is a lack of international consistency in the guidelines used for screening and diagnosis of GDM in different countries and over time (Tieu et al. 2017). In 1998, the Australasian Diabetes in Pregnancy Society (ADIPS) recommended universal screening of pregnant women 26–28 gestational weeks using the Glucose Challenge Test (GCT) (Hoffman et al. 1998). The diagnosis was made according to ADIPS guideline published in 1991, which was based on modified World Health Organisation (WHO) diagnostic criteria. The screening was considered positive if the women’s 1-hour venous plasma glucose level after non-fasting 50g glucose load was ≥ 7.8 mmol/L or ≥ 8.0 after non-fasting 75g glucose load. If the screening was positive, confirmation of GDM diagnosis was made if the women's fasting venous plasma glucose level ≥5.5 mmol/L or ≥8.0 mmol/L at 2 hours following 75g Oral Glucose Tolerance Test (OGTT) (Hoffman et al. 1998).

In 2008, the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study was published (HAPO Study Cooperative Research Group 2008). The HAPO study is a large multinational prospective observational study that investigated the association between maternal hyperglycaemia and adverse pregnancy outcomes among women with hyperglycaemia less severe than diabetes. It found strong continuous associations between maternal glucose levels below the cut-off of diabetes diagnosis and adverse pregnancy outcomes. Following the publication of the HAPO study results, in 2010 the International Association of Diabetes in Pregnancy Study Group (IADPSG) formulated a new guideline for testing and diagnosis of GDM that recommended a diagnosis of GDM if 75g OGTT test resulted in one or more of the following glucose measures

- fasting Plasma glucose ≥5.1 mmol/L
- one-hour plasma glucose ≥ 10.0 mmol/L
- two-hour plasma glucose ≥8.5 mmol/L (IADPSG Consensus Panel 2010).

In 2013, ADIPS adopted the IADPSG diagnostic criteria as a recommended diagnosis of GDM and published a new guideline that recommended screening of all pregnant women at 24–28 weeks of gestation by a 75g OGTT.

For women with identified risk factors for GDM, ADIPS recommended a 75g OGTT at the first opportunity after conception (Nankervis et al. 2013). The guideline identified the following factors as being high-risk factors for GDM:

- GDM in a previous pregnancy
- previously high blood glucose level
- being of Asian, Indian, Indigenous, Pacific Islander, Maori, Middle Eastern or non-white African background
- maternal age greater or equal to 40 years
- a family history of diabetes
- Body Mass Index (BMI) >35 kg/m^2
- previously given birth to a macrosomic baby (birthweight >4500g or >90th centile)
- women with Polycystic ovarian syndrome
- using medications such as corticosteroid or antipsychotics (Nankervis et al. 2013).

2.1.3 Prevalence of diabetes during pregnancy

Globally, 16.2% of live births are to women with some form of hyperglycaemia in pregnancy. Of these, the majority (86.4%) are due to GDM and 13.6% are due to pre-existing diabetes (International Diabetes Federation 2017). The increase in both pre-existing diabetes and GDM is associated with the increase in a number of risk factors: the rising prevalence of type 1 and type 2 diabetes in the general population; higher rates of obesity; and the increase in the number of pregnancies in older women (Khalifeh et al. 2014; NICE 2015). This increase is also associated with the increase in screening and detection (Lavery et al. 2017).

In Australia, approximately 300,000 women give birth each year, with more than 10% of these women having either pre-existing or GDM (1.1% pre-existing diabetes and 9.4% GDM) (AIHW 2017a). As in other parts of the world, the prevalence of diabetes in Australia has risen in parallel with the increasing risk factors such as obesity, less physical activity and changes in the ethnic mix of the population (Shand et al. 2008). For instance, there was a 22% increase in the age-standardised incidence rate of GDM between 2000-2001 and 2005-2006 (Templeton & Pieris-Caldwell 2008), and for pre-existing diabetes, there was an increase in the prevalence from 0.4% to 0.6%, which represents an increase of 50% over a 10-year period (Abouzeid et al. 2014).

Prevalence of GDM in Australia using the new IADPSG recommended diagnostic criteria

More women are likely to be diagnosed with GDM using the new diagnostic guidelines based on IADPSG criteria (Nankervis et al. 2013). In 2011, a prospective study performed in Wollongong a large town in New South Wales (NSW) found that the prevalence of GDM increased from 9.6% using the old ADIPS criteria to 13.0% using IADPSG criteria (Moses et al. 2011). Results of a sample from the public and the private sector in Wollongong show that between 2012 and 2014 the prevalence of diabetes in pregnancy was 13.1% with 0.4% being pre-existing diabetes and 12.7% being GDM (Moses et al. 2016). Wollongong is known for its' high level of compliance with the universal testing of GDM (Moses et al. 2016) which explains the high prevalence of GDM relative to the prevalence of GDM in Australia.

2.1.4 Outcomes of diabetes during pregnancy

As described in Chapter 1, diabetes in pregnancy is associated with adverse outcomes during pregnancy, childbirth, and the longer-term for both mothers and infants (Chamberlain et al. 2013). Diabetes in pregnancy complications are more likely to affect women with pre-existing diabetes than those with GDM (Alwan, Tuffnell & West 2009; Fong et al. 2014; Shand et al. 2008; Visser & De Valk 2015).

Pre-existing diabetes

Women with pre-existing diabetes are at higher risk of developing gestational hypertension than those without diabetes and more likely to experience microvascular and macrovascular complications. Microvascular complications include retinopathy and nephropathy (McIntyre et al. 2009). Macrovascular complications, such as ischaemic heart disease, which is a rare condition in pregnancy, affect around 1 in 10,000 pregnancies (Fayomi & Nazar 2007).

A Canadian study by Feig et al. (2014) shows that the risk of perinatal mortality is higher among babies born to women with pre-existing diabetes than those born to women without diabetes (Relative risk (RR) 2.33, 95% CI (1.59-3.43)) (Feig et al. 2014). Other national and international studies show that the prevalence of perinatal mortality ranged from 0.2% to 3.9% among women with pre-existing diabetes type 1, and 1.2% to 5.9% among women with pre-existing diabetes type 2 (McIntyre et al. 2009). The risk of stillbirths is five times higher among women with pre-existing diabetes compared to women without diabetes (Egan et al. 2015). Congenital malformation is the main cause of death among infants born to women with pre-existing diabetes (McIntyre et al. 2009). Hyperglycaemia resulting from pre-existing diabetes during embryogenesis is associated with an increase in the risk of congenital malformations (Correa et al. 2008). A population-based study conducted in the north of England by Bell et al. (2012) found that the risk of any major non-chromosomal congenital malformation is three times higher among pregnancies with pre-existing diabetes than those without diabetes (RR 3.8, 95% CI (3.2-4.5)) (Bell et al. 2012). Major congenital malformations include:

- cardiac malformation (dextrocardia, patent ductus arteriosis and ventricular septal defect)
- musculoskeletal (caudal regression)
- central nervous system (spina bifida)
- ear, nose, and throat
- genitourinary (hypospadias complex) (Yang et al. 2006).

The risk of preterm birth is also higher among women with pre-existing diabetes than those without diabetes. Results from a Canadian population-based study by Yang et al. (2006) show that the risk of preterm birth is five times higher among women with pre-existing diabetes compared to women without diabetes (Yang et al. 2006). In NSW between 1998 and 2002, preterm births occurred in about 19.5% of liveborn babies born to women with pre-existing diabetes compared to 5.2% among those born to women without diabetes (Shand et al. 2008).

Fetal macrosomia and being large for gestational age (LGA) are the main adverse outcomes that affect babies born to women with pre-existing diabetes (Wong et al. 2002). In France around 43% of babies born to women with pre-existing diabetes type 1 and 28.9% of those born to women with pre-existing diabetes type 2 are large for gestational age, which is defined as birthweight greater than 90^{th} percentile for a certain gestational age (Billionnet et al. 2017).

Gestational diabetes

Pregnancies affected by GDM have a moderate increase in the risk of adverse perinatal outcome compared to women without diabetes (Billionnet et al. 2017). Adverse perinatal outcomes include pre-eclampsia, preterm birth, shoulder dystocia, high birthweight, congenital malformation, and five minute Apgar score less than seven

(Aviram et al. 2016; Billionnet et al. 2017; Buchanan, Xiang & Page 2012; Ovesen et al. 2015). A national-study of all births in France in 2012, by Billionnet et al. (2017) found that compared to women without diabetes, women with GDM are at a higher risk of eclampsia or preeclampsia (adjusted odds ratio (AOR) 1.6, 95% CI (1.5-1.7)), preterm birth (AOR 1.2, 95% CI (1.2-1.3)), asphyxia (AOR 1.2, 95% CI (1.1-1.3), LGA (AOR 1.8, 95% CI (1.7-1.8)), cardiac malformation (AOR 1.2, 95% CI (1.1-1.3)), and respiratory distress (AOR 1.3, 95% CI (1.2-1.3)). Results from this French study show that for women with term pregnancies, there is a slight increase in the proportion of perinatal mortality among those with GDM (0.21%) compared to women without diabetes (0.15%) (AOR 1.3, 95% CI (1.1-1.6)) (Billionnet et al. 2017).

Both pre-existing diabetes and GDM are associated with an increase in the risk of shoulder dystocia and birth trauma, particularly among macrosomic babies. (Billionnet et al. 2017; Buchanan, Xiang & Page 2012; Visser & De Valk 2015). This will be explored in detail in the next section of this chapter (literature review section).

Toward uniform definitions of diabetes during pregnancy-associated outcomes

In 2015, IADPSG published a systematic review (IADPSG et al. 2015). with the aim of developing uniform definitions for the important and widely used outcomes in studies of diabetes during pregnancy. These definitions will enable a comparison of research findings and their conclusions. These definitions are widely used in the recently published diabetes in pregnancy outcomes research (Abell et al 2019; Alessi et al 2018; Bianchi et al 2018; Simmons et al 2018).

2.2 Literature review

This literature review aims to better understand the literature in relation to the following factors: decisions around interventions among women with diabetes (induction of labour and method of birth); perinatal outcomes; and women's demographics. The main sources of the literature reviewed were online databases, including Scopus, PubMed, Medline and Cochrane Library. The following keywords/mesh terms were used: gestational diabetes, pregnancy in diabetes, diabetes mellitus type1, diabetes mellitus type 2, hyperglycaemia, pregnancy outcome, caesarean section, labour, obstetric, induced labour, fetal macrosomia, birthweight, low birthweight, large for gestational age, small for gestational age, gestational age, obstetric labour complications, episiotomy, perineum, laceration, obstetric anal sphincter injury, perineal trauma, infection, wound infection, stillbirth, fetal death, neonatal death, perinatal death, perinatal mortality, infant mortality, preterm birth, live birth, neonatal intensive care units, neonatal intensive care, special care nursery, Apgar score, neonatal resuscitation, resuscitation, congenital abnormalities, birth defect.

Other sites and sources for the literature review were individual websites for national and regional obstetrics and gynaecology professional organisations and societies, and diabetes during pregnancy societies such as ADIPS. In addition, many references cited in the selected articles were included. Different types of articles selected for inclusion in this literature review include randomised controlled trails, cohort studies, case-controlled studies, case series studies, reviews, systematic reviews, and obstetric guidelines.

2.2.1 Method of birth for women with diabetes during pregnancy

Women with diabetes during pregnancy have a higher prevalence of caesarean section (Alwan, Tuffnell & West 2009; Feig et al. 2006). This practice occurs in the context of no clinical consensus around the optimal method of birth for women with diabetes during pregnancy and a lack of evidence to support the choice of elective caesarean section without other obstetric indications (Maso et al. 2014; Stuart, Matthiesen & Källén 2011).

Guidelines for method of birth

There are number of national and professional society guidelines that use different evidence and strength of recommendations on diabetes during pregnancy. There is no internationally accepted guideline regarding the preferred elective method of birth for women with diabetes during pregnancy. This reflects the lack of evidence and practice consensus at an international level. Table 2.1 shows a range of national and international guidelines for time and method of birth for women with diabetes during pregnancy.

Table 2.1: Guidelines for time and method of birth for women with diabetes during pregnancy

Institution	Guideline	Recommendation
(ACOG 2005)[a]	Pre-gestational Diabetes Mellitus	A caesarean section may be considered if the estimated fetal weight is greater than 4500g
(ACOG 2018)[a]	Gestational diabetes mellitus	Women should be counselled regarding the risks and benefits of a scheduled caesarean section when the estimated fetal weight ≥ 4500g
(ACOG 2016)[a]	Fetal macrosomia	For women with diabetes caesarean section may be considered for suspected fetal macrosomia with an estimated fetal weight of at least 4500g
ADIPS 2005	Position statement / Consensus guidelines for the management of patients with of type 1 and type 2 diabetes in relation to pregnancy	Induction of labour or operative delivery should be based on obstetric and/or fetal indications.
ADIPS 1998	Gestational diabetes mellitus -- management guidelines	Birth before full term is not indicated unless there is evidence of macrosomia, polyhydramnios, poor metabolic control or other obstetric indications
NICE 2015	Diabetes in pregnancy	Advise[(b)] pregnant women with type 1 or type 2 diabetes and no other complications to have an elective birth by induction of labour, or by elective caesarean section if indicated, between 37+0 weeks and 38+6 weeks of pregnancy. Advise[(b)] women with gestational diabetes to give birth no later than 40+6 weeks, and offer elective birth (by induction of labour, or by caesarean section if indicated) to women who have not given birth by this time

ACOG: American College of Obstetricians and Gynecologists. ADIPS: Australasian Diabetes in Pregnancy Society. NICE: National Institute for Health and Care Excellence
(a) Level of evidence B: Recommendations are based on limited or inconsistent scientific evidence.
(b) Advise: the expert group are confident that the intervention do more good than harm to the majority of patients and be cost effective.

Table 2.1 demonstrates that there are no strong recommendations regarding timing and method of birth and that the recommendations were built on limited and inconsistent evidence. After reviewing published studies regarding timing and method of birth, the NICE expert group concluded that the quality of the studies which compared pregnancy outcome after elective birth or expectant birth was low and very low (NICE 2015).

The lack of strong and comprehensive guidelines regarding the optimal timing and method of birth for women with diabetes during pregnancy most likely contributes to the variations seen in current clinical practice.

Practice for method of birth

As previously described, there is no internationally accepted guideline around the best method of birth for women with diabetes during pregnancy. This is compounded by a lack of literature providing strong evidence to inform decision making around method of birth (onset of labour and method of birth) and the risk or protective associations of perinatal outcomes. Women with diabetes during pregnancy have a significantly higher rate of intervention during pregnancy including both caesarean section and induction of labour than women in the general population (Confidential Enquiry into Maternal and Child Health (CEMACH) 2005).

In the UK in 2016, 64.7% of women with pre-existing diabetes type 1 and 56.9% of those with type 2 diabetes gave birth by caesarean section, compared to 28% of women in the UK general population (National Health Service 2017).

There have been no national studies in Australia on the indications for induction of labour and method of birth for women with diabetes during pregnancy. The only national report that provides information about method of birth is *Diabetes in pregnancy: its impact on Australian women and their babies* (AIHW 2010), which shows that 39% of women with pre-existing diabetes and 22% of women with GDM gave birth without going into labour compared to 18% of women without diabetes.

Moreover, 59.2% of women with pre-existing diabetes and 40.1% of women with GDM gave birth by caesarean section compared to 30.0% of women without diabetes. This AIHW report did not provide information on the onset of labour and method of birth by gestation, and there were no analyses on the indication for caesarean section and whether it was an intervention to minimise the risk of adverse perinatal outcomes for women with diabetes. This is despite the rate ratio of the caesarean section being 1.97 and 1.33 among women with pre-existing diabetes and GDM respectively compared to women without diabetes giving birth (AIHW 2010).

The differences between the guidelines listed in Table 2.1 may reflect the timing of the guidelines, the available evidence, and expert opinion and practice. The practice for method of birth can be affected by health service policies and behaviour of healthcare professionals (NICE 2015).

It is therefore important to examine factors that can affect both onset of labour and method of birth, and the related impact on perinatal outcomes for women with diabetes during pregnancy. These will be examined in the following sections of the literature review.

Fetal macrosomia

There is no international consensus on the definition of fetal macrosomia (ACOG 2016; Boulet et al. 2003; Hong et al. 2009; Koyanagi et al. 2013). For example, fetal macrosomia is defined as a birthweight greater than 4000g (Koyanagi et al. 2013), 4500g (Hong et al. 2009) and 5000g (Boulet et al. 2003). For babies born to women with diabetes, macrosomia is defined as birthweight greater than or equal to 4000g (IADPSG et al. 2015).

Fetal macrosomia is associated with increased risks of interventions and adverse outcomes for both mothers and babies. In its guideline "Fetal macrosomia", The American College of Obstetricians and Gynecologists (ACOG 2016) stratify the risk of macrosomia in general obstetric population into three categories according to birthweight:

- Birthweight between 4000 and 4499g is associated with an increase in the risk of labour abnormality and neonatal complications (ACOG 2016).
- Birthweight between 4500 and 4999g is associated with additional risk of maternal and neonatal morbidity (ACOG 2016).
- Birthweight equal to or greater than 5000g is associated with additional risk of perinatal mortality (ACOG 2016).

Women with diabetes during pregnancy have a higher rate of macrosomia and LGA babies than women without diabetes (Billionnet et al. 2017; CEMACH 2005; He et al. 2015; Shand et al. 2008; Wang et al. 2017).

Between 2002 and 2003 the rate of macrosomia (birthweight ≥4000g) among infants born to women with pre-existing diabetes was 21% in England and Wales (CEMACH 2005). This rate was almost double the UK national rate of macrosomia (11.0%) (CEMACH 2005).

Results from a USA study by Black et al. (2013) showed that the rate of birthweight > 4000g was 13.6% among singleton babies born to women with GDM compared to 7.7% of those born to women without diabetes, and the Adjusted odds ratio (AOR) for LGA was 1.96, 95% CI (1.43-2.68) (Black et al. 2013). Surprisingly, results from AIHW (2010) national report showed that the age-standardised rate of macrosomia (birthweight ≥4000g) among live-born babies born to women with GDM was lower than those born to women without diabetes (13.9%, 95% CI (13.2-14.6) vs (14.9%, 95% CI (14.1-15.6)) among male babies and (8.8%, 95% CI (8.3-9.4) vs 8.9%, 95% CI (8.4-9.5) among female babies) (AIHW 2010). However, this difference was not statistically significant as the 95% CI overlap for both male and female babies.

Shoulder dystocia and birth trauma

Macrosomia resulting from maternal hyperglycaemia is different from macrosomia associated with other factors. Compared to macrosomic infants born to women without diabetes, macrosomic infants of women with diabetes during pregnancy are characterised by higher total body fat, greater upper extremities circumference, larger shoulders and higher measurements for upper extremities skin fold. Macrosomic infants of women with diabetes during pregnancy tend to have smaller head to abdominal circumference ratio than those of women without diabetes (McFarland, Trylovich & Langer 1998; Nasrat et al. 1997).

The difference in fetal body shape and higher fat deposit in the upper extremities are responsible for the higher rate of shoulder dystocia among macrosomic infants of women with diabetes during pregnancy than those of women without diabetes (McFarland, Trylovich & Langer 1998). The relative risk of shoulder dystocia among women with diabetes during pregnancy is 5.9, (95% CI (4.39-7.98) compared to women without diabetes. As well, shoulder dystocia among women with diabetes was associated with an increase the odds of perinatal mortality (OR 17.21, 95% CI (8.51-34.83)), birth trauma (OR 15.47, 95% CI (8.17-29.28)), and a five minute Apgar score less than seven (11.06, 95% CI (5.90-20.44)) (Langer et al. 1991). In a hospital-based retrospective study, a similar conclusion was made by Acker, Sachs & Friedman.(1985), who found that shoulder dystocia among women with diabetes was five times higher than among women without diabetes;(Acker, Sachs & Friedman 1985), however, this study was subject to bias as there was no adjustment for potential confounders. Das et al. (2009) found that 73.2 % of babies born to women with diabetes had at least one of the adverse outcomes (birth injury, respiratory distress and hypoglycaemia) compared to 49.6% among babies born to women without diabetes (Das et al. 2009). In addition, babies born to women with diabetes during pregnancy were more likely to stay in hospital for more than three days than those born to women without diabetes (22.9% vs 14.2%). Due to the small sample size of this study (41 macrosomic babies to women with diabetes and 262 macrosomic babies to women without diabetes) and rarity of the outcome, composite outcomes were compared. Das et al (2009) did not find a significant difference between the incidence of brachial plexus injury and fracture due to the small numbers of these adverse outcomes.

In contrast, a significant difference in the rate of brachial plexus injury between infants weighing 4000g or more who were born to women with GDM compared to those born to women without diabetes (0.7% and 0.1%), respectively, was found in a California, USA, study by Esakoff et al. (2009). In addition to brachial plexus injury, there was a significant difference in the rate of shoulder dystocia and respiratory distress syndrome, which were both higher among macrosomic infants born to women with GDM (Esakoff et al. 2009). Esakoff et al's (2009) findings were consistent with an earlier study by Langer et al. (1991) that found the rate of shoulder dystocia among macrosomic infants born to women with diabetes during pregnancy was 14.7% compared to 4.4% for those born to women without diabetes (Langer et al. 1991).

Infants born to women with diabetes during pregnancy with a birthweight range 3750–4000g had the same risk of shoulder dystocia as that of infants weighing 4250–4500g who were born to women without diabetes (Nesbitt, Gilbert & Herrchen 1998). This suggests that infants born to women with diabetes during pregnancy may have poorer outcomes than infants born to women without diabetes even with the same birthweight. This necessitates the need for specific advice on management for mothers with diabetes during pregnancy who expect macrosomic babies.

It is not possible to draw a definitive conclusion regarding the outcome of infants born to women with GDM during pregnancy due to the heterogeneity of the studies. For instance, some of the studies analysed both pre-existing diabetes and GDM together (Das et al. 2009; Langer et al. 1991; Nesbitt, Gilbert & Herrchen 1998). In addition, there was no information about the diagnostic criteria of GDM.

2.2.2 Neonatal outcomes by method of birth

As described in the previous section, infants born to women with diabetes during pregnancy are more likely to have shoulder dystocia than those born to women without diabetes. The risk of shoulder dystocia is also associated with method of birth. Nesbitt, Gilbert & Herrchen (1998) found that for women with diabetes during pregnancy the risk of shoulder dystocia was higher among women who had instrumental vaginal birth compared to those who had normal vaginal birth. Table 2.2 shows their results for different birthweight groups (Nesbitt, Gilbert & Herrchen 1998):

Table 2.2: Proportion of shoulder dystocia by birthweight and method of birth for women with diabetes during pregnancy

Birthweight (gram)	Proportion of shoulder dystocia	
	Normal vaginal birth	Instrumental vaginal birth
4000 - <4250	8.4	12.2
4250 - <4500	12.3	16.7
4500 - <4750	19.9	27.3
4750 - 5000	23.5	34.8

Consistent with the Nesbitt et al. (1998) results, Athukorala et al. (2007), found an increase in the risk of shoulder dystocia among infants born to women with GDM who had instrumental vaginal birth compared to those who had spontaneous vaginal birth (RR 9.58, 95% CI (3.70-24.81)) (Athukorala et al. 2007).

Caesarean section is a method of birth that can be used for women with diabetes during pregnancy to potentially reduce the risk of fetal hypoxia and labour complications associated with macrosomia such as shoulder dystocia, brachial plexus injuries and fractures (Garabedian & Deruelle 2010; Maso et al. 2014). However, not all birth injuries can be prevented by caesarean section. For instance, brachial plexus injury can happen in both vaginal births and caesarean sections (Alexander et al. 2006; ACOG 2014). This is supported by the results of a case series review of birth records of 17 cases of brachial plexus palsies after caesarean section, at the Los Angeles County University of Southern California Women's Hospital (Gherman et al. 1997). Nine cases that occurred after a complicated breech and two cases with difficult cephalic birth were excluded. Six cases were identified after an uncomplicated caesarean section, and all had evidence of persistent nerve root avulsion at one year of age (Gherman et al. 1997). However, evidence to date shows the risk of injury remains lower following caesarean section than for an instrumental vaginal birth (Kolderup, Laros Jr & Musci 1997).

Most birth injuries, such as neonatal fractures, heal spontaneously or with supportive therapy, while others such as persistence brachial plexus palsy need surgical repair (Garabedian & Deruelle 2010; Rouse et al. 1996). The longer-term outcomes of brachial plexus injuries, including neurologic complications, range between 5% and 22% of affected babies (Ecker et al. 1997). Therefore, iatrogenic brachial plexus injuries can occur with caesarean section even though most will heal spontaneously. For this reason, the choice of performing caesarean to prevent birth injuries should be balanced against the risks of the adverse outcome of caesarean section on both the mother and the baby.

To investigate the association between method of birth and persistent infant injury (injuries clinically evident at six months of age), Kolderup, Laros Jr & Musci (1997) reviewed 2,924 birth records for macrosomic infants (≥ 4000g). They found a significant association between method of birth and the increase in the risk of birth injury, and that instrumental vaginal birth by forceps was associated with around a fourfold increase (RR 4.1, 95% CI (2.7-6.2)) in the risk of persistent injury compared to spontaneous vaginal birth or caesarean section (Kolderup, Laros Jr & Musci 1997).

Researchers have studied the number of caesarean sections needing to be performed to prevent one permanent birth injury. A decision analytic model to compare three policies of the elective caesarean section for both women with diabetes during pregnancy and women without diabetes was constructed by Rouse et al. (1996) The policies are: 1) elective caesarean section without ultrasound estimation, 2) elective caesarean section for estimated birthweight of 4000g or more, and 3) elective caesarean section for estimated birthweight of 4500g or more. After a literature search, the rate of 6.7% was used as a probability of permanent brachial plexus injuries to model the number of caesarean section needed to prevent one permanent brachial plexus palsy. For women without diabetes, 3,695 and 2,345 caesarean sections were needed for the 4500g and 4000g policies respectively, while for women with diabetes during pregnancy 443 and 489 caesarean sections were needed for the estimated birthweight of ≥ 4500 and ≥ 4000g, respectively (Rouse et al. 1996).

This Rouse et al. (1996) study was followed by the Ecker et al. (1997) study, which used a wider range of rates of permanent brachial plexus injury for their model (5-22%)

(Ecker et al. 1997). This study found that between 219 and 962 caesarean sections were needed for women with diabetes during pregnancy to prevent one permanent brachial plexus injury for the estimated birthweight ≥ 4000g; and 91 to 400 caesarean sections for the estimated birthweight ≥ 4500g (Ecker et al. 1997).

As explained earlier, not all birth injuries can be prevented by caesarean section and the number of caesarean sections needed to prevent one permanent birth injury is very high. Pooling of studies and or contemporaneous large population-based studies are indicated to estimate the number of caesarean sections needed to prevent birth injuries. This is particularly relevant as the rate of macrosomia and LGA babies continues to increase over time with the rising rates of obesity and diabetes in pregnancy internationally (Abouzeid et al. 2014; Lahmann, Wills & Coory 2009; Surkan et al. 2004).

The literature on the association of method of birth on other neonatal outcomes such as Apgar score, admission to neonatal intensive care unit, neonatal resuscitation, and perinatal mortality is insufficient. Stuart, Matthiesen & Källén (2011) conducted a population-based study to investigate the association between method of birth and adverse neonatal outcomes among women with diabetes during pregnancy (Stuart, Matthiesen & Källén 2011). The main outcome of the Stuart et al. (2011) study was five minute Apgar score less than seven. The study found that babies born to mothers who had an elective caesarean section at 38 weeks gestation had a lower risk of a five minute Apgar score less than seven compared to those born at 39 weeks gestation or more, regardless of their method of birth (AOR 0.51, 95% CI (0.28-0.90)) (Stuart, Matthiesen & Källén 2011). However, this study did not find a significant difference in the risk of perinatal death between groups who had an elective caesarean section at 38 weeks and those who continued to 39 weeks or more.

Outcomes of routine induction of labour

The aim of planned induction of labour birth for women with diabetes during pregnancy is to reduce the rate of fetal hypoxia, fetal macrosomia and shoulder dystocia (NICE 2015). However, it may also be associated with an increase in the rate of adverse pregnancy outcomes such as caesarean section and fetal transient tachypnoea (Al-Agha et al. 2010; NICE 2015).

In a recent randomised control trial, women with GDM were randomised to either have induction of labour between 38+0 and 39+0 weeks gestation or expectant management, with the main outcome of the study being caesarean section rate (Alberico et al. 2017). The study did not find a significant difference in the incidence of caesarean section between the induction of labour group and expectant management group (12.6% vs 11.8%, RR 1.06, 95% CI (0.64-1.77)) (Alberico et al. 2017). Nor did the study find a significant difference in the secondary maternal outcomes, including postpartum hemorrhage and perineal tears; admission to intensive care unit and maternal mortality; neonatal outcomes birthweight ≥ 4000g; five minute Apgar score less than seven; hypoglycaemia; admission to NICU, and respiratory distress. The only significant difference in neonatal outcome in the study was in the incidence of hyperbilirubinaemia, which was significantly higher among the induction group (RR 2.46, 95% CI (1.11-5.46)). This study (Alberico et al. 2017). was the only study included in the recently published Cochrane systematic review of randomised trials that compared perinatal outcomes by planned birth (induction or caesarean section) and expectant mangement at term for women with GDM (Biesty et al. 2018).

Kjos et al.'s. (1993) randomised control trial found that expectant management not only did not reduce the rate of the caesarean section, but it was associated with an increase in the rate of LGA babies with no significant increase in the rate of shoulder dystocia (Kjos et al. 1993). However, this study was underpowered and did not show a difference in the rate of maternal and neonatal morbidity because of the small number of women (n = 200) included in the study. In addition, this study was considered to be of low quality due to the lack of information on the randomisation process and whether it was affected by potential confounders (NICE 2015).

To study the impact of time of induction of labour on perinatal outcomes, Worda et al. (2017), included women with insulin controlled GDM in a study of randomised women who had an induction of labour at 38 gestational age and those who had an induction at 40 weeks gestational age. This study did not find a significant difference in birthweight, five minutes Apgar score, or admission to NICU. In addition, there was no significant difference in the rate of caesarean section after induction of labour. However, babies born to women who had induction of labour at 38 weeks were at a higher risk of developing hypoglycaemia (RR 2.14, 95% CI (1.02-4.49)) (Worda et al. 2017). Several other observational studies have investigated the association of induction of labour with the risk of caesarean section. The results of these observation studies are summarised in Table 2.3.

Table 2.3: Published observation studies that investigate the effect of induction of labour on caesarean section rate

Authors and's name, year	Study design	Pre-existing diabetes/ GDM	GDM diagnosis test	Conclusion
(Melamed et al. 2016)	retrospective population-based study	GDM	50g GCT[a]	Induction of labour at 38 or 39 weeks associated with a reduction in risk of caesarean section compared to expectant management Induction at 39 weeks may associate with an increase in the risk of admission to NICU
(Bas-lando et al. 2014)	retrospective case–control matched study, based	GDM	50g GCT[a]	Higher rate of caesarean section after induction among women with GDM compared to non-diabetic mothers a non-significant difference in the rate of maternal outcomes
(Sutton et al. 2014)	secondary analysis multicentre RCT	Mild GDM	100g OGTT[b]	Induction of labour in women with mild GDM does not increase the rate of caesarean section at <40 weeks' gestation. No difference in composite perinatal outcome[c]
(Alberico et al. 2010)	retrospective cohort study	GDM	50g GCT[a]	No significant difference in the rate of caesarean section or macrosomic infants

(Levy et al. 2002)	retrospective cohort study	Both	-	Induction of labour was not an independent risk factor for caesarean section

(a) Glucose Challenge Test
(b) Oral Glucose Tolerance Test
(c) Includes one of the following outcomes hypoglycaemia, hyperbilirubinemia, respiratory distress syndrome and birth trauma

It is not possible to draw a definitive conclusion from the studies included in Table 2.3 due to heterogeneity of these studies. For example, Levy et al. (2002) included both pre-existing diabetes and GDM in the analysis and their study did not differentiate between labour and no labour caesarean section, (Levy et al. 2002) while Alberico et al.(2010) had selection bias with a significantly higher rate of very obese women in the elective birth group (Alberico et al. 2010). Other major forms of heterogeneity included the inclusion thresholds of gestational diabetes; gestational age(s); and comparison groups. Bas -Lando et al. (2014), for instance, compared women with diabetes to women without diabetes (Bas-lando et al. 2014).

Conway et al.(1998) evaluated a protocol that was introduced in 1993 to include ultrasonographically estimated fetal weight into the management decisions on timing and method of birth for women with diabetes during pregnancy (Conway & Langer 1998). These protocols included three recommendations:

- If estimated fetal weight was approperiate for gestational age, expectant management was recommended
- If estimated fetal weight was greater or equal to 4250g, an elective caesarean section was performed
- If estimated fetal weight was LGA but it less than 4250g, an induction of labour was performed.

Conway & Langer (1998) study showed a significant reduction in the rate of shoulder dystocia and a significant increase in the rate of caesarean section between the period before the introduction of the protocol in 1993 and the period after the introduction of the protocol (Conway & Langer 1998).

2.2.3 Timing of induction of labour

In a population-based longitudinal study by Hod et al (1998), three policies in three different time periods for management of women with GDM were compared. The policy of combining desired mean maternal glycaemia ≤ 5.3 mmol/l; caesarean section for estimated weight 4000g; and induction of labour at 38 weeks gestation for LGA was associated with significant decreases in macrosomic and LGA births without a significant change in the rate of caesarean section (Hod et al. 1998).

In contrast, Peled et al. (2004) concluded that good glycaemic control and early induction of labour could improve perinatal outcomes, including shoulder dystocia and perinatal mortality. However, induction of labour was associated with significant increase in the rate of caesarean section (Peled et al. 2004).

As can be seen, there is no strong evidence to support the elective caesarean section for women with diabetes and no evidence to support the optimum timing of induction of labour. There is a need for further evidence at a population-based level. Evidence from published literature in this area is of largely low level, with small or very small sample sizes mostly used.

2.2.4 Maternal outcomes

The decision-making process around timing and method of birth for women with diabetes during pregnancy should include an assessment of the risk of maternal morbidity and mortality. The literature shows that women with diabetes have a higher risk of labour and perinatal and long-term complications compared to women without diabetes.

In NSW, Shand et al (2008) found that compared to women without diabetes, the odds of a third- or fourth-degree perineal tear among women with pre-existing diabetes and GDM are 1.70, 95% CI (0.94-3.01) and 1.43, 95% CI (1.24-1.65) respectively; the odds of admission to intensive care unit (ICU) are 9.08, 95% CI (5.89-13.89) and 1.89, 95% (CI 1.45-2.47), respectively; and the odds of readmission to hospital more than 10 days after birth are 6.13, 95% CI (4.57-8.20) and 1.30, 95% CI (1.09-1.54) respectively (Shand et al. 2008). In a population-based study in NSW, Ampt et al. (2013) found a 24% increase in the odds of third-and fourth-degree perineal tear among multiparous women with diabetes during pregnancy compared to women without diabetes (AOR 1.24, 95%CI (1.07-1.44). They also found that for women without diabetes, instrumental vaginal birth was associated with an increase in the odds of third- and fourth-degree perineal tear (Ampt et al. 2013). Moreover, results from a hospital-based study in Northern California show that giving birth to a baby with birthweight between 4000-4499g was associated with an increase in the odds of fourth-degree perineal tear (AOR 2.45, 95% CI (2.16-2.79)), the odd ratios of fourth-degree perineal tear increased with the increase in birthweight (4500-4999g, AOR 4.24, 95% CI (3.30-5.43) and ($\geq$ 5000g, AOR 7.27 95% CI (3.58-14.75)) (Stotland et al. 2004).

There is an association between caesarean section and the increase in the risk of adverse maternal outcomes, including immediate risks such as infection, haemorrhage, risks from anaesthesia and mortality, delay risks such as thromboembolism, delayed recovery, and hospital readmission (D'Souza & Arulkumaran 2013).

Davies et al (2010) found pre-existing diabetes and GDM are more prevalent in obese women. The adjusted odds ratio of developing GDM in obese women (BMI 30-34.9) is (2.6, 95% CI (2.1-3.4)), and in the morbidly obese (BMI ≥ 35) it is (4.0, 95% CI (3.1-5.2)). Obese women with diabetes during pregnancy who undergo caesarean section are at higher risk of wound infection (OR 9.3, 95% CI (4.5-19.2)) and the rate of serious wound complication is 12% (Davies et al. 2010). Among obese women who undergo elective caesarean section, obesity is an independent risk factor for postoperative infection and endomyometritis even with the prophylactic administration of antibiotics (Myles, Gooch & Santolaya 2002).

Maternal outcomes by method of birth for women without diabetes have been investigated in population-based studies, for example, Bjorstad et al. (2010). Population-based studies are needed to investigate maternal outcomes by method of birth for women with diabetes during pregnancy. Specifically, there is a gap in the literature regarding the maternal outcome for women with diabetes during pregnancy after a vaginal birth and after a no labour caesarean section.

2.2.5 Factors affecting decision around onset of labour and method of birth

Institutional effect

Birth intervention, including method of birth, is influenced by institutional practice. In Australia, there are two primary institutional settings where maternity care is delivered – the public hospital and the private hospital. Previously published population-based studies in Australia have shown that obstetric interventions are higher in private hospitals than in public hospitals (Dahlen et al. 2012; Dahlen et al. 2014; Einarsdóttir et al. 2013; Robson, Laws & Sullivan 2009). Using the Australian National Perinatal Data

Collection, Robson, Laws and Sullivan (2009) found that rates of both caesarean section and instrumental vaginal birth were higher among women who gave birth in private hospitals compared to those who gave birth in public hospitals (Robson, Laws & Sullivan 2009). A population-based study in NSW by Dahlen et al. (2012) found that, compared to low-risk women who gave birth in public hospitals, low-risk primiparous and multiparous women who gave birth in private hospitals had a higher rate of caesarean section (primiparous 27% vs 18%, multiparous 27% vs 16%), instrumental vaginal birth (primiparous 29% vs 18%, multiparous 7% vs 3%), induction of labour (primiparous 31% vs 23%, multiparous 29.5% vs 18.4%) and episiotomy (primiparous 28% vs 12%, multiparous 8% vs 2%). This study also found obstetric interventions in private hospitals was almost doubled from the period between 1996/1997 and 2000/2008, while there was steady increase of these interventions in public hospitals (Dahlen et al. 2012). Similarly, a population-based study in Western Australia by Einarsdóttir et al (2013) showed a significantly higher rate of obstetric interventions in private hospitals compared to public hospitals (no labour caesarean section 25.2% vs 18.0%, induction of labour 36.5% vs 26.9%) (Einarsdóttir et al. 2013).

Between 1998 and 2002, 16% of women with diabetes during pregnancy gave birth in NSW private hospitals and 84% gave birth in public hospitals (Shand et al. 2008). To date no published study in Australia has examined the rate of obstetric interventions and perinatal outcomes among women with diabetes during pregnancy in private and public hospitals. This will be examined in Chapter 7 of this thesis.

The influence of maternal socio-demographic factors

The association between maternal socio-demographic factors and diabetes in pregnancy and perinatal outcome have been examined in the literature. The rate of GDM differs by maternal country of birth. In Sweden, the highest rate of GDM was found among women born in Africa, followed by women born in Asia, compared to women born in Nordic countries (2.9%, 2.5% and 0.7% respectively) (Fadl, Ostlund & Hanson 2012). Interestingly, these researchers did not find a significant difference between the rate of caesarean section and the rate of shoulder dystocia between Nordic and non-Nordic born mothers (Fadl, Ostlund & Hanson 2012). A similar population-based, cross sectional study in Victoria, Australia, (Carolan et al. 2012). adds further evidence to the differential risk of GDM by maternal country of birth. They found women born in Asia had the highest rate of GDM at 11.5% compared to 3.7% among women born in Australia.

In results comparable with those of the Victorian study, a population-based cohort study in NSW found that compared to women born in Australia and New Zealand, women born in south Asia had the highest risk of developing GDM (OR 4.22, 95% CI (4.01-4.44)) followed by women born in northeast and southeast Asia (OR 3.24, 95% CI (3.16-3.34)) (Anna et al. 2008). Similar results were found by Dahlen et al. (2015), in a study conducted at Blacktown Hospital in NSW: non-Australian born women had a higher rate of GDM (13.7%) compared to Australian born women (6.8%) (Dahlen et al. 2015).

Age is a strong risk factor for GDM (Carolan et al. 2012). Women with GDM are more likely to be older than women without GDM; the average age for women with GDM is 30.8 years compared to 28.7 years for women without GDM (Abouzeid et al. 2015).

Low socioeconomic status is also a risk factor for GDM, with women living in the most deprived areas more likely to have GDM than women living in less deprived areas (Abouzeid et al. 2015). Moreover, living in the two lowest areas of deprivation increased the risk of developing GDM (OR 1.74, 95% CI (1.69-1.80)) and 1.65, 95% CI (1.60-1.70)) compared to living in the highest quartile area (Anna et al. 2008).

2.2.6 Summary of the literature review and identified gaps in the literature

There is a high prevalence of induction of labour and no labour caesarean section among women with diabetes during pregnancy. There is inconsistency in the national and international professional guidelines regarding the recommended method of birth for women with diabetes during pregnancy. Several factors can affect the choice of method of birth for women with diabetes during pregnancy, including maternal sociodemographic factors, institutional factors, and complications such as high birthweight, shoulder dystocia, and birth trauma. The literature is inconsistent regarding the effect of method of birth on neonatal and maternal outcomes. A number of studies suggest elective births, either by induction of labour or caesarean section before labour, can be associated with a reduction in the rate of adverse neonatal outcomes. Most of these studies focused on shoulder dystocia and birth trauma. Only a few studies investigated the association between performing no-labour caesarean section on other neonatal outcomes such as five minute Apgar score, admission to NICU/SCN, and neonatal resuscitation.

Most of the studies that investigated the association between method of birth and perinatal and maternal outcomes are hospital-based studies with small sample sizes and are more than 20 years old and reflect the demographic and risk profile of the times as well as the models of care which may no longer be relevant today.

The literature on method of birth for women with diabetes during pregnancy shows the more than 85% of the studies that investigate the association between method of birth and perinatal outcomes are published between 1985 and 2010 (Acker, Sachs & Friedman 1985; Athukorala et al. 2007; Ecker et al. 1997; Garabedian & Deruelle 2010; Kolderup, Laros Jr & Musci 1997; Langer et al. 199; Nesbitt, Gilbert & Herrchen 1998; Rouse et al. 1996). Although these studies are published 20-30 years ago, they were core evidence regarding the association of method of birth for women with diabetes during pregnancy and perinatal outcomes. For example, four of these studies have been cited in the recently published ACOG guideline Gestational Diabetes Mellitus (2018): Acker, Sachs & Friedman 1985 (Evidence level II-3), Langer et al. 1991 (Evidence level II-3), Nesbitt, Gilbert & Herrchen 1998 (Evidence level III) and Rouse et al. 1996 (Evidence level II-3).

The literature review of this thesis identified one population-based study (Stuart, Matthiesen & Källén 2011) that was published after 2010. This study investigated the association between method of birth and perinatal outcomes including Apgar score and perinatal death Stuart, Matthiesen & Källén 2011).

The lack of current literature and the rarity of adverse maternal and perinatal outcome indicates the need for large population-based studies to investigate maternal and perinatal outcome by method of birth for women with diabetes during pregnancy.

2.3 Rationale for the thesis

As mentioned in Chapter 1, this thesis includes a series of four population-based studies that aimed to address some of the gaps in the literature about method of birth for women with diabetes during pregnancy. Using the NSW Perinatal Data Collection (PDC), these studies will provide evidence-based results to help inform the choice of method of birth for women with diabetes during pregnancy. Overall, this research will inform the association between method of birth and maternal and neonatal outcomes for women with diabetes during pregnancy giving birth in NSW. It will contribute to the body of knowledge of diabetes during pregnancy and provide information for women, maternity clinicians, policy makers and governments to assist health service planning and joint decision making around method of birth for women with diabetes during pregnancy. The intention of each study will now be briefly described.

Study one (Chapter 4): Caesarean section and diabetes during pregnancy: An NSW population study using the Robson classification.

The Robson classification for caesarean section is a classification that "is totally inclusive and mutually exclusive" (Betran et al. 2014). It is clinically relevant and prospective, it is based on parity, previous caesarean section, gestational age, onset of labour, fetal presentation and number of fetuses (Betran et al. 2014). The Robson classification allows the comparison of caesarean section rate subgroups as well as the contribution of caesarean section in each group to the total caesarean section rate. In this study, the use of Robson classification to classify caesarean section among women with diabetes during pregnancy who gave birth in NSW will provide population evidence on the main contributor to the high rate of caesarean section among women with diabetes during pregnancy. The second part of the study will compare the rate of the caesarean section between women with diabetes during pregnancy (pre-existing and GDM) and women without diabetes within each group of Robson classification.

Study two (Chapter 5): Neonatal outcomes of live-born term singletons in vertex presentation born to mothers with diabetes during pregnancy by mode of birth: a New South Wales population-based retrospective cohort study

This study will investigate the association of method of birth with adverse neonatal outcomes for macrosomic and non-macrosomic term singletons in vertex presentation born to women with diabetes during pregnancy (pre-existing and GDM). The main outcomes of the study will be five minute Apgar score less than seven, admission to NICU/SCN, and the need for neonatal resuscitation. This study will provide population evidence on the association of method of birth and adverse neonatal outcomes. It will help inform decisions around method of birth for women with diabetes during pregnancy.

Study three (Chapter 6): Obstetric anal sphincter injuries among women with gestational diabetes and women without gestational diabetes: a NSW population-based cohort study.

The decision around method of birth should take maternal outcomes into account. This study will investigate the rate of third- and fourth- degree perineal trauma among women with GDM who gave birth vaginally. It will provide population evidence on the association of birthweight and method of birth (spontaneous vaginal or instrumental vaginal) on the maternal outcome.

Study four (Chapter 7): Obstetric interventions among women with diabetes during pregnancy who gave birth in public and private hospitals.

Previously published studies conducted on the childbearing population in Australia showed that obstetric interventions are higher among women who give birth in private hospitals than those who give birth in public hospitals. However, there is no published population-based study that has examined the differences in these rates among women with diabetes during pregnancy who give birth in public and private hospitals. This population-based study will provide population evidence around the differences in the rate of interventions between public and private hospitals and its association with perinatal outcomes for women with diabetes during pregnancy. It will determine the effect of hospital sector on the choice of method of birth for women with diabetes during pregnancy.

Chapter 3: Research methods

This chapter provides summary information on the study design, study population and data used in this PhD research. It also provides information on data analysis and ethics approval. Some details on study population and data analysis are also provided in each result chapter (Chapters 4 to 7).

3.1 Choosing the study design

Properly designed Randomised Controlled Trials (RCT) provide the highest level of evidence (Level I) (ACOG 2018). However, due to ethical consideration, the RTC study design is not feasible or appropriate for the research questions of this thesis. Well-designed Observational studies can provide similar impact to RCT (Song & Chung 2010). They provide level II-2 evidence (ACOG 2018). A cohort study design provides the second level of evidence after a RCT (Burns, Rohrich & Chung 2011). Cohort studies can be prospective or retrospective (Song &Chung 2010). The advantages of a retrospective cohort study design are 1) suitable for investigating rare exposure and multiple outcomes, 2) it can calculate disease rates in both exposed and unexposed groups over time 3) inexpensive (Song &Chung 2010).

Cohort studies using population data are increasingly used and relied upon to influence decision making and change health policy (Hershman & Wright 2012). Using population health data provides real experience and facilitates generalisability of the results (Morrato, Elias & Gericke 2007). Additionally, it provides answers to questions on the effect of the public health issue and the effective intervention to reduce the effect (Morrato, Elias & Gericke 2007). These studies have the advantages of a large sample size and, long term follow up with minimal cost (Hershman & Wright 2012). However, observational studies using population data have limitations such as missing some important variables that are associated with the outcome, as explained later in this chapter. Another limitation is the inability to balance knowing and unknowing confounders may result in error in the interpretation of the result (Hershman & Wright 2012). To reduce the effect of knowing confounders in the analysis of this thesis, a regression model was used to adjust for knowing confounders. A regression model is the preferred/ predominantly used approach for adjustment for confounding in health research (Hershman & Wright 2012).

3.2 Study design

A population-based retrospective cohort study

3.2 Study population

Study one: All women who gave birth in New South Wales between 1 January 2002 and 31 December 2012.

Study two: All live-born term singletons in vertex presentation born in NSW to mothers with diabetes during pregnancy (pre-existing diabetes and GDM) between 1 January 2002 and 31 December 2012.

Study three: All women with GDM and women without GDM who gave birth vaginally with cephalic presentation in NSW between 1 January 2007 and 31 December 2013.

Study four: All women with diabetes during pregnancy (pre-existing diabetes and GDM) who gave birth to term singletons in NSW between 1 January 2002 and 31 December 2012.

The study populations will be discussed in detail in the relevant chapters.

3.3 Data

A research extract from the NSW PDC was used in this PhD research. The NSW PDC is a population-based surveillance system that includes all births occurring in NSW public and private hospitals, and home births. It includes all live births and stillbirths of at least 20 weeks gestational age or at least 400 grams birthweight. The PDC data collection began in 1987 and has been operated continuously since 1990 (The Centre for Health Record Linkage (CHeReL) 2018).

For every birth that occurs in NSW a PDC notification form (paper or electronic form) is completed by birth attendance midwife or medical practitioner. This PDC notification form includes:

- maternal demographic characteristics such as maternal age, country of birth, and smoking status
- the woman's obstetric history, including the number of previous pregnancies, number of previous caesarean sections and if a caesarean section occurred in the woman's last birth
- maternal medical and obstetric conditions such as pre-existing and pregnancy-related hypertension and pre-existing diabetes and gestational diabetes
- labour and birth information such as the onset of labour (spontaneous or induction of labour) and method of birth
- outcomes such as birthweight, gestational age, Apgar score, admission to neonatal intensive care unit or special care nursery and perinatal death type (CHeReL 2018).

After completion, PDC notification forms are sent to the Data Integrity and Governance Unit, Information Management and Quality, in the Health System Information and

Performance Reporting Branch of the NSW Ministry of Health. From here the data are checked, validated and compiled into the statewide PDC. Each baby has a unique record in the PDC, even in the case of multiple births (CHeReL 2018).

The NSW PDC includes birth notifications that occur in NSW, including those of women whose usual place of residence is outside NSW and who give birth in NSW. Notifications of interstate births to a mother resident in NSW are not included in the dataset (CHeReL 2018).

3.3.1 Number of women reported in the NSW PDC during the study period

During the period analysed (2002 to 2013), the NSW PDC shows that 1,103,380 women gave birth in NSW. Figure 3.1 shows the number of women who gave birth in NSW between 2002 and 2013 and the proportion of women with pre-existing diabetes and women with GDM. For consistency and due to the sudden change in the proportion of women with pre-existing diabetes between 2012 and 2013, as shown in Figure 3.1, the studies in this thesis that included pre-existing diabetes were limited to the period from 2002 to 2012.

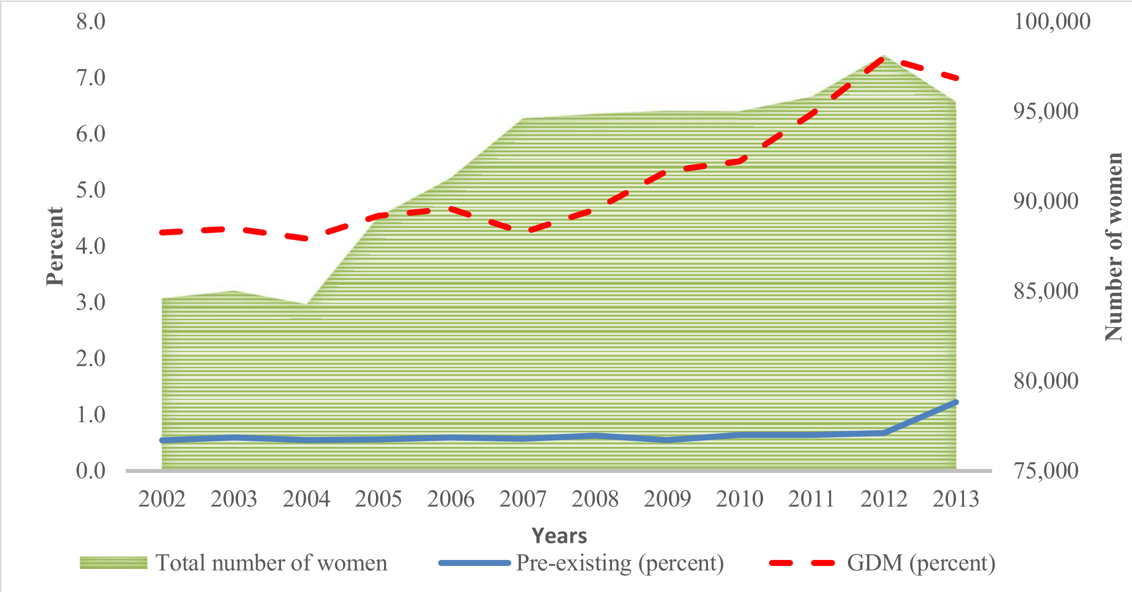

Figure 3.1: Proportion of women with pre-existing diabetes, women with GDM and number of total women included in NSW PDC 2002–2013

3.3.2 Validation Studies on the NSW PDC

NSW PDC is a dataset that is validated by several published studies. Below is a list of validation studies on the NSW PDC relevant to this thesis.

Ampt et al (2013): In this study, records from the NSW PDC were randomly selected to form the PDC sample, which was compared with medical records of corresponding patients. The study found that dichotomised, perinatal outcomes variables such as birthweight, gestational age, Apgar score, perineal trauma and birth status are reported in NSW PDC with high reliability (Kappa values 0.95-1.00), high accuracy (Positive Predictive value >96%) and a high level of ascertainment (sensitivities >94%) (Ampt et al. 2013).

Lam (2011): In this study, birth records from NSW PDC were assessed against to the Admitted Patient Data Collection (APDC) for births that occurred in 2005. The study found that for birth outcome variables, 95% of matched records were coded consistently between APDC and PDC. For mother and baby discharge status, 99% of matched records were coded consistently (Lam 2011).

Chen et al. (2010): This study used longitudinal linkage of the PDC (from 1998 to 2005) and APDC (from 2000 to 2005). The linked data were used as a gold standard to validate a history of caesarean section including the last birth by caesarean section (yes/no) and number of previous caesarean sections in the PDC data. The study found that the reported last birth by caesarean section and number of previous caesarean section in the PDC had high (> 95%) sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) (Chen et al. 2010).

Roberts et al. (2009): In this study, labour and birth events from PDC were compared to data from a population-based validation study as a gold standard. The study found that with the exception of augmentation of labour, the reporting of PDC to labour and birth events was reliable and accurate and can be used in evaluation of obstetric care (Roberts et al. 2009).

3.3.3 Limitations of the NSW PDC related to this thesis

Reporting of GDM

Chen et al. (2012) investigated the prevalence of GDM, pre-eclampsia and pregnancy hypertension in PDC, APDC alone, linked PDC and APDC, antenatal hospitalisation records, and PDC plus all hospital records. The study also investigated the effect size (odds ratios) on outcomes and found that the prevalence of GDM, pre-eclampsia and pregnancy hypertension was higher in the linked datasets than PDC or APDC alone. For instance, the prevalence of GDM among primiparous women was 4.4% in PDC, 5.0% in APDC and 5.6% in linked PDC and APDC. In multiparous women the prevalence of GDM was 4.6%, 5.3% and 6.1% respectively. For primiparous women there was no significant difference in the effect size of GDM on small for gestational age (SGA), LGA and caesarean section between the PDC and the linked PDC and APDC datasets (difference in odds ratios < 5%), However, there were some differences in odds ratios of preterm birth and induction of labour. (Chen et al. 2012). Odds ratios and 95% confidence intervals of GDM on neonatal outcomes from different datasets are presented in Table 3.1.

Table 3.1: **Odds ratios and 95% confidence intervals of GDM on neonatal outcomes from different datasets stratified by parity**
(Chen et al. 2012)

Data source	OR (95% CI)			
	SGA or LGA	**Preterm birth**	**Caesarean section**	**Induction**
		Primiparous		
PDC	1.09 (0.96-1.24)	1.19 (1.05-134)	1.44 (1.34-1.54)	2.40 (2.24-2.57)
APDC	1.04 (0.92-1.18)	1.30 (1.16-1.46)	1.56 (1.46-1.67)	2.11 (1.98-2.25)
PDC & APDC	1.04 (0.93-1.17)	1.33 (1.20-1.48)	1.50 (1.40-1.59)	1.98 (1.86-2.10)
		Multiparous		
PDC	1.38 (1.28-1.50)	1.29 (1.16-1.44)	1.41 (1.33-1.50)	2.23 (2.11-2.37)
APDC	1.38 (1.28-1.48)	1.44 (1.31-1.59)	1.52 (1.43-1.60)	1.97 (1.86-2.09)
PDC & APDC	1.34 (1.25-1.44)	1.37 (1.25-1.50)	1.50 (1.42-1.58)	1.81 (1.72-1.91)

Moreover, Bell et al. (2008) compared information on diabetes (pre-existing and GDM of 1200 women who gave birth in NSW in 2002 from PDC, APDC and medical records. The study found that APDC report diabetes with higher sensitivity and accuracy than PDC (Bell et al. 2008).

Inconsistency in reporting some of the variables

In 2006, changes occurred in the way that some of the variables were recorded in the NSW PDC. For example, recording of perineal status was changed from ‘Intact, 1st degree tear/graze, 2nd degree tear, 3rd degree tear, 4th degree tear, Episiotomy, Combined tear and episiotomy and Other’, to ‘Intact, 1st degree tear/graze, 2nd degree tear, 3rd degree tear, 4th degree tear and Other’. The main difference between the two ways of recording is that before 2007 it was not possible to identify degree of tear for those who had episiotomy because all combined tear and episiotomy were in one category. As well, new variables were included in the data such as ‘Post-partum haemorrhage requiring blood transfusion'. For consistency, 2007 marks the beginning of the study three period and the maternal outcomes in study four.

Lacking some variables

The PDC data lacks information on some important informant related to diabetes such as Body Mass Index (BMI), which may be a residual confounding this research. On the one hand, a large proportion of women with diabetes during pregnancy have a high BMI, including those women are at higher risk of caesarean section (Simmons 2011). On the other hand, BMI is also an independent risk factor for adverse neonatal outcomes such as admission to NICU and low Apgar score (Avcı et al. 2015). To minimise the effect of the absence of BMI, analysis of neonatal outcomes were stratified by birthweight. The NSW PDC also lacks information on shoulder dystocia. As shown in the literature review (Chapter 2), women with diabetes during pregnancy are at higher risk of infants born with shoulder dystocia than women without diabetes (Langer et al. 1991). However, in this analysis it was not possible to adjust for shoulder dystocia due to the lack of this information in the PDC.

3.4 Statistical analysis:

Women's and babies' characteristics were compared using Chi-square test for categorical variables or an Independent Samples T-Test for continuous variables. Multivariate analysis was undertaken using a logistic regression model. Odds ratios adjusted odds ratios and 95% confidence interval were produced. The details of the different adjustments are provided in the individual study chapters.

The analyses in this thesis were done separately for pre-existing diabetes and GDM. The reason for this is that pre-existing diabetes and GDM have different effects on perinatal outcomes, and they require different clinical management because pre-existing diabetes poses challenges in clinical management (Abouzeid et al. 2014; McElduff et al. 2005).

The analyses were performed by using the Statistical Package for the Social Sciences (SPSS) software Versions 22.0 and 24.0 (Armonk, NY: IBM Corporation). A P-value < 0.05 was considered statistically significant. Details of the statistical analyses will be described for each study separately.

3.5 Details of ethics approval

Ethics approval for this PhD research was granted by the University of Technology Sydney Human Research Ethics Committee (UTS HREC ETH16-0219).

The use of de-identified data was approved by the Executive Director, Centre for Epidemiology and Evidence, NSW Ministry of Health.

Chapter 4: Study one: Caesarean section and diabetes during pregnancy: A NSW population study using the Robson classification

This chapter was previously published Zeki, R., Oats, J.J.N., Wang, A.Y., Li, Z., Homer, C.S.E. & Sullivan, E.A. 2018, 'Cesarean section and diabetes during pregnancy: An NSW population study using the Robson classification', *Journal of Obstetrics and Gynaecology Research*, vol. 44, no. 5, pp. 890-8.

List of presentation and publication from this chapter:

This study was presented at the Perinatal Society of Australia & New Zealand (PSANZ) 2017 annual Congress in Canberra, Australia as detailed below.

Poster presentation. Caesarean section and diabetes during pregnancy: a NSW population study using the Robson classification. The Perinatal Society of Australia & New Zealand (PSANZ) annual Congress in Canberra, Australia (2-5 April 2017).

This Chapter is the accepted version of the article: Cesarean section and diabetes during pregnancy: An NSW population study using the Robson classification, which has been published in final form at https://obgyn.onlinelibrary.wiley.com/doi/10.1111/jog.13605 as detailed below.

Zeki, R., Oats, J.J.N., Wang, A.Y., Li, Z., Homer, C.S.E. & Sullivan, E.A. 2018, 'Cesarean section and diabetes during pregnancy: An NSW population study using the Robson classification', *Journal of Obstetrics and Gynaecology Research*. vol. 44, no. 5, pp. 890-8.

Authors' contributions and signatures are available in Appendix 2. The published article is available in Appendix 3.

This chapter was previously published Zeki, R., Oats, J.J.N., Wang, A.Y., Li, Z., Homer, C.S.E. & Sullivan, E.A. 2018, 'Cesarean section and diabetes during pregnancy: An NSW population study using the Robson classification', *Journal of Obstetrics and Gynaecology Research*, vol. 44, no. 5, pp. 890-8.

4.1 About this chapter

The Robson classification for caesarean section is the WHO recommended classification for caesarean section. This chapter has two aims: to investigate the main contributor(s) to caesarean section rates among women with diabetes (pre-existing and GDM) and women without diabetes who gave birth in NSW between January 2002 to December 2012; and to compare the rate of caesarean section among women with diabetes during pregnancy and women without diabetes across all Robson classification groups.

This is the first population study in the literature that applies the Robson classification for caesarean section to women with diabetes during pregnancy. This study will provide information on the association of maternal obstetric history with method of birth. It will also provide baseline information for monitoring caesarean section rates among women with diabetes during pregnancy.

This chapter is written and formatted according to the Journal of Obstetrics and Gynaecology Research guidelines.

This chapter was previously published Zeki, R., Oats, J.J.N., Wang, A.Y., Li, Z., Homer, C.S.E. & Sullivan, E.A. 2018, 'Cesarean section and diabetes during pregnancy: An NSW population study using the Robson classification', *Journal of Obstetrics and Gynaecology Research*, vol. 44, no. 5, pp. 890-8.

4.2 Abstract

Aims: To identify the main contributors to cesarean section (CS) among women with and without diabetes during pregnancy using the Robson classification and to compare CS rates within Robson groups.

Methods: A population-based cohort study was conducted of all women who gave birth in New South Wales, Australia, between 2002 and 2012. Women with pre-gestational diabetes (Types 1 and 2) and gestational diabetes mellitus (GDM) were grouped using the Robson classification. Adjusted odds ratios (AOR) and 95% Confidence Interval (CI) were calculated using multivariable logistic regression.

Results: The total CS rate was 53.6% for women with pre-gestational diabetes, 36.8% for women with GDM, and 28.5% for women without diabetes. Previous CS contributed the most to the total number of cesarean sections in all populations. For preterm birth, the contribution to the total was 20.5% for women with pre-gestational diabetes and 5.7% for women without diabetes. Compared to women without diabetes, for nulliparous with pre-gestational diabetes, the odds of CS was 1.4 (95% CI, 1.1-1.8) for spontaneous labor and 2.0 (95% CI, 1.7-2.3) for induction of labor.

Conclusion: A history of CS was the main contributor to the total cesarean section. Reducing primary CS is the first step to lowering the high rate of CS among women with diabetes. Nulliparous women were more likely to have cesarean sections if they had pre-gestational diabetes. This increase was also evident in all multiparous women

This chapter was previously published Zeki, R., Oats, J.J.N., Wang, A.Y., Li, Z., Homer, C.S.E. & Sullivan, E.A. 2018, 'Cesarean section and diabetes during pregnancy: An NSW population study using the Robson classification', *Journal of Obstetrics and Gynaecology Research*, vol. 44, no. 5, pp. 890-8.

giving birth. The high rate of preterm births and CSs reflects the clinical issues for women with diabetes during pregnancy.

Keywords: Cesarean section, Gestational diabetes, Pregnancy, Pregnancy in Diabetics, Robson classification.

4.3 Introduction

Diabetes during pregnancy is an increasing problem worldwide (Hunt & Schuller 2007). In Australia, 0.5% of women have pre-gestational diabetes (Type 1 and type 2 diabetes) and up to 13.0% of women develop gestational diabetes mellitus (GDM). (AIHW 2010; Moses et al. 2011). Pre-gestational diabetes occurs before pregnancy and continues after pregnancy (Abouzeid et al. 2014). GDM is defined as pregnancy-induced hyperglycemia or glucose abnormality that existed previously but was undiagnosed prior to pregnancy (Nankervis et al. 2013).

The rate of cesarean section (CS) is positively associated with an increase in plasma glucose level during pregnancy (HAPO Study Cooperative Research Group 2008). The Hyperglycemia and Adverse Pregnancy Outcomes study showed an increase of 8 to 11% in the odds of CS with one standard deviation increase in plasma glucose level (HAPO Study Cooperative Research Group 2008). The 2005–2007 Australian data show that 59.2% of women with pre-gestational diabetes and 40.1% of women with GDM gave birth by CS, compared with 30.0% for women without diabetes (AIHW 2010).

This chapter was previously published Zeki, R., Oats, J.J.N., Wang, A.Y., Li, Z., Homer, C.S.E. & Sullivan, E.A. 2018, 'Cesarean section and diabetes during pregnancy: An NSW population study using the Robson classification', *Journal of Obstetrics and Gynaecology Research*, vol. 44, no. 5, pp. 890-8.

In order to better understand current clinical practice around the method of birth for women with and without a diagnosis of diabetes during pregnancy, a clinically relevant classification system of CS is required. In 2015, the World Health Organization (WHO) recommended that the Robson classification be used as a global standard for evaluating, monitoring and comparing CS rates (WHO 2015). The Robson classification is 'mutually exclusive and totally inclusive' and is based on women's parity, plurality, presentation, gestational age, history of previous CS and onset of labor (Robson 2001). To date, three hospital-based studies have applied the Robson classification to women with diabetes during pregnancy (Caroll et al. 2013; Courtney et al. 2013; Torloni et al. 2009). However, there have not been any population-based studies applying the Robson classification to pre-gestational diabetes and GDM, despite suggestions by the classification users (Betran et al. 2014; Torloni et al. 2009).

Our study, using New South Wales (NSW) population data, had two aims. Firstly, to use the Robson classification to identify the main contributors to CS among women with pre-gestational diabetes, women with GDM and women without diabetes during pregnancy. The second part of the study aimed to compare CS rates between women with diabetes during pregnancy and those without, within each Robson classification group.

This chapter was previously published Zeki, R., Oats, J.J.N., Wang, A.Y., Li, Z., Homer, C.S.E. & Sullivan, E.A. 2018, 'Cesarean section and diabetes during pregnancy: An NSW population study using the Robson classification', *Journal of Obstetrics and Gynaecology Research*, vol. 44, no. 5, pp. 890-8.

4.4 Method

Study design and outcome

A population-based retrospective cohort study was conducted. The main outcome of the study was CS.

Data source

This study used data and definitions from the NSW Perinatal Data Collection (PDC). The PDC is a population-based surveillance system of all births in NSW, Australia. It contains information about NSW public and private hospital births and home births, and about all women who have had live births and stillbirths of at least 20 weeks' gestational age or at least 400 grams birthweight (CHeReL 2016b). NSW is the most populous state, with a third of the total Australian population and more than 95 000 women giving birth every year (Australian Bureau of Statistics (ABS) 2016).

PDC information is collected from the electronic notification form that is completed by the attending midwife or doctor at birth. It includes information on maternal demographics, health, pregnancy, labor and birth, as well as perinatal outcomes. The completed forms are sent to NSW Ministry of Health, where the information is validated and compiled into the PDC (CHeReL 2016b).

Study population

This study included all women (n=1 007 843) who gave birth in NSW between 1 January 2002 and 31 December 2012. Of these, 6030 (0.6%) women had pre-gestational

This chapter was previously published Zeki, R., Oats, J.J.N., Wang, A.Y., Li, Z., Homer, C.S.E. & Sullivan, E.A. 2018, 'Cesarean section and diabetes during pregnancy: An NSW population study using the Robson classification', *Journal of Obstetrics and Gynaecology Research*, vol. 44, no. 5, pp. 890-8.

diabetes (Type 1 and type 2 diabetes), 51 135 (5.1%) had GDM, and 950 678 (94.3%) did not have diabetes during pregnancy.

Diagnosis of GDM

During the study period, there was only one guideline used in NSW for the diagnosis of GDM. This was the Australasian Diabetes In Pregnancy Society (ADIPS) guideline that recommended screening for GDM at 26 to 28 weeks' gestation using the glucose challenge test (GCT). If the non-fasting GCT measured at one-hour post-load plasma glucose level was ≥7.8 mmol/L after 50g glucose load or ≥ 8.0 mmol/L after 75g glucose load, a 75g two-hour oral glucose tolerance test (OGTT) was recommended. (Hoffman et al. 1998). GDM was then diagnosed if the fasting venous plasma glucose level was ≥ 5.5 mmol/L and/or at two hours following the 75g glucose load was ≥8.0 mmol/L (Hoffman et al. 1998).

Pre-gestational diabetes and GDM are different in their effect on pregnancy outcomes, with pre-gestational diabetes being associated with more complicated outcomes (Abouzeid et al. 2014; AIHW 2010; Shand et al. 2008). In addition, pre-gestational diabetes poses considerable challenges in clinical management (McElduff et al. 2005). For this reason statistical analysis was done separately for pre-gestational diabetes and GDM.

Statistical analysis

The socio-demographic factors of women with pre-gestational diabetes and women with GDM were compared with women without diabetes using a Chi square test for categorical variables and an Independent Samples T-Test for continuous variables.

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Women were classified according to Robson criteria into 10 groups correlating with their obstetric history (Table 4.1).

Table 4.1: **Extended Robson 10 groups**

(Robson 2001)

1	Nulliparous, single cephalic, gestational age ≥37 weeks, spontaneous labor
2	Nulliparous, single cephalic, gestational age ≥37 weeks, induction of labor or no labor CS
2(a)	*Nulliparous, single cephalic, gestational age ≥37 weeks, induction of labor*
2(b)	*Nulliparous, single cephalic, gestational age ≥37 weeks, no labor CS*
3	Multiparous, without previous CS, single cephalic, gestational age ≥37 weeks, spontaneous labor
4	Multiparous, without previous CS, single cephalic, gestational age ≥37 weeks, induction of labour or no labor CS
4(a)	*Multiparous, without previous CS, single cephalic, gestational age ≥37 weeks, induction of labor*
4(b)	*Multiparous, without previous CS, single cephalic, gestational age ≥37 weeks, no labor CS*
5	All multiparous, with at least one previous CS, single cephalic, gestational age ≥37 weeks
6	All nulliparous, single breech pregnancy
7	All multiparous, single breech, including women with previous CS
8	All women, multiple pregnancies including women with previous CS
9	All women, single transverse, oblique or other lie including women with previous CS
10	All women, single cephalic, gestational age ≤36 weeks, including women with previous CS

Six variables inform the classification: parity, plurality, presentation, gestational age, history of previous CS, and type of labor. Women in groups 2 and 4 were further

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grouped according to their onset of labor into those who had an induction of labor and those who had a CS with no labor.

Summary statistics were produced using the extended Robson classification 10 groups stratified by diabetes status. These include:

a. the proportion of the obstetric population of each group

b. the rate of CS within each group

c. the relative contribution of each group to the total CS rate (the proportion of CSs in each Robson group according to the total number of CSs)

d. the absolute contribution of each group to the total CS rate (rate of CS in each Robson group in relation to the total population).

Multivariable logistic regression was used to investigate the likelihood of CSs for women with diabetes compared with women without diabetes. Adjusted odds ratios (AOR) and 95% confidence intervals (95% CI) were calculated. Adjustment was made for maternal age, maternal country of birth (Australian born – Yes/No), smoking status, birthweight (< 2500g, 2500–3999g and ≥ 4000g) and pre-gestational and maternal hypertension.

The analysis was performed by using the Statistical Package for the Social Sciences (SPSS) software Version 22.0 (Armonk, NY: IBM Corporation). A P value < 0.05 was considered statistically significant.

Details of ethics approval

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The use of de-identified data was approved by the Executive Director, Centre for Epidemiology and Evidence, NSW Ministry of Health. Ethics approval was granted by University of Technology Sydney Human Research Ethics Committee (UTS HREC ETH16-0219).

4.5 Results

There were significant differences in maternal socio-demographic factors between women with diabetes during pregnancy and women without diabetes (Table 4.2). A higher proportion of women aged ≥ 35 years was observed among women with diabetes during pregnancy – 32.5% of women with pre-gestational diabetes and 34.9% of women with GDM – compared to 21.3% among women without diabetes. Multiparous women represented 63.0% of women with pre-gestational diabetes and 59.7% of women with GDM, compared with 57.4% of women without diabetes (Table 4.2).

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Table 4.2: Women's socio-demographic factors by diabetes status 2002-2012

	Pre- gestational diabetes n=6030 n(%)	P value†‡	Gestational diabetes n=51 135 n(%)	P value†§	No diabetes n=950 678 n(%)
Age					
mean (SD)	31.7 (5.6)	<0.001¶	32.2 (5.3)	<0.001¶	29.9 (5.6)
< 20	96 (1.6)		511 (1.0)		36 205 (3.8)
20-24	584 (9.7)		3398 (6.6)		135 636 (14.3)
25-29	1353 (22.4)	<0.001	11 440 (22.4)	<0.001	263 235 (27.7)
30-34	2033 (33.7)		17 957 (35.1)		312 697 (32.9)
35-39	1499 (24.9)		13 607 (26.6)		168 304 (17.7)
≥ 40	463 (7.7)		4217 (8.2)		34 359 (3.6)
Not stated	2 (0.0)		5 (0.0)		242 (0.0)
Parity					
Nulliparous	2222 (36.8)	<0.001	20 570 (40.2)	<0.001	403 372 (42.4)
Multiparous	3799 (63.0)		30 540 (59.7)		545 804 (57.4)
Not stated	9 (0.1)		25 (0.0)		1502 (0.2)
Plurality					
Singleton	5912 (98.0)	0.004	50 130 (98.0)	<0.001	936 428 (98.5)
Multiple	118 (2.0)		1005 (2.0)		14 250 (1.5)
Country of birth					
Australian	4036 (66.9)	<0.001	25 527 (49.9)	<0.001	672 362 (70.7)
Overseas born	1979 (32.8)		25 436 (49.7)		275 022 (28.9)
Not stated	15 (0.2)		172 (0.3)		3294 (0.3)
Smoking					
Smoked	840 (13.9)	0.111	4769 (9.3)	<0.001	125 787 (13.2)
Did not smoke	5172 (85.8)		46 159 (90.3)		821 935 (86.5)
Not stated	18 (0.3)		207 (0.4)		2956 (0.3)

† Excludes not stated values
‡ P value for Pre-gestational diabetes compared to no diabetes
§ P value for GDM compared to no diabetes
¶ Using Independent Samples T Test

Table 4.3 presents the extended Robson classifications for women with pre-gestational diabetes, women with GDM and women without diabetes. Nulliparous women who had an induction of labor or a CS with no labor (Robson group 2) represented the largest

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percentages of women in both pre-gestational diabetes and GDM categories – 20.8% and 21.4%, respectively compared to only 14.4% of women without diabetes. Group 3 (multiparous who went into spontaneous labor) was the largest group of women without diabetes contributed to 27.3% of the total population. The second largest group of women with diabetes during pregnancy was multiparous women who had induction of labor. Although the percentages of women with diabetes during pregnancy in groups 4 and 2 were relatively similar to each other, the contribution of group 4 to the total number of CS was significantly lower than the contribution of group 2. Among women with and without diabetes during pregnancy, the highest contribution to the total number of CSs was among multiparous women who had a history of previous CS (group 5). This group contributed to 30.9% of all CSs performed among women with pre-gestational diabetes, 34.8% among women with GDM and 34.8% among women without diabetes (Table 4.3). The main indication for CS in this group was elective repeat CS. The rate of the elective repeat CS was 69.5% among women with pre-gestational diabetes, 61.3% among women with GDM, and 74.1% among women without diabetes.

The rates of vaginal birth after CS (VBAC) among women in group 5 was 8.6% among women with pre-gestational diabetes, 14.1% among women with GDM and 19.5% among women without diabetes.

Women who had experienced preterm births (Robson group 10) represented 16.8% of the total number of women with pre-gestational diabetes. This percentage was significantly larger than the percentage of group 10 women without diabetes (4.9%).

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Group 10 women contributed to 20.5% of the total number of CSs among women with pre-gestational diabetes, 7.4% among women with GDM and 5.7% of the total number of CS among women without diabetes (Table 4.3). Forty six percent of women with pre-gestational diabetes in group 10 had a no labor CS and 21.6% had induction of labor respectively contributed to 14.5% and 2.5% of the total number of CSs among women with pre-gestational diabetes.

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Table 4.3: Summary statistics for cesarean section by diabetes 2002-2012

	Pre-gestational diabetes				Gestational diabetes				No diabetes			
		CS				CS				CS		
Robson groups	Women n (%)	n	Relative[†] %	Absolute rate[‡] % (95% CI)	Women n (%)	n	Relative[†] %	Absolute rate[‡] % (95% CI)	Women n (%)	n	Relative[†] %	Absolute rate[‡] % (95% CI)
1	384 (6.4)	88	2.7	1.5 (1.2-1.8)	6777 (13.3)	1139	6.1	2.2 (2.1-2.4)	218 798 (23.3)	32 163	12.0	3.4 (3.4-3.5)
2	1244 (20.8)	771	24.1	12.9 (12.0-13.8)	10 860 (21.4)	4842	25.9	9.5 (9.3-9.8)	135 583 (14.4)	58 986	22.0	6.3 (6.2-6.3)
2(a)	938 (15.7)	465	14.5	7.8 (7.1-8.5)	9212 (18.1)	3194	17.1	6.3 (6.1-6.5)	11 2145 (11.9)	35 548	13.3	3.8 (3.7-3.8)
2(b)	306 (5.1)	306	9.5	5.1 (4.5-5.7)	1648 (3.2)	1648	8.8	3.2 (3.1-3.4)	23 438 (2.5)	23 438	8.8	2.5 (2.5-2.5)
3	604 (10.1)	36	1.1	0.6 (0.4-0.8)	9044 (17.8)	331	1.8	0.7 (0.6-0.7)	25 6210 (27.3)	5936	2.2	0.6 (0.6-0.6)
4	1167 (19.5)	250	7.8	4.2 (3.7-4.7)	9923 (19.5)	1590	8.5	3.1 (3.0-3.3)	111 002 (11.8)	17 904	6.7	1.9 (1.9-1.9)
4(a)	1030 (17.2)	113	3.5	1.9 (1.5-2.2)	8982 (17.7)	649	3.5	1.3 (1.2-1.4)	98 401 (10.5)	5303	2.0	0.6 (0.5-0.6)
4(b)	137 (2.3)	137	4.3	2. 3 (1.9-2.7)	941 (1.9)	941	5.0	1.9 (1.7-2.0)	12 601 (1.34)	12 601	4.7	1.3 (1.3-1.4)
5	1082 (18.1)	989	30.9	16.5 (15.5-17.6)	7562 (14.9)	6494	34.8	12.8 (12.5-13.1)	115 954 (12.4)	93 305	34.8	9.9 (9.9-10.0)
6	127 (2.1)	115	3.6	1.9 (1.6-2.3)	883 (1.7)	861	4.6	1.7 (1.6-1.8)	18 594 (2.0)	17 127	6.4	1.8 (1.8-1.9)
7	169 (2.8)	145	4.5	2.4 (2.0-2.8)	1031 (2.0)	957	5.1	1.9 (1.8-2.0)	15 456 (1.6)	13 350	5.0	1.4 (1.4-1.4)
8	118 (2.0)	90	2.8	1.5 (1.2-1.8)	1005 (2.0)	692	3.7	1.4 (1.3-1.5)	14 250 (1.5)	8914	3.3	0.9 (0.9-1.0)
9	75 (1.3)	64	2.0	1.1 (0.8-1.3)	455 (0.9)	389	2.1	0.8 (0.7-0.8)	6701 (0.7)	4859	1.8	0.5 (0.5-0.5)
10	1007 (16.8)	657	20.5	11.0 (10.2-11.8)	3259 (6.4)	1388	7.4	2.7 (2.6-2.9)	46 033 (4.9)	15 304	5.7	1.6 (1.6-1.7)
Total[§]	**5977 (100.0)**	**3205**	**100.0**	**53.6 (51.8-55.5)**	**50 799 (100.0)**	**18 683**	**100.0**	**36.8 (36.3-37.3)**	**938 581 (100.0)**	**267 848**	**100.0**	**28.5 (28.4-28.6)**

† Relative contribution: proportion of CS in each Robson group according to the total number of CS.
‡ Absolute contribution: rate of CS in each Robson group in relation to the total population.
§ Excludes 12 486 (1.2%) women with not stated Robson classification.

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Table 4.4 shows that the total CS rate was significantly higher among women with pre-gestational diabetes than among women without diabetes (AOR 2.4, 95% CI, 2.3-2.6). With the exception of women in Robson groups 6, 7 and 9 (women who had non-cephalic pregnancies), the rate of CS was significantly higher among women with pre-gestational diabetes compared to women without diabetes across all other Robson groups.

For women with pre-gestational diabetes, the highest rate of CS was among women with a history of previous CS (group 5). This rate was significantly higher among women with pre-gestational diabetes than women without diabetes (91.4% and 80.5%) (AOR 2.5, 95% CI, 2.0-3.1). Half (49.6%) of nulliparous women who had induction of labor (group *2(a)*) had a CS compared to 31.7% of women without diabetes in the same group (AOR 2.0, 95% CI, 1.7-2.3) (Table 4.4).

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Table 4.4: Rate of CS within each Robson group for women with Pre-existing diabetes compared to women who did not have diabetes 2002-2012

Robson groups	Pre-gestational diabetes		No diabetes†
	CS%	AOR‡ (95% CI)	CS%
1	22.9	1.4* (1.1-1.8)	14.7
2	62.0	2.0* (1.7-2.2)	43.5
2(a)	49.6	2.0* (1.7-2.3)	31.7
2(b)	100.0	-	100.0
3	6.0	2.1* (1.5-2.9)	2.3
4	21.4	1.3* (1.1-1.5)	16.1
4(a)	11.0	1.8* (1.5-2.2)	5.4
4(b)	100.0	-	100.0
5	91.4	2.5* (2.0-3.1)	80.5
6	90.6	0.9 (0.4-1.7)	92.1
7	85.8	0.8 (0.5-1.3)	86.4
8	76.3	1.8* (1.2-2.8)	62.6
9	85.3	1.8 (0.9-3.5)	72.5
10	65.2	3.1* (2.7-3.5)	33.2
Total	**53.6**	**2.4* (2.3-2.6)**	**28.5**

† Reference group.
‡ AOR, odd ratio was adjusted for maternal age, maternal country of birth (Australian born Yes/No), smoking status, birthweight (< 2500g, 2500-3999g and ≥ 4000g) and maternal and obstetric hypertension.
* p<0.005.

Table 4.5 shows that 36.8% of women with GDM gave birth by CS compared to 28.5% of women without diabetes (AOR 1.3, 95% CI, 1.2-1.3). The highest rate of CS was for women with GDM (97.5%) and women without diabetes (92.1%) among group 6 nulliparous who had a breech presentation.

For both nulliparous and multiparous women with GDM who had an induction of labor (groups *2(a)* and *4(a)*) there was an increase in the rate of CS compared with women without diabetes in the same groups (AOR 1.1, 95% CI, 1.0-1.1 for nulliparous women) and (AOR 1.2, 95% CI, 1.1-1.3 for multiparous women) (Table 4.5).

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Table 4.5: Rate of CS within each Robson group for women who had gestational diabetes compared to women who did not have diabetes 2002-2012

Robson groups	Gestational diabetes		No diabetes†
	CS%	AOR‡ (95% CI)	CS%
1	16.8	1.1 (1.0-1.1)	14.7
2	44.6	0.9* (0.9-1.0)	43.5
2(a)	34.7	1.1* (1.0-1.1)	31.7
2(b)	100.0	-	100.0
3	3.7	1.4* (1.3-1.6)	2.3
4	16.0	0.9* (0.8-0.9)	16.1
4(a)	7.2	1.2* (1.1-1.3)	5.4
4(b)	100.0	-	100.0
5	85.9	1.4* (1.3-1.5)	80.5
6	97.5	4.2* (2.6-6.8)	92.1
7	92.8	1.7* (1.3-2.1)	86.4
8	68.9	1.2* (1.0-1.3)	62.6
9	85.5	1.7* (1.3-2.2)	72.5
10	42.6	1.2* (1.1-1.3)	33.2
Total	**36.8**	**1.3* (1.2-1.3)**	**28.5**

† Reference group.
‡ AOR, odd ratio was adjusted for maternal age, maternal country of birth (Australian born Yes/No), smoking status, birthweight (< 2500g, 2500-3999g and ≥ 4000g) and maternal and obstetric hypertension.
* Significant.

4.6 Discussion

Our study is the first population-based study to use the Robson classification to compare CS rates among women with and without diabetes during pregnancy. Previous published studies that used the Robson classification to analyze CS rates among women with diabetes during pregnancy are hospital-based studies with limited sample size and generalizability (Caroll et al. 2013; Courtney et al. 2013; Torloni et al. 2009). Our study provides population data and confirms these hospital studies' results (Caroll et al. 2013; Courtney et al. 2013; Torloni et al. 2009).

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We found previous CS was the main driver for CS, regardless of whether the women had diabetes during pregnancy or not. A previous study that used the Robson classification on the Australian general population also found that previous CS was the highest contributor to the total number of CSs (Sullivan 2010). Our results also confirm results from international studies that found group 5 is the main contributor to the total number of CSs (Jayot & Nizard 2016; Kelly et al. 2013; Tan et al. 2015; Vogel et al. 2015).

Among women in the Robson group 5 (women with a history of CS), we found the CS rate was significantly higher among women with pre-gestational diabetes and women with GDM compared with women without diabetes. One explanation may be that women with diabetes during pregnancy have lower rates of successful VBAC than women without diabetes (Cormier et al. 2010; Dharan et al. 2010). This is supported by data showing the rate of unsuccessful VBAC among women who trialed labor is 38% among women with pre-gestational diabetes (Dharan et al. 2010), and 36% among women with GDM (Cormier et al. 2010), compared to 24% among women without diabetes (Dharan et al. 2010). Among our study population, women without diabetes had more than double the rate of successful VBAC than women with pre-gestational diabetes and were five percentage points more likely to have a successful VBAC compared with women with GDM. This indicates that primary CS among women with diabetes during pregnancy has a greater effect on consecutive methods of birth than among women without diabetes. There is compelling evidence, therefore, to suggest that reducing the rate of the primary CS can help to reduce the overall rate of CS.

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The second highest contributor to the total number of CSs was group 2 (nulliparous who had induction of labor or no-labor CS), regardless of whether women had diabetes or not. However, within this group, the contribution of CS relative to the total population rate was significantly higher among women with diabetes during pregnancy than women without diabetes. This is due in part to the over-representation of women with diabetes during pregnancy in this group (20.8% of women with pre-gestational diabetes and 21.4% of women with GDM, compared to 14.4% of women without diabetes) (Table 4.3).

In addition, previously published research shows that women with diabetes during pregnancy who had induction of labor are at higher risk of CS than women without diabetes (Bas-lando et al. 2014). In our population, nulliparous women with pre-gestational diabetes who had induction of labor had double the odds of having a CS compared to women without diabetes. Half (49.6%) of these women had a CS, which is consistent with the rate of 48.5 % among women with Type one diabetes published by Carroll et al. (2013) (Caroll et al. 2013). The evidence, therefore, suggests a more judicious approach to inducing labor in nulliparous women with diabetes may help reduce the primary CS rate.

In women with pre-gestational diabetes, the rate of preterm labor is high (ACOG 2005; AIHW 2010; CEMACH 2005; Shand et al. 2008). Among our population, group 10 women with preterm birth represented 16.8% of women with pre-gestational diabetes. The high rate of preterm birth is likely related to iatrogenic interventions among women with pre-gestational diabetes (Boulvain, Stan & Irion 2001; CEMACH 2005). In our

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study only one third (32.2%) of these women with pre-gestational diabetes in group 10 had a spontaneous preterm birth, while the majority of them had either no labor CS (46.2%) or induction of labor (21.6%) before 37 weeks gestation. CS among women in group 10 contributed 20.5% of the total number of CSs among women with pre-gestational diabetes. Our research is consistent with the findings of a 2009 Brazilian tertiary hospital study using the Robson classification to investigate the rate of CS among women with diabetes during pregnancy, which found that 21.0% of the total CS was contributed by women in group 10 (Torloni et al. 2009). Among our study population in group 10, women with pre-gestational diabetes had double the rate of CS than among women without diabetes.

We found the rates of CS among women with diabetes during pregnancy were higher than those among women without diabetes across most Robson groups. This is consistent for both women with pre-gestational diabetes and women with GDM. Although, the difference in CS rates between women with GDM and women without diabetes was statistically significant, it is difficult to draw definitive conclusions regarding the clinical significance of this finding due to the large sample size.

Strength and limitations

The use of the WHO-recommended Robson classification with large population data provides population-based information on the rate of CS among women with diabetes during pregnancy and the contribution of each group to the total number of CS. Hospital-based studies have provided the impetus for this study, but they have not delivered results of sufficient scope, reliability and generalizability to inform clinical

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decision making. By using population data that reports childbirth related diagnosis and procedures with high levels of accuracy (Roberts et al. 2009), our results can be used as a reference population for other studies investigating the method of birth and diabetes during pregnancy.

There were no data items on the management of diabetes during pregnancy, nor maternal Body Mass Index (BMI) in the NSW PDC data set. This is a limitation of the study because a large proportion of women with diabetes during pregnancy have high BMI which is associated with increases in the risk of CS among women with diabetes during pregnancy (Simmons 2011). Further studies are required to evaluate the impact of maternal BMI on CS.

A further limitation of our study was the possible underestimation of the number of women with diabetes. In our study the proportion of GDM from the NSW PDC data was 5.1%, which is marginally lower than that found in an earlier validation study based on two data sets – the Admitted Patient Data Collection (APDC) and PDC – which found 5.6% of primiparous and 6.1% of multiparous had GDM (Chen et al. 2012). However, that study reassuringly found that irrespective of the data source of GDM status the odds ratio of CS among women with GDM compared with women without GDM was consistent at 1.4 (95% CI, 1.3-1.5) for PDC versus 1.5 (95% CI, 1.4-1.6) from the combined data from the PDC and APDC for primiparous and 1.4 (95% CI, 1.3-1.5) versus 1.5 (95% CI, 1.4-1.6) for multiparous women (Chen et al. 2012).

The Robson classification is a clinically informative and simple classification system for examining CS among women with medical conditions and obstetric complications

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such as diabetes during pregnancy. It provides a granularity around a set of actions leading to CS.

In our population-based study, the highest contributing factor to having a CS was from women with a history of CS, whether or not they had diabetes during pregnancy. For women with diabetes during pregnancy, the CS is high across most Robson groups compared with women without diabetes. Focusing on primary prevention of CS would help in reducing the overall rate of CS among women with diabetes during pregnancy.

Acknowledgements

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Disclosure

No author has any potential conflict of interest.

4.7 Chapter summary

This chapter investigated the main contributor to cesarean section rates among women with diabetes and women without diabetes. It also compared the rates of cesarean section among women with and without diabetes. The results of this chapter provide a baseline for monitoring cesarean section rates among women with diabetes during pregnancy. The key points of this chapter are:

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- One fifth of women with diabetes during pregnancy (20.8%-pre-gestational, 21.4%-GDM) are nulliparous women who were either induced or had no labor with cesarean section, which represents the largest group of women with diabetes during pregnancy.

- The largest group of women without diabetes are multiparous women who have spontaneous onset of labor.

- A history of previous cesarean section is the main contributor to the cesarean section rates for both women with diabetes and women without diabetes.

- The main indication for cesarean section among women with a history of previous cesarean section is 'elective repeat cesarean section', which represents 69.5%, 61.3%, and 74.1% among women with pre-gestational diabetes, women with GDM, and women without diabetes, respectively.

- Sixteen percent of women with pre- gestational diabetes experienced preterm births; this group contributes 20.5% of the total cesarean sections among women with pre- gestational diabetes. Approximately half (46.0%) of women within this group had a no labor cesarean section.

- The rate of cesarean section was significantly higher among women with pre-gestational diabetes than women without diabetes, except for non-cephalic presentations.

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- There was a statistically significant increase in the odds of cesarean section among women with GDM compared to women without diabetes across nine out of ten Robson groups.

The next chapter (Chapter 5) will clarify if this increase in the cesarean section rates is associated with improvement in neonatal outcomes by investigating the association between method of birth and neonatal outcomes.

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Chapter 5: Study two: Neonatal outcomes of live-born term singletons in vertex presentation born to mothers with diabetes during pregnancy by mode of birth: a New South Wales population-based retrospective cohort study

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A publication from this chapter:

This Chapter is the accepted version of the article: 'Neonatal outcomes of live-born term singletons in vertex presentation born to mothers with diabetes during pregnancy by mode of birth: a New South Wales population-based retrospective cohort study, which has been published in final form at https://bmjpaedsopen.bmj.com/content/2/1/e000224 as detailed below.

Zeki, R., Wang, A.Y., Lui, K., Li, Z., Oats, J.J.N., Homer, C.S.E. & Sullivan, E.A. 2018, 'Neonatal outcomes of live-born term singletons in vertex presentation born to mothers with diabetes during pregnancy by mode of birth: a New South Wales population-based retrospective cohort study', *BMJ Paediatrics Open*, vol. 2, no. 1. p. e000224. doi: 10.1136/bmjpo-2017-000224

Authors' contributions and signatures are available in Appendix 2. The published article is available in Appendix 3.

5.1 About this chapter

As shown in Chapter 4, women with diabetes during pregnancy have higher rates of caesarean section than women without diabetes. In the context of women with diabetes in pregnancy, this chapter will investigate the association between method of birth and neonatal outcomes for singleton babies that are live-born at term with a vertex presentation. This study is the first Australian and the largest international population-based study that investigates the association between method of birth and neonatal outcomes. The neonatal outcomes include the following measures and interventions as a

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proxy for neonatal morbidity: Apgar score at five minutes, admission to NICU/SCN, neonatal resuscitation, and neonatal death.

This chapter is written and formatted according to the Journal of BMJ Paediatrics Open guidelines.

5.2 Abstract

Objectives: To investigate the association between the mode of birth and adverse neonatal outcomes of macrosomic (birthweight ≥4000g) and non-macrosomic (birthweight <4000g) live-born term singletons in vertex presentation (TSV) born to mothers with diabetes (pre-existing and gestational diabetes mellitus (GDM)).

Design: A population-based retrospective cohort study.

Setting: New South Wales, Australia.

Patients: All live-born TSV born to mothers with diabetes from 2002 to 2012.

Intervention: Comparison of neonatal outcomes by mode of birth (Pre-labour caesarean section (CS) and planned vaginal birth resulted in intrapartum CS, non-instrumental or instrumental vaginal birth).

Main outcomes measures: Five minutes Apgar score <7, admission to neonatal intensive care unit (NICU) or special care nursery (SCN) and the need for resuscitation.

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Results: Among the 48 882 TSV born to mothers with diabetes, pre-labour CS was associated with a significant increase in the rate of admission to NICU/SCN compared to planned vaginal birth.

For TSV to mothers with pre-existing diabetes, compared to non-instrumental vaginal birth, instrumental vaginal birth was associated with increased odds of the need for resuscitation in macrosomic (adjusted odds ratios (AOR) 2.6; 95% confidence interval (CI);(1.2 to 7.5)) and non-macrosomic TSV (AOR 3.3; 95% CI; (2.2 to 5.0)).

For TSV to mothers with GDM, intrapartum CS was associated with increased odds of the need for resuscitation compared to non-instrumental vaginal birth in non-macrosomic TSV (AOR 2.3; 95% CI; (2.1 to 2.7)). Instrumental vaginal birth was associated with increased likelihood of requiring resuscitation compared to non-instrumental vaginal birth for both macrosomic (AOR 2.3; 95% CI; (1.7 to 3.1)) and non-macrosomic (AOR 2.5; 95% CI; (2.2 to 2.9)) TSVs.

Conclusion: Pregnant women with diabetes, particularly those with suspected fetal macrosomia, need to be aware of the increased likelihood of adverse neonatal outcomes following instrumental vaginal birth and intrapartum CS when planning mode of birth.

What is known about this topic:

Diabetes during pregnancy is associated with adverse neonatal and long term baby outcomes. There is no agreement in the national and international guidelines about the best mode of birth for women with diabetes during pregnancy.

What this study adds:

This chapter was previously published Zeki, R., Wang, A.Y., Lui, K., Li, Z., Oats, J.J.N., Homer, C.S.E. & Sullivan, E.A. 2018, 'Neonatal outcomes of live-born term singletons in vertex presentation born to mothers with diabetes during pregnancy by mode of birth: a New South Wales population-based retrospective cohort study', *BMJ Paediatrics Open*, vol. 2, no. 1.

Diabetic women who gave birth to macrosomic TSV are likely to give birth by intrapartum CS and those who gave birth to non-macrosomic by instrumental birth. Intrapartum CS and instrumental vaginal birth are associated with increased likelihood of adverse neonatal outcomes.

Keywords

Gestational diabetes

Pre-existing diabetes

Birth

Caesarean section

Apgar score

Neonatal intensive care unit

Resuscitation

Abbreviations

AOR: Adjusted odds ratio

ADIPS: Australasian Diabetes in Pregnancy Society

CI: Confidence interval

CS: Caesarean section

NICU: Neonatal intensive care unit

This chapter was previously published Zeki, R., Wang, A.Y., Lui, K., Li, Z., Oats, J.J.N., Homer, C.S.E. & Sullivan, E.A. 2018, 'Neonatal outcomes of live-born term singletons in vertex presentation born to mothers with diabetes during pregnancy by mode of birth: a New South Wales population-based retrospective cohort study', *BMJ Paediatrics Open*, vol. 2, no. 1.

NICE: National Institute for Health and Care Excellence

NSW: New South Wales

PDC: Perinatal Data Collection

SCN: special care nursery

TSV: Term singletons in vertex presentation

This chapter was previously published Zeki, R., Wang, A.Y., Lui, K., Li, Z., Oats, J.J.N., Homer, C.S.E. & Sullivan, E.A. 2018, 'Neonatal outcomes of live-born term singletons in vertex presentation born to mothers with diabetes during pregnancy by mode of birth: a New South Wales population-based retrospective cohort study', *BMJ Paediatrics Open*, vol. 2, no. 1.

5.3 Introduction

Diabetes during pregnancy is associated with increased incidence of adverse baby outcomes (Chamberlain et al. 2013). Babies born to mothers with diabetes during pregnancy are at higher risk of perinatal mortality and morbidity including preterm birth, congenital abnormality, neonatal hypoglycaemia and macrosomia (Maso et al. 2014).

There is little consistency internationally regarding recommendations on the mode of birth for women with diabetes during pregnancy. Variations are seen in both national and professional society guidelines and recommendations (Maso et al. 2014). The American College of Obstetricians and Gynecologists guidelines recommend caesarean section (CS) for women with diabetes during pregnancy with an estimated birthweight >4500g (ACOG 2005, 2013). The National Institute for Health and Care Excellence (NICE) guideline in the United Kingdom recommends induction of labour or elective CS if indicated, between 37^{+0} and 38^{+6} weeks of gestation for women with pre-existing diabetes (NICE 2015). For women with gestational diabetes (GDM), the NICE guideline recommends elective birth no later than 40^{+6} weeks of gestation (NICE 2015). The Australasian Diabetes in Pregnancy Society (ADIPS) guidelines advise that for women with pre-existing diabetes, elective CS should be considered if estimated birthweight exceeds 4,250–4,500g (McElduff et al. 2005). For women with uncomplicated GDM, ADIPS guideline does not recommend birth before term unless there is an obstetric indication (Hoffman et al. 1998).

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The rate of CS is high among women with diabetes during pregnancy in Australia (AIHW 2010). The leading reasons for a planned CS (pre-labour CS) are for the prevention of stillbirth and the reduction of birth complications associated with macrosomia (Boulvain, Stan & Irion 2001; Maso et al. 2014). Currently, there are no population-based studies in Australia that have evaluated the neonatal outcomes of babies born to mothers with diabetes according to the mode of birth.

Our study aimed to compare adverse neonatal outcomes for live-born term singletons in vertex presentation (TSV) born to mothers with diabetes during pregnancy (pre-existing diabetes and GDM) by mode of birth stratified macrosomia (macrosomic and non-macrosomic TSV).

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5.4 Method

Data source

A population-based retrospective cohort study was conducted using the New South Wales (NSW) Perinatal Data Collection (PDC) (CHeReL 2016a). The PDC is a population-based surveillance system. It includes all births occurring in NSW public and private hospitals as well as home births. Women giving birth to live-births and stillbirths of at least 20 weeks or at least 400g birthweight are included in the database. Around 32% of the Australian population lives in NSW, and more than 95 000 women give birth in this state annually (Australian Bureau of Statistics 2017) (Centre for Epidemiology and Evidence 2015).

The NSW PDC is based on electronic forms that are completed at birth by the attendants. Information on maternal demographics, maternal health, pregnancy, obstetric complications, labour and perinatal outcomes are included in the form. The forms are submitted to NSW Ministry of Health where the information is validated and compiled into the state-wide PDC (CHeReL 2016a).

Study population

There were 48 983 TSV born during the study period of these 101 stillbirth (18 (0.4%) born to mothers with pre-existing diabetes and 83 (0.2%) born to mothers with GDM). Due to our inability to identify times of stillbirth (antepartum or intrapartum), these stillbirths were excluded from the study. The study includes all live-born TSV (n=48 882) born in NSW to mothers with diabetes during pregnancy between 1st January 2002

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and 31st December 2012. Of these, 4501 (9.2%) were born to mothers with pre-existing diabetes and 44 381 (90.8%) were born to mothers with GDM.

Of our study population, 276 (0.4%) TSV were excluded from the multivariate logistic regression due to admission to neonatal intensive care unit (NICU) or special care nursery (SCN) with one or more diagnosed birth defects, and 71 (0.1%) were excluded because of missing data (mode of birth, birthweight, and admission to NICU or SCN due to birth defect). A total of 4 458 live-born TSV born to mothers with pre-existing diabetes and 44 148 born to mothers with GDM were included in the multivariate logistic regression.

Study factors and outcome measurements

Pre-existing diabetes includes Type I and Type II. GDM is defined as glucose intolerance that is diagnosed for the first time during pregnancy which may include hyperglycaemia induced by pregnancy or previously undiagnosed existing abnormalities of glucose tolerance (Nankervis et al. 2013).

Modes of birth include non-instrumental and instrumental vaginal birth, pre-labour CS (often known as an elective CS) and intrapartum CS. Planned vaginal births are births that were primarily intended to be non-instrumental vaginal births, although they might end with intrapartum CS, instrumental vaginal birth or non-instrumental vaginal birth.

The definition for macrosomia adopted by the International Association of Diabetes in Pregnancy Study Group of birthweight $\geq$ 4000g was used (IADPSG et al. 2015). 'Large for gestational age' was defined as a birthweight greater than the 90th percentile for

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gestational age and ‘small for gestational age’ is birthweight less than the 10^{th} percentile (IADPSG et al. 2015).

Adverse neonatal outcomes were 5-min Apgar score <7, neonate admission to NICU or SCN, and the need for resuscitation which included resuscitation by intermittent positive pressure respiration by bag and mask, intubation, and intermittent positive pressure respiration, external cardiac massage and ventilation.

Statistical analysis

Maternal characteristics and baby outcomes were compared by mode of birth using Chi-square test. Trend analysis was used to compare the rate of pre-labour CS by year using Mantel-Haenszel test for trend analysis.

Multivariate logistic regression was used to investigate the likelihood of adverse neonatal outcomes by mode of birth. Two analyses were conducted; the first compared TSV born by pre-labour CS with TSV born by all other modes of birth combined as planned vaginal births. This first analysis was performed to inform the decision of performing pre-labour caesarean section or proceed to planned vaginal birth. The second compared TSV born by non-instrumental vaginal birth, TSV who were planned as vaginal births but for whom resorting to instrumental birth and intrapartum CS, and TSV born by pre-labour CS. The second analysis was performed to help inform the decision in the situation were vaginal birth is planned.

Adjusted odds ratio (AOR) and 95% confidence interval (CI) were presented. The adjustment was made for maternal age, maternal country of birth (Australian-born

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mothers, overseas-born mothers), parity (no previous pregnancies, one, two, three or more previous pregnancies), smoking during pregnancy (smoked, did not smoke), essential and pregnancy-induced hypertension, and hospital sector (public, private). The analysis was performed using Statistical Package for Social Science software SPSS Version 22.0 (Armonk, NY: IBM Corporation). p value < 0.05 or CI not including 1 was considered statistically significant.

5.5 Results

Maternal characteristics and baby outcomes are presented in Tables 5.1 and 5.2. Among mothers who went into labour, 38.8% of mothers with pre-existing diabetes and 31.5% of mothers with GDM gave birth by instrumental vaginal birth or intrapartum CS. The highest proportion of mothers aged <25 years were among mothers with pre-existing diabetes who gave birth by instrumental vaginal birth (16.9% p<0.001) (Table 5.1). The proportion of primiparae mothers was higher among those who had instrumental vaginal birth (70.5% and 77.3% among mothers with pre-existing diabetes and mothers with GDM respectively) (Tables 5.1 and 5.2). There were 17 neonatal deaths of these two (0.4 per 1000 live-born TSV) born to women with pre-existing diabetes and 15 (0.3 per 1000 live-born TSV) born to women with GDM.

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Table 5.1: Maternal characteristics and birth outcomes for live-born term singletons in vertex presentation (TSV) born to women with pre-existing diabetes, 2002–2012

	pre-labour caesarean section		Non-instrumental vaginal birth		Instrumental vaginal birth		intrapartum caesarean section	
	n=1286	%	n=1969	%	n=397	%	n=849	%
Age Years								
< 20	11	0.9	33	1.7	10	2.5	9	1.1
20-24	85	6.6	185	9.4	57	14.4	91	10.7
25-29	246	19.1	436	22.1	89	22.4	209	24.6
30-34	434	33.7	675	34.3	143	36.0	271	31.9
35-39	391	30.4	502	25.5	71	17.9	207	24.4
≥ 40	119	9.3	138	7.0	27	6.8	62	7.3
Parity								
Primiparae	304	23.6	487	24.7	280	70.5	553	65.1
Multiparae	980	76.2	1480	75.2	115	29.0	296	34.9
Not stated	2	0.2	2	0.1	2	0.5	0	0.0
Number of previous caesarean section[a]								
None	136	13.9	1380	93.2	96	83.5	149	50.3
One	602	61.4	67	4.5	19	16.5	115	38.9
Two or more	239	24.4	4	0.3	0	0.0	31	10.5
Not stated	3	0.3	29	2.0	0	0.0	1	0.3
Country of birth								
Australian born	862	67.0	1204	61.1	256	64.5	586	69.0
Overseas born	420	32.7	760	38.6	140	35.3	262	30.9
Not stated	4	0.3	5	0.3	1	0.3	1	0.1
Smoking during pregnancy								
Smoked	142	11.0	288	14.6	43	10.8	84	9.9
Did not smoke	1140	88.6	1677	85.2	352	88.7	764	90.0
Not stated	4	0.3	4	0.2	2	0.5	1	0.1
Birthweight g								
Less than 4000	888	69.1	1659	84.3	342	86.1	635	74.8
4000 and over	397	30.9	310	15.7	54	13.6	214	25.2
Not stated	1	0.1	0	0.0	1	0.3	0	0.0
SGA	62	4.8	151	7.7	23	5.8	50	5.9
LGA	508	39.5	332	16.9	70	17.6	291	34.3
sex								
Male	682	53.0	962	48.9	208	52.4	446	52.5
Female	604	47.0	1007	51.1	189	47.6	403	47.5
Gestational age weeks								
37	290	22.6	241	12.2	59	14.9	177	20.8
38	610	47.4	599	30.4	153	38.5	328	38.6
39	321	25.0	605	30.7	103	25.9	202	23.8
40	54	4.2	369	18.7	59	14.9	117	13.8
Greater than 40	11	0.9	155	7.9	23	5.8	25	2.9

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a For multiparae mothers only

Table 5.2: Maternal characteristics and birth outcomes for TSV born to women with gestational diabetes, 2002–2012

	pre-labour caesarean section		Non-instrumental vaginal birth		Instrumental vaginal birth		intrapartum caesarean section	
	n=7958	%	n=24 946	%	n=5017	%	n=6447	%
Age Years								
< 20	22	0.3	300	1.2	49	1.0	73	1.1
20-24	276	3.5	1882	7.5	374	7.5	518	8.0
25-29	1227	15.4	6067	24.3	1274	25.4	1539	23.9
30-34	2690	33.8	8849	35.5	1899	37.9	2219	34.4
35-39	2734	34.4	6161	24.7	1142	22.8	1570	24.4
≥ 40	1008	12.7	1684	6.8	279	5.6	527	8.2
Not stated	1	0.0	3	0.0	0	0.0	1	0.0
Parity								
Primiparae	1644	20.7	7747	31.1	3877	77.3	4329	67.1
Multiparae	6309	79.3	17 191	68.9	1138	22.7	2114	32.8
Not stated	5	0.1	8	0.0	2	0.0	4	0.1
Number of previous CS[a]								
None	939	14.9	16 086	93.6	922	81.0	978	46.3
One	3820	60.5	844	4.9	195	17.1	965	45.6
Two or more	1534	24.3	21	0.1	5	0.4	157	7.4
Not stated	16	0.3	240	1.4	16	1.4	14	0.7
Country of birth								
Australian born	4353	54.7	12 323	49.4	2172	43.3	3131	48.6
Overseas born	3587	45.1	12 546	50.3	2824	56.3	3291	51.0
Not stated	18	0.2	77	0.3	21	0.4	25	0.4
Smoking during pregnancy								
Smoked	607	7.6	2549	10.2	299	6.0	554	8.6
Did not smoke	7315	91.9	22 308	89.4	4695	93.6	5872	91.1
Not stated	36	0.5	89	0.4	23	0.5	1	0.0
Birthweight g								
Less than 4000	6628	83.3	22 400	89.8	4588	91.4	5494	85.2
4000 and over	1327	16.7	2544	10.2	428	8.5	953	14.8
Not stated	3	0.0	2	0.0	1	0.0	0	0.0
Small for gestational age	496	6.2	2590	10.4	667	13.3	651	10.1
Large for gestational age	1652	20.8	2502	10.0	402	8.0	930	14.4
sex								
Male	4194	52.7	12 471	50.0	2709	54.0	3665	56.8
Female	3762	47.3	12 470	50.0	2305	45.9	2782	43.2
Not stated	2	0.0	5	0.0	3	0.1	0	0.0
Gestational age weeks								
37	921	11.6	2133	8.6	379	7.6	572	8.9
38	3271	41.1	6337	25.4	1138	22.7	1639	25.4
39	3000	37.7	8503	34.1	1695	33.8	2044	31.7
40	597	7.5	6118	24.5	1367	27.2	1580	24.5
Greater than 40	169	2.1	1855	7.4	438	8.7	612	9.5

a For multiparae mothers only

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Figure 5.1 shows an increasing trend in pre-labour CS for both macrosomic and non-macrosomic TSV. The largest increase was seen among macrosomic TSV (*p*=0.048). Followed by non-macrosomic TSV born to mothers with pre-existing diabetes (*p*=0.032).

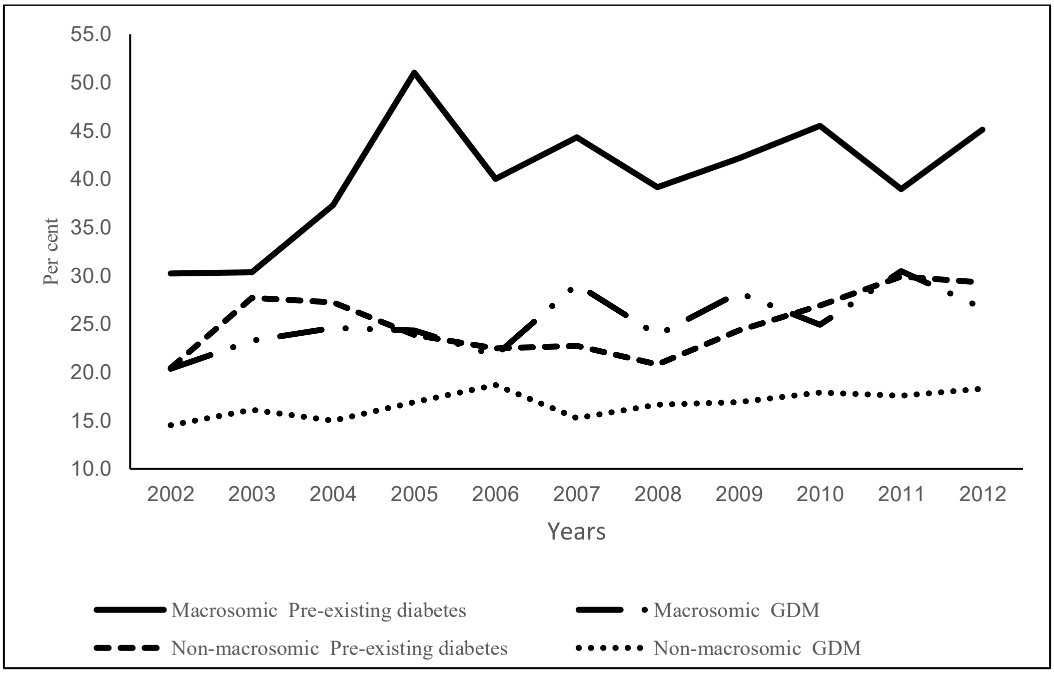

Figure 5.1: Rates of pre-labour caesarean section

Among mothers with pre-existing diabetes in the planned vaginal birth group, the highest rate of instrumental vaginal birth was among mothers to non-macrosomic TSV who had induction of labour (13.2%) (Figure 5.2). Mothers with GDM who had induction of labour and gave birth to non-macrosomic TSV had the highest rate of instrumental vaginal birth (15.2%) (Figure 5.3).

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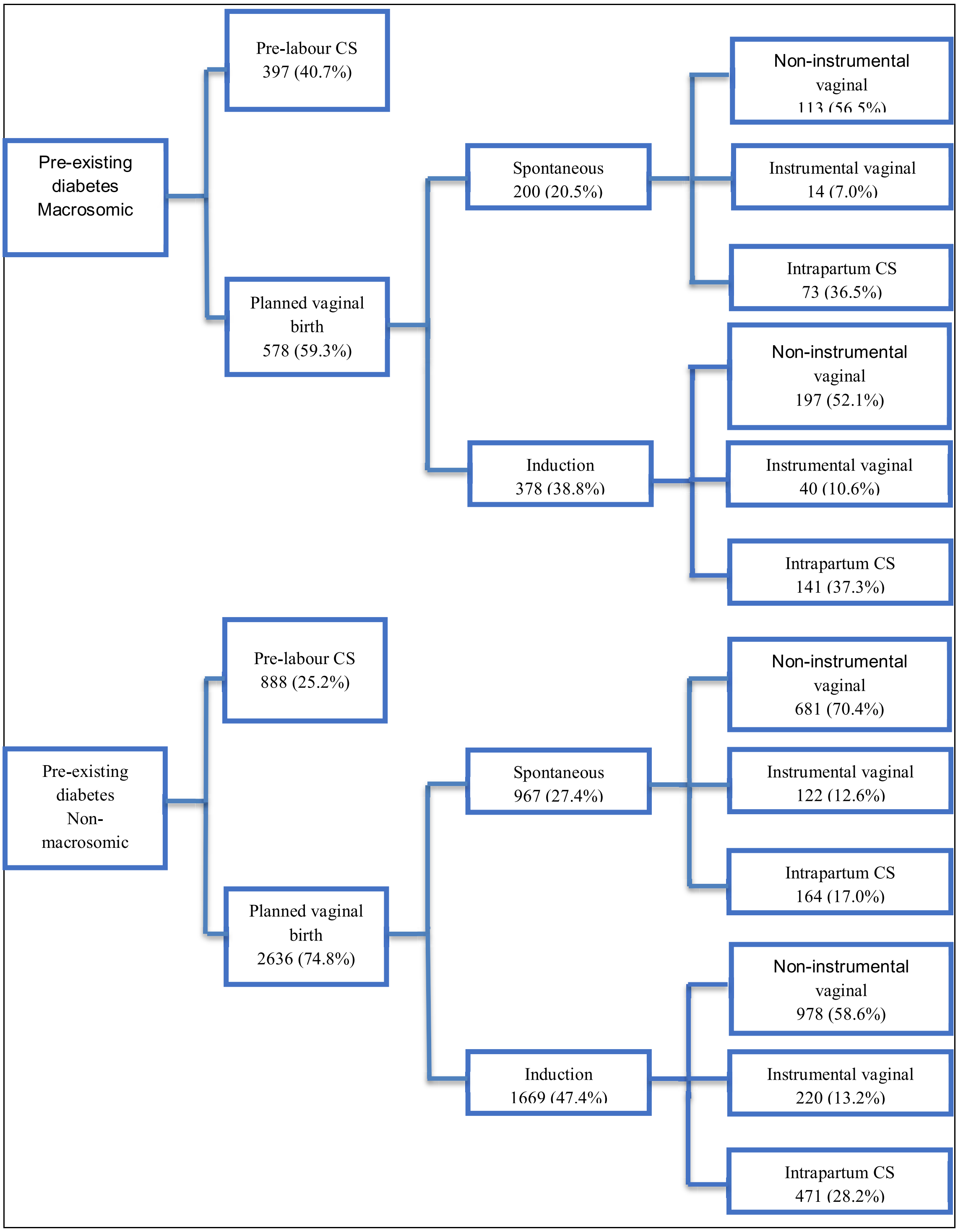

Figure 5.2: Onset of labour and mode of birth for mothers with pre-existing diabetes who gave birth to macrosomic and non-macrosomic TSV

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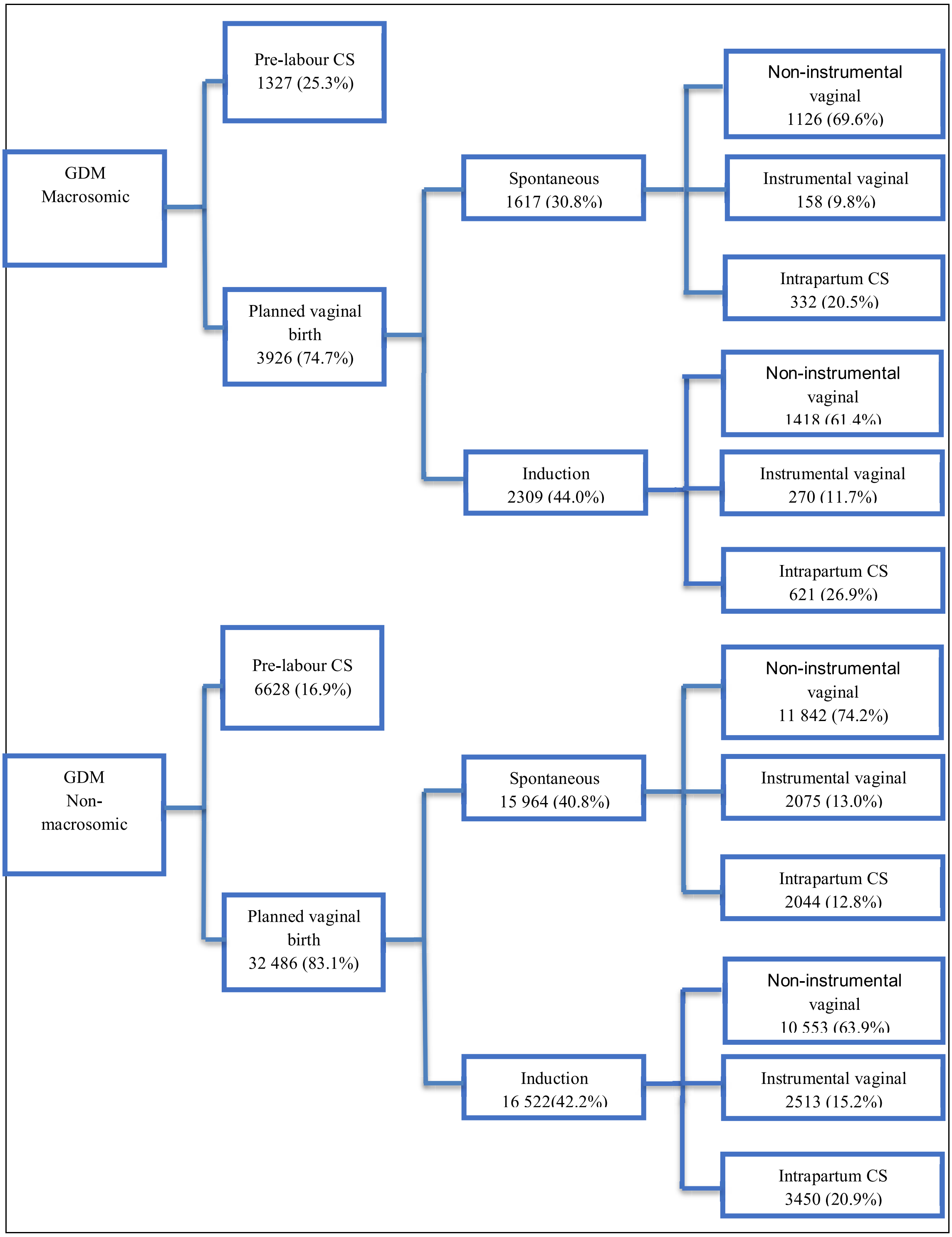

Figure 5.3: Onset of labour and mode of birth for mothers with GDM who gave birth to macrosomic and non-macrosomic TSV

There were no significant changes in the rate of admission to NICU/SCN for TSV born to mothers with pre-existing diabetes and for macrosomic TSV born to mothers with

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GDM from 2002 to 2012. There was a significant increase in the rate of high-level resuscitation for non-macrosomic TSV born to mothers with GDM between 2002 and 2012.

No labour CS compared to planned vaginal birth

For TSV born to mothers with pre-existing diabetes by pre-labour CS, there was a significant increase in the odds of admission to NICU/SCN compared to TSV born by planned vaginal birth (AOR 2.3, 95% CI; (1.7 to 3.2) for macrosomic; AOR 1.6, 95% CI; (1.4 to 1.9) for non-macrosomic TSV) (Table 5.3).

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Table 5.3: Adjusted odds ratios for adverse neonatal outcomes of TSV born to women with diabetes during pregnancy after pre- labour CS and planned vaginal birth, 2002–2012

	Planned vaginal birth[a]		pre-labour caesarean section		
	n	**%**	**n**	**%**	**AOR[b] (95% CI)**
			Pre-existing diabetes		
Birthweight less than 4000g	**2613**		**880**		
5 Min Apgar score <7	37	1.4	10	1.1	0.8 (0.4-1.6)
Admitted to NICU/SCN	1180	45.2	495	56.3	1.6*(1.4-1.9)
Need for resuscitation[c]	183	7.0	51	5.8	0.9 (0.6-1.2)
Birthweight 4000g and over	**574**		**391**		
5 Min Apgar score <7	16	2.8	1	0.3	0.1*(0.0-0.9)
Admitted to NICU/SCN	329	57.3	285	72.9	2.3*(1.7-3.2)
Need for resuscitationc	76	13.2	32	8.2	0.7 (0.4-1.1)
			Gestational diabetes		
Birthweight less than 4000g	**32 330**		**6590**		
5 Min Apgar score <7	362	1.1	62	0.9	1.0 (0.7-1.3)
Admitted to NICU/SCN	8613	26.6	2107	32.0	1.4*(1.3-1.4)
Need for resuscitation[c]	1752	5.4	326	4.9	1.1 (0.9 -1.2)
Birthweight 4000g and over	**3911**		**1317**		
5 Min Apgar score <7	76	1.9	22	1.7	1.0 (0.6-1.6)
Admitted to NICU/SCN	1288	32.9	610	46.3	1.9*(1.7-2.2)
Need for resuscitation[c]	423	10.8	99	7.5	0.7*(0.5-0.9)

a Reference group
b Odds ratios were adjusted for maternal age, maternal country of birth, the number of previous pregnancies, smoking during pregnancy, essential and pregnancy-induced hypertension and hospital sector.
c Need for resuscitation includes intermittent positive pressure respiration by bag and mask, intubation and intermittent positive pressure respiration as well as external cardiac massage and ventilation.
*p< .0.05

Spontaneous vaginal birth compared to other modes of birth

TSV born to mothers with pre-existing diabetes

For non-macrosomic TSV, pre-labour CS, instrumental vaginal birth and intrapartum CS were associated with increased odds of admission to NICU/SCN compared to non-instrumental vaginal birth (AOR 2.1, 95% CI; (1.8 to 2.5) for pre-labour CS; AOR 1.8, 95% CI; (1.4 to 2.3) for instrumental vaginal birth; AOR 2.4, 95% CI; (2.0 to 3.0) for

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intrapartum CS). Both instrumental vaginal birth and intrapartum CS were associated with a significant increase in the odds of requiring resuscitation compared to non-instrumental vaginal birth (AOR 3.3, 95% CI; (2.2 to 5.0) for instrumental vaginal birth; AOR 2.3, 95% CI; (1.6 to 3.4) for intrapartum CS) (Table 5.4).

For macrosomic TSV, instrumental vaginal birth was associated with a significant increase in the odds of requiring resuscitation (AOR 2.6, 95% CI; (1.2 to 5.7)) and admission to NICU/SCN (AOR 2.1, 95% CI; (1.1 to 3.9)) compared to non-instrumental vaginal birth (Table 5.4).

TSV born to mothers with GDM

Among non-macrosomic TSV, compared with non-instrumental vaginal birth, all other modes of birth were associated with increased odds of admission to NICU/SCN (AOR 1.5, 95% CI; (1.4 to 1.6) for instrumental vaginal birth; AOR 1.9, 95% CI; (1.7–2.0) for intrapartum CS; AOR 1.6, 95% CI; (1.5 to 1.7) for pre-labour CS), and need for resuscitation (AOR 2.5, 95% CI, (2.2–2.9) for instrumental vaginal birth; AOR 2.3, 95% CI; (2.1 to 2.7) for intrapartum CS; AOR 1.5, 95% CI; (1.3 to 1.7) for pre-labour CS) (Table 5.4).

Among macrosomic TSV born to GDM mothers, compared to non-instrumental vaginal birth, the rate of requiring resuscitation was higher after instrumental vaginal birth (AOR 2.3, 95% CI; (1.7 to 3.1)) and lower after pre-labour CS (AOR 0.7, 95% CI; (0.6 to 0.9)) (Table 5.4).

This chapter was previously published Zeki, R., Wang, A.Y., Lui, K., Li, Z., Oats, J.J.N., Homer, C.S.E. & Sullivan, E.A. 2018, 'Neonatal outcomes of live-born term singletons in vertex presentation born to mothers with diabetes during pregnancy by mode of birth: a New South Wales population-based retrospective cohort study', *BMJ Paediatrics Open*, vol. 2, no. 1.

Table 5.4: Adjusted odds ratios for adverse neonatal outcomes of TSV born to women with diabetes during pregnancy by mode of birth, 2002–2012

	Non-instrumental vaginal[a]		Instrumental vaginal birth			Intrapartum caesarean section			pre-labour caesarean section		
	n	%	n	%	AOR[b] (95% CI)	n	%	AOR[b] (95% CI)	n	%	AOR[b] (95% CI)
						Pre-existing diabetes					
Birthweight Less than 4000g	**1647**		**338**			**628**			**880**		
5 Min Apgar score <7	19	1.2	6	1.8	1.7 (0.6-4.5)	12	1.9	1.6 (0.7-3.6)	10	1.1	0.9 (0.4-2.1)
Admitted to NICU/SCN	633	38.4	170	50.3	1.8*(1.4-2.3)	377	60.0	2.4*(2.0-3.0)	495	56.3	2.1*(1.8-2.5)
Need for resuscitation[c]	74	4.5	46	13.6	3.3*(2.2-5.0)	63	10.0	2.3*(1.6-3.4)	51	5.8	1.3 (0.9-1.9)
Birthweight 4000g and over	**310**		**54**			**210**			**391**		
5 Min Apgar score <7	12	3.9	3	5.6	0.8 (0.2-3.7)	1	0.5	0.1* (0.0-0.5)	1	0.3	0.1*(0.0-0.5)
Admitted to NICU/SCN	137	44.2	34	63.0	2.1* (1.1-3.9)	158	75.2	3.9*(2.6-5.9)	285	72.9	4.1*(2.9-5.7)
Need for resuscitation[c]	32	10.3	14	25.9	2.6*(1.2-5.7)	30	14.3	1.3 (0.7-2.3)	32	8.2	0.8 (0.5-1.4)
						Gestational diabetes					
Birthweight Less than 4000g	**22 304**		**4565**			**5461**			**6590**		
5 Min Apgar score <7	177	0.8	87	1.9	2.4*(1.8-3.1)	98	1.8	2.1*(1.6-2.7)	62	0.9	1.3 (0.9-1.7)
Admitted to NICU/SCN	5299	23.8	1354	29.7	1.5*(1.4-1.6)	1960	35.9	1.9*(1.7-2.0)	2107	32.0	1.6*(1.5-1.7)
Need for resuscitation[c]	822	3.7	433	9.5	2.5*(2.2-2.9)	497	9.1	2.3* (2.1-2.7)	326	4.9	1.5*(1.3-1.7)
Birthweight 4000g and over	**2539**		**426**			**946**			**1317**		
5 Min Apgar score <7	49	1.9	14	3.3	1.8 (0.9-3.5)	13	1.4	0.7 (0.3-1.3)	22	1.7	1.0 (0.6-1.7)
Admitted to NICU/SCN	752	29.6	138	32.4	1.3* (1.0-1.7)	398	42.1	1.9*(1.6-2.3)	610	46.3	2.3*(2.0-2.7)
Need for resuscitation[c]	259	10.2	76	17.8	2.3*(1.7-3.1)	88	9.3	1.0 (0.7-1.3)	99	7.5	0.7*(0.6-0.9)

a Reference group.
b Odds ratios were adjusted for maternal age, maternal country of birth, the number of previous pregnancies, smoking during pregnancy, essential and pregnancy-induced hypertension and hospital sector.
c Need for resuscitation includes intermittent positive pressure respiration by bag and mask, intubation and intermittent positive pressure respiration as well as external cardiac massage and ventilation. *P<0.05.

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5.6 Discussion

To our knowledge, this Australian study is the largest population-based investigation of neonatal outcomes related to mode of birth in live-born TSV born to mothers with diabetes during pregnancy. The study results showed that, among TSV born to mothers with diabetes during pregnancy, pre-labour CS was associated with a significant increase in the rate of admission to NICU/SCN compared to planned vaginal birth. Both instrumental vaginal birth and intrapartum CS were associated with increased odds of requiring resuscitation compared to non-instrumental vaginal birth.

The use of a large validated population-based dataset with high accuracy (Roberts et al. 2009) generates a high level of evidence that cannot be achieved in hospital settings. Our study provides population-level evidence on the association between mode of birth and neonatal outcomes of TSV born to mothers with diabetes during pregnancy in NSW. Our study also provides information about clinical practice for mothers with diabetes during pregnancy. The validation study by Ampt et al. on the NSW PDC shows that the PDC had high sensitivity (≥ 94.7%) and high positive predictive value (≥ 96.1%) in reporting dichotomized outcome variables such as 5-min Apgar score <7 and neonatal resuscitation (Ampt et al. 2013).

The limitation of the study is the lack of information on reasons for NICU/SCN admissions as macrosomic TSV are routinely admitted to NICU/SCN for expected hypoglycaemia without clinical necessity which increases the rate of admission to NICU/SCN. Some services do have a routine policy of admitting babies born to mothers with diabetes to a NICU/SCN hence the numbers could be higher. Another limitation is

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the lack of information on maternal body mass index and on umbilical artery PH and lactate levels. To remove the confounding related to birth defects, we excluded TSV admitted to NICU/SCN because of birth defects from our multivariable logistic regression. However, we are unable to adjust for maternal body mass index, an independent risk factor for adverse pregnancy outcomes such as low Apgar score and a higher rate of admission to NICU (Avcı et al. 2015). We used stratification by estimated fetal macrosomia using birthweight to limit the impact of maternal body mass index on the mode of birth and neonatal outcomes. We are also unable to adjust for shoulder dystocia as it was not captured in NSW PDC. We also lack information on second stage CS which did not allow us to compare between intrapartum CS and instrumental vaginal birth.

There was no significant difference in the odds of 5-min Apgar score <7 between TSV born after pre-labour CS and those born after planned vaginal birth for mothers who had pre-existing diabetes or GDM. Stuart et al. (2011) found a significant reduction in the odds of 5-min Apgar score <7 among TSV born to mothers with diabetes during pregnancy who were born after pre-labour CS at 38 weeks gestation compared to those born after planned vaginal birth at 39 weeks gestation (Stuart, Matthiesen & Källén 2011).

TSV born to mothers with diabetes during pregnancy can be affected by a number of morbidities including respiratory distress syndrome, hypoglycaemia and hypocalcaemia that can lead to an increase in the likelihood of admission to NICU/SCN[5]. In addition, CS is associated with increased odds of neonatal respiratory morbidity (Zanardo et al. 2004). The NICE guideline recommended admission to NICU if babies who were born

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to mothers with diabetes had one of the following symptoms: hypoglycaemia, respiratory distress or jaundice, signs of cardiac decompensation, neonatal encephalopathy or polycythaemia, the need for tube feeding or who were born preterm (NICE 2015).

Our study found that instrumental vaginal birth and intrapartum CS were associated with an increase in the odds of the need for resuscitation and admission to NICU/SCN compared to non-instrumental vaginal birth. One indication for instrumental vaginal birth and intrapartum CS is fetal compromise (Royal College of Obstetricians and Gynaecologists (RCOG) 2011a), which is also an indication for neonatal resuscitation (Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) 2015). Thus, requiring resuscitation might have been associated with fetal compromise, not the use of instrumental vaginal birth or intrapartum CS. However, instrumental vaginal birth alone is also considered a risk factor for requiring neonatal resuscitation (RANZCOG 2015).

Our study found that women with diabetes have a low rate of non-instrumental vaginal birth and high rate of giving birth by intrapartum CS and instrumental birth. This is consistent with previous studies (Boriboonhirunsarn & Waiyanikorn 2016; Stuart, Matthiesen & Källén 2011). Among our population, of mothers who went into labour, 38.8% of those with pre-existing diabetes and 31.5% of those with GDM gave birth by instrumental vaginal birth or intrapartum CS compared with 29.4% of women in the NSW general population (Hilder L et al. 2014). One in four mothers (25.9%) with planned vaginal birth gave birth to a macrosomic TSV by intrapartum CS, and one in five mothers (20.5%) with planned vaginal birth gave birth to a non-macrosomic TSV

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by instrumental vaginal birth. Given that both intrapartum CS and instrumental birth are associated with increased odds of adverse neonatal outcomes, the high proportion of resorting to instrumental vaginal birth for non-macrosomic TSV or intrapartum CS for macrosomic TSV should be considered when planning vaginal births.

Although pre-labour CS was associated with a reduction in some adverse neonatal outcomes, specifically requiring resuscitation for macrosomic TSV, pre-labour CS is associated with adverse maternal outcomes. In the general population, CS is associated with immediate risk to the mother of infection, haemorrhage, anaesthetic risks and mortality (D'Souza 2013). It is also associated with an increased likelihood of repeat elective caesarean section in future pregnancies and increased risk of stillbirth and placenta praevia and accreta, uterine rupture, and peripartum hysterectomy (D'Souza 2013). The risk of adverse maternal outcomes following CS might be escalated for women with diabetes during pregnancy since they are at higher risk of adverse maternal outcomes (such as infection and impaired wound healing) than women without diabetes (Takoudes et al. 2004).

Conclusion

Of mothers with planned vaginal birth, one in four gave birth to a macrosomic TSV by intrapartum CS and one in five gave birth to a non-macrosomic TSV by instrumental vaginal birth. The potential risk of adverse neonatal outcomes associated with intrapartum CS and instrumental vaginal birth should be considered when planned for birth of women with diabetes. Close monitoring and readiness to intervene are needed

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when planned labour for TSV, particularly when the baby is macrosomic as CS is often required to expedite birth.

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Authors' contributions

All authors were involved in the conception and design of the work and interpretation of the data for the manuscript. RZ involved in initial drafting of the work. RZ, ZL, AYW involved in analysing the data. ALL authors involved in the critical revision of the manuscript for intellectual content and approved the paper as submitted. All authors agree to be accountable for all aspects of the work and in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Competing interests

None declared.

Ethics

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Ethical approval was granted by University of Technology Sydney Human Research Ethics Committee (UTS HREC ETH16-0219). The use of the de-identified data was approved by Executive Director, Centre for Epidemiology and Evidence/ NSW Ministry of Health.

5.7 Chapter summary

This chapter investigated the association between method of birth and adverse neonatal outcomes. The key points of this chapter are:

- More than one third (38.3%) of mothers with pre-existing diabetes and 31.5% of mothers with GDM, who went into labour gave birth by either instrumental vaginal birth or intrapartum caesarean section.
- A quarter (25.9%) of mothers of macrosomic TSV babies who went into intrapartum gave birth by caesarean section.
- One fifth (20.5%) of mothers of non-macrosomic TSV who went into labour had instrumental vaginal births.
- Both intrapartum caesarean section and instrumental vaginal birth were associated with increased odds of adverse neonatal outcomes.
- Pre-labour caesarean section was associated with an increase in the odds of admission to NICU/SCN.

Risk of an adverse maternal outcome(s) is an important factor to consider when determining method of birth. The next chapter (Chapter 6) will investigate the

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association between method of birth and the risk of Obstetric Anal Sphincter Injuries (OASIs) among women with GDM compared to women without diabetes.

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Chapter 6: Study three: Obstetric anal sphincter injuries among women with gestational diabetes and women without gestational diabetes: a NSW population-based cohort study.

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List of presentation and publication from this chapter:

This study was presented at the Perinatal Society of Australia & New Zealand (PSANZ) 2018 annual Congress in Auckland, New Zealand as detailed below.

Oral presentation. Obstetric anal sphincter injuries among women with gestational diabetes and women without diabetes: a NSW population-based cohort study. The Perinatal Society of Australia & New Zealand (PSANZ) annual Congress in Auckland, New Zealand (2-5 April 2017).

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This Chapter is the accepted version of the article Obstetric anal sphincter injuries among women with gestational diabetes and women without gestational diabetes: A NSW population-based cohort study which has been published at https://obgyn.onlinelibrary.wiley.com/doi/10.1111/ajo.12950 as detailed below:

Zeki, R., Li, Z., Wang, A.Y., Homer, C.S.E., Oats, J.J.N., Marshall, D., Sullivan, E.A. Obstetric anal sphincter injuries among women with gestational diabetes and women without gestational diabetes: A NSW population-based cohort study, *Australian and New Zealand Journal of Obstetrics and Gynaecology*, published online on 17 February 2019.

Authors' contributions and signatures are available in Appendix 2.

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6.1 About this chapter

The results of Chapter 5 show that instrumental vaginal birth and labour are associated with an increase in the risk adverse neonatal outcomes. This chapter will investigate the association between method of birth (spontaneous vaginal, and instrumental vaginal including both forceps and vacuum extraction) on maternal outcomes for women who gave birth vaginally. For this study the maternal outcome is obstetric anal sphincter injury (OASIs). Obstetric anal sphincter injuries including third- and fourth-degree perineal tears result in significant maternal morbidity. This chapter also investigates the association of episiotomy and method of birth referred to as (combined episiotomy) with method of birth and the risk of OASIs. Because of their risk of OASIs, the population of interest is women with GDM, who make up 91.3% of women with diabetes who gave birth vaginally in NSW between 2007 and 2013.

The rate of GDM of women included in this chapter is for the period 2007 to 2013. For this reason, it is lower than the rate included in the literature review which is during the period after the publication of new ADIPS Guideline (Nankervis et al. 2013) that recommended a new diagnosis criteria for GDM. More women are likely to be diagnosed with GDM using the new diagnostic guidelines thus explaining the difference.

This chapter is written and formatted according to the Australian and New Zealand Journal of Obstetrics and Gynaecology guidelines.

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6.2 Abstract

Background: Obstetric anal sphincter injuries (OASIs) are associated with maternal morbidity, however it is uncertain whether Gestational Diabetes (GDM) is an independent risk factor when considering birth weight, mode of birth and episiotomy.

Aims: To compare rates of OASIs between women with gestational diabetes (GDM) and women without GDM by mode of birth and birthweight. To investigate the association between episiotomy, mode of birth and the risk of OASIs.

Methods: A population-based cohort study of women who gave birth vaginally in NSW, from 2007 to 2013. Rates of OASIs were compared between women with and without GDM, stratified by mode of birth, birthweight and a multi-categorical variable of mode of birth and episiotomy. Adjusted Odds Ratios (AOR) and 95% Confidence interval (CI) were calculated by multivariable logistic regression.

Results: The rate of OASIs was 3.6% (95% CI 2.6-2.7) versus 2.6% (95% CI 3.4-2.8) ($p<0.001$) among women with and without GDM, respectively. Women with GDM and a macrosomic baby (birthweight ≥4000g), had a higher risk of OASIs with forceps (AOR 1.76, 95% CI (1.08-2.86, p=0.02) or vacuum (AOR 1.89, 95% CI (1.17-3.04, p=0.01), compared with those without GDM. For primiparous women with GDM and all women without GDM, an episiotomy with forceps was associated with lower odds of OASIs than forceps only. (primiparous GDM, forceps-episiotomy AOR 2.49, 95% CI (2.00-3.11), forceps AOR 5.30, 95% CI (3.72-7.54)), (primiparous without GDM, forceps-episiotomy AOR 2.71, 95% CI (2.55-2.89), forceps AOR 5.95, 95% CI (5.41-

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6.55)) and (Multiparous without GDM, forceps-episiotomy AOR 3.75, 95% CI (3.12-4.50), forceps AOR 6.20, 95% CI (4.96-7.74)).

Conclusion: Women with GDM and a macrosomic baby should be counselled about the increased risk of OASIs with both vacuum and forceps. With forceps birth this risk can be partially mitigated by performing a concomitant episiotomy.

Short Communications

Women with GDM and a macrosomic baby should be counselled about the increased risk of OASIs with instrumental birth. For forceps births this risk can be reduced by performing an episiotomy.

Keywords

Gestational diabetes, Obstetric anal sphincter injury, Perineal trauma, Episiotomy, Birth, Birthweight, Perineum, Lacerations

6.3 Introduction

Obstetric anal sphincter injuries (OASIs) occurred in 4322 (2.1%) women who gave birth vaginally in Australia in 2012 (Hilder L et al. 2014). OASIs include both third- and fourth-degree perineal tears (RCOG 2015). Third-degree tears are defined as perineal injury affecting the anal sphincter complex (RCOG 2015). Fourth-degree perineal tears affect the anal mucosa and the anal sphincter complex (RCOG 2015). Short- and long-term health problems have been reported to be associated with OASIs. Short-term complications can include perineal pain, oedema, bruising, and urinary

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retention (EkÉUs, Nilsson & Gottvall 2008; Harvey et al. 2015). Long-term complications can include anxiety, depression, sexual dysfunction and anal incontinence, including flatal incontinence and leakage of stool (EkÉUs, Nilsson & Gottvall 2008; Harvey et al. 2015; Williams et al. 2005)

Several demographic factors have been identified as associated with OASIs. Asian ethnicity, maternal older age, first-time mother and giving birth in public hospitals are all associated with an increase in the risk of OASIs (Ampt et al. 2013; Baghestan et al. 2010; Brown et al. 2018). Instrumental vaginal birth, including forceps and vacuum births, has been identified as a major risk factor for OASIs (Baghestan et al. 2010; Dahlen et al. 2007). Birthweight is associated with OASIs, with a NSW population-based study showing a rate increase of 21% and 25% for every 200g increase in birthweight, in primiparous and multiparous women, respectively (Ampt et al. 2013). For macrosomic babies (birthweight ≥4000g) there was a significant increase with adjusted odd-ratio of 2.64(Dahlen et al. 2007). In addition to high birthweight, shoulder dystocia has been identified as an independent risk factor for OASIs (Gurol-Urganci et al. 2013). Women with gestational diabetes mellitus (GDM) are at increased risk of OASIs due to the high birthweight baby compared to women without GDM (Ampt et al. 2013; Baghestan et al. 2010; Kc, Shakya & Zhang 2015; Stotland et al. 2004). Previously published research shows that among women with GDM, the odds ratio of OASIs was 1.3 (95% CI; 1.1-1.6), compared to women without GDM (Baghestan et al. 2010).

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There is evidence that selective episiotomy can reduce the risk of OASIs (RCOG 2015). A Cochrane systematic review shows that compared to routine episiotomy, selective episiotomy with spontaneous vaginal birth is associated with a slight reduction in the rate of OASIs (Jiang et al. 2017). The most recent Royal College of Obstetricians and Gynaecologists (RCOG) 3rd and 4th degree tear green-top guideline recommended performing mediolateral episiotomy with instrumental vaginal birth, citing a significant reduction in OASI (RCOG 2015). To date, no published population-based study has investigated the association between GDM and the risk of OASIs by both mode of birth and birthweight.

Our population-based study of women who gave birth vaginally in NSW has two aims:

1. To compare the rate of OASIs between women with or without GDM by mode of birth and birthweight.

2. To investigate the association between episiotomy, mode of birth and the risk of OASIs.

6.4 Method

Data source

The New South Wales (NSW) Perinatal Data Collection (PDC) was used as the data source. The PDC is a population-based surveillance system that covers all births occurring in NSW public and private hospitals as well as home births. The PDC

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includes all live births and stillbirths of at least 20 weeks or at least 400g birthweight (CHeReL 2017).

Information on maternal demographics, maternal health, pregnancy, obstetric complications, labour and birth as well as perinatal outcomes are included in the completed form. The NSW Ministry of Health receives the completed form, validates and compiles the information into a statewide PDC (CHeReL 2017).

Study population

All women who gave birth vaginally in NSW (465,124) from 1 January 2007 to 31 December 2013 were included. Women with pre-existing diabetes (2296, 0.5%) and women who had breech presentation (2518, 0.5%) were excluded from the analysis. Of the 460,310 women remaining in the analysis, 23,965 (5.2%) women had GDM and 436,345 (94.8%) women were without a diagnosis of GDM during pregnancy.

Study factors and outcome measurements

GDM is defined as glucose intolerance that is diagnosed for the first time during pregnancy. It may include pregnancy-induced hyperglycemia or undiagnosed hyperglycemia that existed before pregnancy (Nankervis et al. 2013).

Between 2007 and 2012, the Australian guidelines (Hoffman et al. 1998) recommended screening for GDM using the glucose challenge test (GCT) at 26 to 28 weeks gestation. A 75g two-hour oral glucose tolerance test (OGTT) was recommended if the non-fasting GCT measured at one-hour post-load plasma glucose level was

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- ≥7.8 mmol/L after 50g glucose load, or
- ≥ 8.0 mmol/L after 75g glucose load

GDM was diagnosed if

- fasting venous plasma glucose level was ≥ 5.5 mmol/L, and/or
- venous plasma glucose level was ≥8.0 mmol/L at two hours following the 75g glucose load.

In 2013 a new guideline was published by the Australasian Diabetes In Pregnancy Society (ADIPS) (Nankervis et al. 2013). This guideline recommends routine testing for GDM at 24 to 28 weeks gestation using 75g OGTT. GDM is diagnosed if

- fasting glucose is ≥5.1 mmol/L or
- 1-hr glucose is ≥ 10.0 mmol/L or
- 2-hr glucose is ≥ 8.5 mmol/L.

The mode of birth includes spontaneous vaginal birth (vaginal birth which did not require instrumental assistance), and instrumental vaginal birth including both forceps and vacuum extraction. Episiotomy is recorded dichotomously as yes, no.

The outcome of the study was third- and fourth-degree perineal tears referred to as Obstetric Anal Sphincter injuries (OASIs). In the PDC, perineal status is recorded as intact, 1st-degree tear/graze, 2nd-degree tear, 3rd-degree tear, 4th-degree tear, and 'other'. Third- and fourth-degree tears were combined, and all other types of tears were combined with 'intact'. A previously published validation study of the NSW PDC found

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third- and fourth-degree tears were adequately recorded in the PDC (Kappa value > 0.75) (Roberts et al. 2009).

Statistical analysis

Maternal sociodemographic factors and obstetric characteristics were compared among women with GDM and women without GDM using a Chi-square test for categorical variables and an Independent Samples t-test for maternal age.

Two multivariate logistic regression models were employed. The first model investigated the odds ratio of OASIs for women with GDM compared with women without GDM. Data were stratified by macrosomia (IADPSG et al. 2015) and mode of birth (spontaneous vaginal birth, forceps delivery, and vacuum extraction). The second model investigated the likelihood of OASIs where an episiotomy was employed in the mode of birth.

Parity was included as an interaction term in the analysis to examine if it was an effect modifier. In model one (OASIs among women with GDM compared to women without GDM) parity was stratified into two groups, primiparous and multiparous for women who had a vacuum extraction and gave birth to macrosomic babies. For similar women who had either a spontaneous vaginal birth or forceps birth, the analysis was not stratified by parity as the interaction of parity with GDM were not significant. In model two (OASIs among women who had episiotomies and gave birth vaginally compared to women who had spontaneous vaginal birth without episiotomy), parity was found to be an effect modifier in the association between episiotomy and OASIs. For this reason,

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the analysis was stratified by parity. For model two, a multi-category variable was created for episiotomy and mode of birth, with spontaneous vaginal birth without episiotomy the reference group.

Odds ratios (OR), adjusted odds ratios (AOR), and 95% confidence intervals (CI) were produced. Variables associated with the outcomes in the univariate analysis ($p<0.2$) and factors identified in the literature as potentially predictive were entered in the logistic regression model. Adjustment for the first model was made for maternal age groups (< 25 years, 25–34 years, and ≥35 years), maternal country of birth (Australian born, overseas born), parity (nullipara, multipara), plurality (singleton, multiple), last birth by caesarean section (yes, no), onset of labour (spontaneous, induction), episiotomy performed (yes, no), hospital sector (public, private), and baby sex (male, female), gestational age at birth (< 37 weeks, ≥ 37 weeks). Adjustment for the second model was made for maternal age groups, maternal country of birth, plurality (singleton, multiple), last birth by caesarean section (yes, no), onset of labour (spontaneous, induction), hospital sector (public, private), baby sex (male, female), and birthweight (<4000g, ≥4000g). The percentages of combined episiotomy with mode of birth stratified by parity were calculated.

Details of ethics approval

The use of de-identified data was approved by the Executive Director, Centre for Epidemiology and Evidence, NSW Ministry of Health. Ethics approval was granted by University of Technology Sydney Human Research Ethics Committee (UTS HREC ETH16-0219).

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6.5 Results

During the period studied, 863 (3.6%) of women with GDM had OASIs, and 11,561 (2.6%) women without GDM had OASIs (p <0.001). The majority of women had third-degree perineal tears, 3.4% and 2.5 for women with without GDM respectively, with similar fourth-degree tear rates of 0.2% between the groups.

Table 1 presents the maternal and newborn characteristics of women with and without GDM. As seen in Table 1, the baseline maternal and newborn characteristics, there were significant differences between women with and without GDM. Those with GDM were were significantly older (≥35y: 30.8% vs 19.5%, p<0.001), more likely to be born overseas (51.4% vs 31.0 %, p<0.001), more likely to be induced (52.1% vs 28.6%, p<0.001), had a higher rate of episiotomy (20.5% vs17.4%, p<0.001). However the GDM group had a lower rate of macrosomia (7.8% vs 11.4%, p<0.001). Among women who gave birth to macrosomic babies, there was no significant difference in the percentage of instrumental vaginal birth between women with GDM (14.7%) and those without GDM (15.7%) (p= 0.29).

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Table 6.1: Maternal and newborn characteristics of women who had GDM and women without GDM

	Without GDM (n=436345) n (%)	With GDM (n= 23965) n (%)	P value[a]
Age (Years)			
Mean (SD)	29.5 (5.6)	31.7 (5.2)	< 0.001
less than 25	86 451 (19.8)	2090 (8.7)	< 0.001
25 - 34	264 791 (60.7)	14 485 (60.4)	
35 or more	85 023 (19.5)	7389 (30.8)	
Not stated	80 (0.0)	1 (0.0)	
Country of birth			
Australian born	299 042 (68.5)	11 529 (48.1)	< 0.001
Overseas born	135 364 (31.0)	12 326 (51.4)	
Not stated	1939 (0.4)	110 (0.5)	
Parity			
Nulliparous	183 742 (42.1)	9995 (41.7)	0.185
Multiparous	252 258 (57.8)	13 969 (58.3)	
Not stated	345 (0.1)	1 (0.0)	
Last birth by caesarean section[b]			
Yes	11476 (4.5)	565 (4.0)	0.005
No	240 691 (95.4)	13 399 (95.9)	
Not stated	91 (0.0)	5 (0.0)	
Onset of labour			
Spontaneous	311 695 (71.4)	11473 (47.9)	<0.001
Induced	124 601 (28.6)	12491 (52.1)	
Not stated	49 (0.0)	1 (0.0)	
Method of birth			
Spontaneous vaginal birth	366 255 (83.9)	19 595 (81.8)	< 0.001
Forceps	24 634 (5.6)	1666 (7.0)	
Vacuum	45 456 (10.4)	2704 (11.3)	
Plurality			
Singleton	433 210 (99.3)	23 743 (99.1)	< 0.001
Multiple	3135 (0.7)	222 (0.9)	
Episiotomy			
Yes	75 852 (17.4)	4923 (20.5)	< 0.001
No	360 412 (82.6)	19 041 (79.5)	

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Not stated	81 (0.0)	1 (0.0)	
Hospital sector			
Public	34 2317 (78.5)	20 287 (84.7)	
Private	89 257 (20.5)	3549 (14.8)	< 0.001
Home birth/birth before arrival	4771 (1.1)	129 (0.5)	
Baby sex			
Male	221 297 (50.7)	12 157 (50.7)	0.988
female	214 932 (49.3)	11 805 (49.3)	
Not stated	116 (0.0)	3 (0.0)	
Birthweight (g)			
Less than 3000	80 855 (18.5)	5831 (24.3)	
3000-3499	164 912 (37.8)	9951 (41.5)	< 0.001
3500-3999	140 487 (32.2)	6310 (26.3)	
4000 and over	49 738 (11.4)	1863 (7.8)	
Not stated	354 (0.1)	10 (0.0)	
Gestational age (weeks)			
Less than 37	22 069 (5.1)	1507 (6.3)	
37 and over	414 206 (94.9)	22 456 (93.7)	< 0.001
Not stated	70 (0.0)	2 (0.0)	

a) Excludes not stated values.
b) Mutipara only.

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The results of the multivariate analysis are shown in Table 2. For women who gave birth to macrosomic babies, the odds of OASIs were significantly higher among women with GDM who gave birth by forceps (AOR 1.76, 95% CI (1.08-2.86)) or vacuum (AOR 1.89, 95% CI (1.17-3.04)) compared to women without GDM. Women with GDM who gave birth to macrosomic babies by spontaneous vaginal birth did not have a significant increase in the odds of OASIs (AOR 1.07, 95% CI (0.79-1.43)) compared with those without GDM.

A subgroup analysis, by parity, of women with macrosomic babies, showed vacuum births in multiparous women with GDM had a significant increase in the odds of OASIs compared to women without GDM (AOR 2.66, 95% CI (1.14-6.22)). There was no statistically significant increase in the primiparous groups (AOR 1.67, 95% CI (0.94-2.98)).

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Table 6.2: OASIs by method of birth, birthweight and GDM

Method of birth	OASIs Number (%) Without GDM (Reference group)	With GDM	OR (95% CI)	AOR[a] (95% CI)
		Birthweight < 4000g		
Spontaneous vaginal birth	5582/323924 (1.7)	439/17995 (2.4)	1.43 (1.29-1.57)	1.21*(1.09-1.34)
Forceps	2063/21434 (9.6)	184/1546 (11.9)	1.27 (1.08-1.49)	1.13 (0.96-1.33)
Vacuum	1860/40813 (4.6)	145/2550 (5.7)	1.26 (1.06-1.5)	1.15 (0.96-1.37)
		Birthweight ≥ 4000g		
Spontaneous vaginal birth	1273/41922 (3.0)	50/1590 (3.1)	1.04 (0.78-1.38)	1.07 (0.79-1.43)
Forceps	413/3180 (13.0)	23/120 (19.2)	1.59 (1.00-2.53)	1.76*(1.08-2.86)
Vacuum	369/4618 (8.0)	22/153 (14.4)	1.93 (1.22-3.08)	1.89*(1.17-3.04)

a) AOR, odd ratios were adjusted for maternal age, maternal country of birth, parity, plurality, hospital sector, last birth by caesarean section, onset of labour, episiotomy, baby sex and gestational age.
*p<0.05

Table 6.3 compares the rates of episiotomy, in women with and without GDM, analysed by parity and mode of birth. For primarous and multiparous women who had spontaneous vaginal, there was a statistically significant difference in rates of episiotomy, when comparing GDM status ($p<0.001$). This difference was not statistically significant for primiparous ($p=0.68$) and multiparous ($p=0.05$) women who had forceps-assisted birth and multiparous women who had vacuum extraction ($p=0.083$). The percentage of episiotomy among primiparous women with GDM who had a vacuum extraction was slightly higher than those without GDM ($p=0.04$) (Table 6.3).

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Table 6.3: Percentage of combined episiotomy and method of birth by parity and GDM

Parity		Without GDM n(%)	GDM n(%)	P value
Primiparous	Episiotomy and spontaneous vaginal birth	21 239 (16.5)	1332 (20.4)	<0.001
	Episiotomy and forceps	16 973 (82.2)	1145 (82.7)	0.68
	Episiotomy and vacuum	18 650 (54.1)	1172 (56.4)	0.04
Multiparous	Episiotomy and spontaneous vaginal birth	13 143 (5.5)	871 (6.7)	<0.001
	Episiotomy and forceps	2511 (63.0)	193 (68.9)	0.05
	Episiotomy and vacuum	3303 (30.2)	209 (33.4)	0.083

Table 6.4 presents the odds ratio of OASIs by episiotomy and mode-of-birth, using the spontaneous vaginal birth without episiotomy, analysed by GDM status and parity. Primiparous women with GDM, who had a forceps-assisted birth, had the highest odds of OASIs (AOR 5.30, 95% CI (3.72-7.54)). This odds ratio was reduced to 2.49, 95% CI (2.00-3.11) when episiotomy was performed. For primiparous women without GDM, combined episiotomy with forceps birth or vacuum extraction significantly lowered the odds of OASIs (from 5.95, 95% CI (5.41-6.55) to 2.71 95% CI (2.55-5.89) forceps) and (from 1.99, 95% CI (1.89-2.14) to 1.44 95% CI (1.33-1.55) vacuum). A subgroup analysis was done for primiparous women who gave birth to macrosomic babies. Among women with GDM episiotomy with forceps reduces the odds ratio of OASIs from 5.38, 95% CI (1.42-20.38) to 3.21, 95% CI (1.47-7.05) compared to forceps alone. However, this reduction was not statistically significant. For primiparous women without GDM, the odds of OASIs was lower for women who had an episiotomy with

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forceps than women who did not have an episiotomy, (from 4.07, 95% CI (3.15-5.26) to 1.86, 95% CI (1.58-2.18)).

Table 6.4: OASIs by method of birth, episiotomy and GDM

	OASIs Number (%)	OR (95% CI)	AOR[a] (95% CI)
	With GDM		
Primiparous			
Spontaneous vaginal birth-no episiotomy	258/5198 (5.0)	Reference	Reference
Spontaneous vaginal birth-episiotomy	66/1332 (5.0)	1.00 (0.76-1.32)	0.97 (0.73-1.29)
Forceps-no episiotomy	47/240 (19.6)	4.66 (3.31-6.57)	5.30*(3.72-7.54)
Forceps-episiotomy	141/1145 (12.3)	2.69 (2.17-3.34)	2.49*(2.00-3.11)
Vacuum-no episiotomy	71/907 (7.8)	1.63 (1.24-2.14)	1.79*(1.35-2.36)
Vacuum-episiotomy	79/1172 (6.7)	1.38 (1.07-1.80)	1.42*(1.09-1.86)
Multiparous			
Spontaneous vaginal birth-no episiotomy	143/12192 (1.2)	Reference	Reference
Spontaneous vaginal birth-episiotomy	22/871 (2.5)	2.18 (1.39-3.44)	2.47*(1.55-3.93)
Forceps-no episiotomy	5/87 (5.7)	5.14 (2.05-12.86)	5.65*(2.21-14.43)
Forceps-episiotomy	14/193 (7.3)	6.59 (3.73-11.63)	5.23*(2.85-9.60)
Vacuum-no episiotomy	7/416 (1.7)	1.44 (0.67-3.10)	1.56 (0.72-3.38)
Vacuum-episiotomy	10/209 (4.8)	4.23 (2.20-8.16)	3.85*(1.94-7.64)
	Without GDM		
Primiparous			
Spontaneous vaginal birth-no episiotomy	3822/107332 (3.6)	Reference	Reference
Spontaneous vaginal birth-episiotomy	827/21234 (3.9)	1.09 (1.01-1.18)	1.10*(1.02-1.19)
Forceps-no episiotomy	612/3664 (16.7)	5.44 (4.96-5.97)	5.95*(5.41-6.55)
Forceps-episiotomy	1620/16972 (9.5)	2.87 (2.70-3.04)	2.71*(2.55-2.89)
Vacuum-no episiotomy	968/15823 (6.1)	1.77 (1.64-1.90)	1.99*(1.85-2.14)
Vacuum-episiotomy	932/18648 (5.0)	1.42 (1.32-1.53)	1.44*(1.33-1.55)
Multiparous			
Spontaneous vaginal birth-no episiotomy	1966/224097 (0.9)	Reference	Reference
Spontaneous vaginal birth-episiotomy	237/13142 (1.8)	2.07 (1.81-2.38)	2.06*(1.79-2.36)
Forceps-no episiotomy	97/1472 (6.6)	7.91 (6.40-9.76)	6.20*(4.96-7.74)
Forceps-episiotomy	147/2511 (5.9)	7.03 (5.93-8.35)	3.75*(3.12-4.50)
Vacuum-no episiotomy	226/7644 (3.0)	3.45 (3.00-3.96)	3.11*(2.69-3.59)
Vacuum-episiotomy	100/3302 (3.0)	3.61 (2.95-4.41)	2.34*(1.89-2.89)

a) AOR, odd ratios were adjusted for maternal age, maternal country of birth, plurality, hospital sector, last birth by caesarean section, the onset of labour, baby sex and birthweight.
*p<0.05.

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6.6 Discussion

Our study results show that women with GDM who gave birth to macrosomic baies and had an instrumental vaginal birth , had an increase in the odds of OASIs compared to women without GDM. However, this association was not significant among women who gave birth to macrosomic babies. This study confirms that among primiparous with GDM and all women without GDM, that when a forceps birth is indicated performing an episiotomy is protective against OASIs.

Gestational diabetes is associated with an increase in birthweight (HAPO Study Cooperative Research Group 2008) and the risk of shoulder dystocia when compared with women without GDM giving birth to babies within the same birthweight group (Christoffersson & Rydhstroem 2002; Esakoff et al. 2009). In addition, among women with GDM, instrumental vaginal birth is associated with increased risk of shoulder dystocia compared to spontaneous vaginal birth (Athukorala et al. 2007). The combination of these risk factors may explain why women with GDM who gave birth to macrosomic babies by instrumental vaginal birth had significantly higher odds of having OASIs compared to women without GDM. This interaction could be supported by our findings that there was no significant increase in odds of OASIs in GDM women who gave birth to macrosomic babies spontaneously or, in women without GDM with instrumental birth to babies less that 4000g. However, these non-significant results may be due to the small numbers in these subgroups.

Previously published studies show that an episiotomy with an instrumental vaginal birth is associated with reducing the risk of OASIs (Ampt et al. 2013; de Vogel et al. 2012;

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Gurol-Urganci et al. 2013). Guidelines published by both the Royal College of Obstetricians and Gynaecologists (RCOG) in 2011(RCOG 2011a) and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) in 2016 (RANZCOG 2016) state that in the absence of robust evidence, routine episiotomy with instrumental delivery cannot be recommended and that the use of an episiotomy should be at the decision of the operator. In contrast, the 2015 RCOG practice guideline (The Management of Third- and Fourth-Degree Perineal Tears) recommends performing an episiotomy with instrumental births (RCOG 2015). Our results among primiparous women with GDM and all women without GDM, confirm the results published by Ampt et al. (2013) and Gurol-Urganci et al. (2013) that, an episiotomy with forceps birth reduces the odds of OASIs compared to forceps alone(Ampt et al. 2013; Gurol-Urganci et al. 2013). However, we found that episiotomy at the time of spontaneous vaginal birth increased the odds of OASIs among multiparous women with and without GDM. In contrast, amongst primiparous women with GDM having a spontaneous vaginal birth there was no difference with episiotomy. Even though, episiotomy with spontaneous vaginal birth was associated with statistically significant increase in the odds of OASIs among primiparous women without GDM. This increase may not be clinically significant as the difference in the percentage of OASIs was only 0.3% between spontaneous vaginal birth with and without episiotomy.

Strengths and limitations

A strength of this study is the use of the PDC, a statewide epidemiological collection of all births in NSW. We provide population-based evidence of an association between

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episiotomy and a reduction of OASIs among women with GDM. However, a validation study of the GDM detection in PDC shows a sensitivity of 63.3%, (95% CI 49.4-75.7) (Bell et al. 2008). This sensitivity suggests information bias as it reflects the period before the 2013 ADIPS guideline stating all women should have universal screening for GDM (Nankervis et al. 2013). Therefore, our findings should be interpreted with this caveat.

A limitation of this study is that information on shoulder dystocia is not collected or available from the PDC, therefore we were unable to adjust for this condition in the analysis. Country of birth was used as a proxy for the OASIs and GDM risk factor (Gurol-Urganci et al. 2013; RCOG 2011b) ethnicity, which was not available in the PDC. There was no information available on the compliance of antenatal care providers to the ADIPS GDM screening and diagnosis guidelines.

Conclusion

There was a higher rate of OASIs among women with GDM. The risk of OASIs associated with instrumental births and birthweight ≥ 4000g should be discussed with women with GDM. Our results among primiparous women with GDM and all women without GDM who have forceps birth provide evidence to support the RCOG's general recommendation to perform mediolateral episiotomy with instrumental vaginal birth.

6.7 Chapter summary

This chapter investigated the association between GDM and the risk of OASIs stratified by method of birth and birthweight. It also investigated the association between

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performing an episiotomy with a specific method of birth and the risk of OASIs for these women compared to women without diabetes. The key points of this chapter are:

- The proportion of OASIs among women with GDM was 3.6% compared to 2.6% among women without GDM.
- Women with GDM who had an instrumental vaginal birth (forceps or vacuum) of a baby(s) with a birthweight ≥4000g had a significant increase in the odds of OASIs compared to women without GDM.
- Combined episiotomy with a forceps birth was associated with a significant decrease in the odds of OASIs among primiparous women with GDM and all women without GDM.

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Chapter 7: Study four: Birth intervention, maternal and neonatal outcomes for women with diabetes during pregnancy giving birth in public and private hospitals

7.1 About this chapter

As seen in Chapter 4, interventions among women with diabetes are higher than interventions among women without diabetes. This chapter will compare the perinatal outcomes for women giving birth with diabetes by public private hospital sector, and it is again presented in the form of a paper for publication. Specifically, the chapter will compare rates of adverse perinatal outcomes between women with diabetes during pregnancy who gave birth to term singleton babies in public hospitals and those who gave birth in private hospitals.

This study is the first population-based study in the literature to investigate the association between giving birth in public or private hospitals and perinatal outcomes for women with diabetes during pregnancy.

The rate of women with GDM included in this chapter is during the period between 2002 and 2012. For this reason, it is lower than the rate included in the literature review which is during the period after the publication of new ADIPS (Nankervis et al. 2013) Guideline that recommended a new diagnosis criteria for GDM. More women are likely to be diagnosed with GDM using the new diagnostic guidelines thus explaining the difference.

7.2 Abstract

Objectives: To examine the rate of obstetric interventions for women with diabetes during pregnancy and to investigate the association of hospital sector (public and private) and perinatal outcomes for women with diabetes during pregnancy and their babies.

Method: A population-based study of all women with diabetes during pregnancy (pre-existing and gestational diabetes (GDM)) who gave birth in New South Wales (NSW) Australia to term singleton babies between 1 January 2002 and 31 December 2012. Maternal characteristics and obstetric interventions were compared using Chi-square test. Adjusted odds ratios (AOR) and 95% confidence interval (CI) for perinatal outcomes were calculated by multivariable logistic regression. AOR and 95% CI for perinatal death were calculated using Poisson regression.

Results: One in five women (21.9%) with pre-existing diabetes and just over one in six (17.4%) women with GDM gave birth in private hospitals. The rate of spontaneous vaginal birth was higher in public hospitals than in private hospitals, for both women with pre-existing diabetes (public 42.6% vs private 38.7%) and women with GDM (public 56.8% vs private 40.4%). The rate of admission to NICU/SCN was higher among term singleton babies born to women with pre-existing diabetes in public hospitals than in private hospitals (AOR 2.44, 95% CI (2.08-2.87)). Term singleton babies born to women with GDM in public hospitals had poorer neonatal outcomes that those born in private hospitals, although the study was not able to control for all factors that could explain the differences.

Conclusion: Several socio-demographic factors are associated with poorer outcomes in public hospitals. Further research is needed to investigate the association of hospital sector and perinatal outcomes for women with diabetes during pregnancy.

7.3 Introduction

Diabetes during pregnancy includes both pre-existing diabetes (type 1 and 2) and gestational diabetes mellitus (GDM). In New South Wales (NSW), 0.9% of pregnant women are affected by pre-existing diabetes and 12.6% by GDM (Centre for Epidemiology and Evidence 2017). Diabetes during pregnancy is associated with an increase in obstetric interventions and adverse perinatal outcomes (Billionnet et al. 2017; Maso et al. 2014). Women with diabetes during pregnancy have a higher rate of caesarean section and instrumental vaginal birth (Billionnet et al. 2017; Farrar et al. 2016).

Maternity care in Australia has a two-tiered health care system: a publicly funded, hospital-based model; and a private consultant model. In NSW 76.9% of women gave birth under the hospital-based model, and the remaining 23.1% had private consultant care (Centre for Epidemiology and Evidence 2017). A small percentage (4.8%) of women with private care will give birth in a public hospital, either for medical reasons or the woman's preference (Robson, Laws & Sullivan 2009).

In NSW between 1998 and 2002, 16% of women with diabetes during pregnancy gave birth in private hospitals and 84% gave birth in public hospitals (Shand et al. 2008). It is unknown if the former had different rates of birth interventions and different perinatal outcomes from the latter.

Previous studies have investigated the difference in the rate of obstetric intervention between public and private hospitals among women in the general population in Australia (Dahlen et al. 2012; Dahlen et al. 2014; Einarsdóttir et al. 2013; Robson, Laws & Sullivan 2009; Shorten & Shorten 2002). Results from these studies show women who gave birth in private hospitals experienced more obstetric interventions than those giving birth in public hospitals; this includes higher rates of caesarean section, instrumental vaginal birth and episiotomy.

Results are inconsistent regarding adverse perinatal outcomes. Results from an Australian population-based study by Robson, Laws and Sullivan (2009) showed that singleton babies born to women who gave birth in public hospitals were at higher risk of adverse neonatal outcomes. Associated measurements included a five minutes Apgar score of less than seven; the requirement for higher levels of neonatal resuscitation; increased odds of admission to a neonatal intensive care unit (NICU) or special care nursery (SCN); and being at higher risk of perinatal death (Robson, Laws & Sullivan 2009). However, in another population-based study conducted in NSW, Dahlen et al. (2014) found that among low-risk women, birth in private hospital was associated with higher rates of neonatal morbidity, although there was no difference in perinatal mortality compared to birth in a public hospital (Dahlen et al. 2014). A population-based study in Western Australia (WA) showed that singleton babies born in private hospitals had a lower Apgar score of less than seven but a higher rate of admission to NICU than those born in public hospitals (Einarsdóttir et al. 2013). The differences in the findings of these studies can be due in part to different study populations and the variation in the policies that may have been used across the sectors.

Previously published population-based studies have examined the rate of inventions and perinatal outcomes in the general obstetric population and among low-risk women. As will be explained in the next section, this study aimed to use the NSW Perinatal Data Collection (PDC) to compare adverse perinatal outcomes between public and private hospitals for women with diabetes during pregnancy who gave birth to term singleton babies. To exclude complex pregnancies with diabetes during pregnancy only women with term singleton pregnancies were included in the study population.

7.4 Method

Study design

Population-based retrospective cohort study using NSW PDC.

Data source

The NSW PDC is a population-based surveillance system (CHeReL 2016b). It includes all births occurring in NSW public and private hospitals as well as home births. Women giving birth to live births and stillbirths of at least 20 weeks or at least 400g birthweight are included in the database. One third of the Australian population lives in NSW, and more than 95,000 women give birth in this state annually (Australian Bureau of Statistics 2016; Centre for Epidemiology and Evidence 2015).

The NSW PDC is based on electronic forms that are completed at birth by the attendants. Information on maternal demographics, maternal health, pregnancy, obstetric complications, labour and birth as well as perinatal outcomes are included in the completed form. The forms are submitted to NSW Ministry of Health where the information is validated and compiled into the state-wide PDC.

Study population

Of the 933,626 women who gave birth to term singleton babies in NSW from 1 January 2002 to 31 December 2012, the 51,185 (5.5%) women with diabetes during pregnancy were included in this study. To focus on a hospital births, babies born at home and those born before arrival at the hospital (n= 142, 0.3%) were excluded from the study population; therefore 51,043 women were included. Of these, 4,753 (9.3%) had pre-existing diabetes (type 1 and 2) and 46,290 (90.7%) had GDM. Only live-birth term singleton babies (n= 50,914) were included in the multivariate analysis of neonatal outcomes. Of these, 270 (0.5%) singleton babies admitted to NICU due to a diagnosis of one or more congenital anomalies were excluded from the analysis; therefore 50,644 were included.

Study factors and Outcomes

Pre-existing diabetes includes type 1 and type 2 diabetes. GDM is defined as glucose intolerance that is diagnosed for the first time during pregnancy; it may include hyperglycemia induced by pregnancy or previously undiagnosed existing abnormalities of glucose tolerance (Nankervis et al. 2013).

During the study period, the Australian Diabetes in Pregnancy Society (ADIPS) guideline (Hoffman et al. 1998), which recommends diagnosis of GDM using 75g 2-hours oral glucose tolerance test (OGTT) was used. GDM was diagnosed if fasting venous plasma glucose level was ≥ 5.5 mmol/L and/or if venous plasma glucose level was ≥ 8.0 mmol/L at 2-hours following 75g OGTT.

Maternal outcomes included third- and fourth-degree perineal tear and postpartum haemorrhage (PPH) requiring blood transfusion. The multivariate analysis for maternal outcomes included women who gave birth from 1 January 2007 to 31 December 2012 for two reasons: First, the data item perineal status was recorded as (Intact, 1st degree tear/graze, 2nd degree tear, 3rd degree tear, 4th degree tear, episiotomy, combined tear and episiotomy, other) prior to 2007. Therefore, it was not possible to identify the degree of perineal tear combined with episiotomy. From 2007, the perineal status was recoded as (Intact, 1st degree tear/graze, 2nd degree tear, 3rd degree tear, 4th degree tear, other). The second reason is that the recording of PPH in the PDC started in 2006; however, for 2006, 61% of the records were not stated.

Neonatal measures and outcomes included five minute Apgar score less than seven; neonate admission to NICU or SCN; high-level resuscitation that included intubation and intermittent positive pressure respiration, external cardiac massage and ventilation; and baby transfer to another hospital.

Statistical analysis

Woman's and baby's characteristics as well as birth intervention were compared between private and public hospitals of birth using a Chi-square test. Multivariate logistic regression was used to investigate the likelihood of perinatal outcomes, and Poisson regression was used to investigate the likelihood of stillbirth and perinatal death. AOR and 95% CI were produced. Variables associated with the outcomes in the univariate analysis ($p < 0.2$) and factors identified in the literature as potentially predictive were entered in the regression model. Odds ratios for maternal outcomes were adjusted for maternal age (groups), parity, smoking during pregnancy, method of birth, last birth by caesarean section, maternal country of birth, birthweight (groups), episiotomy, and maternal and pregnancy-associated hypertension. Odds ratios for neonatal outcomes and perinatal death were adjusted for method of birth, parity, maternal age (groups), maternal country of birth, smoking during pregnancy, birthweight (groups), and maternal and pregnancy-induced hypertension.

The analysis was performed using Statistical Package for Social Science software SPSS Version 24.0 (Armonk, NY: IBM Corporation). p value < 0.05 was considered statistically significant.

Ethics

Ethical approval was granted by University of Technology Sydney Human Research Ethics Committee (UTS HREC ETH16-0219). The use of the de-identified data was approved by Executive Director, Centre for Epidemiology and Evidence, NSW Ministry of Health.

7.5 Results

Characteristics and obstetric interventions of women with pre-existing diabetes and women with GDM who gave birth in private and public hospitals are presented in Tables 7.1 and 7.2. Of women with pre-existing diabetes 21.9% and 17.4% of women with GDM gave birth in private hospitals. The proportion of women aged less than 30 years was lower among women who gave birth in private hospitals than those gave birth in public hospitals (private 20.4% vs public 35.9%, $p < 0.001$) for women with pre-existing diabetes) (private 15.5% vs public 33.5%, $p < 0.001$ for women with GDM). The proportion of women who smoked was significantly lower among women who gave birth in private hospitals than those who gave birth in public hospitals (private 1.8% vs public 15.5%, $p < 0.001$ for women with pre-existing diabetes) (private 1.7% vs public 10.7%, $p < 0.001$ for women with GDM) (Tables 7.1 & 7.2).

Of women with pre-existing diabetes who gave birth in private hospitals, 11.0% had an instrumental vaginal birth compared to 7.7% of women who gave birth in public hospitals ($p < 0.001$). No labour caesarean sections were performed on 32.6% of women with pre-existing diabetes who gave birth in private hospitals and 30.7% of those who gave birth in public hospitals ($p < 0.001$). Labour caesarean sections were needed in 17.8% of women with pre-existing diabetes who gave birth in private hospitals and 19.0% of those who gave birth in public hospitals. The rate of episiotomy was also higher in private hospitals (13.4%) than in public hospitals (8.0%) (Table 7.1).

Among women with GDM, the proportion of induction of labour was similar among women who gave birth in private hospitals (41.2%) and women who gave birth in public hospitals (41.1%) (Table 7.2). Although, the rate of induction of labour was similar in public and private hospitals, gestational age at the time of induction of labour was different. Ninety-one percent of women with GDM who had induction of labour in private hospitals were induced between 38 to 40 weeks of gestation compared to 82.6% among women who were induced in public hospitals. Among women who had induction of labour in public hospitals, 10.1% had induction of labour after 40 weeks of gestation (41–43 weeks); this proportion was 3.9% among women who had induction of labour in private hospitals. The rate of no-labour caesarean section was significantly higher among women who gave birth in private hospitals than those who gave birth in public hospitals (private 29.9% vs public 18.4%, $p < 0.001$) (Table 7.2). Among women who gave birth in public hospitals, 44.7% of women with pre-existing diabetes and 40.9% of women with GDM gave birth in level 6 (tertiary) hospitals.

The rate of women who gave birth to live-born term singleton babies with birthweights of ≥4,000g were higher among women who gave birth in public hospitals (23.2% for women with pre-existing diabetes, 12.2% for women with GDM) than women who gave birth in private hospitals (17.4% for women with pre-existing diabetes, 9.7% for women with GDM).

Table 7.1: Characteristics and interventions for women with pre-existing diabetes 2002–2012

	Private (n=1,041)	Public (n=3,712)	p value
Maternal age (Years)			
Less than 20	1 (0.1)	65 (1.8)	
20-29	211 (20.3)	1,268 (34.2)	<0.001
30-39	743 (71.4)	2,092 (56.4)	
>= 40	86 (8.3)	287 (7.7)	
Born in Australia			
Yes	777 (74.6)	2,298 (61.9)	<0.001
No	258 (24.8)	1408 (37.9)	
Not stated	6 (0.6)	6 (0.2)	
Parity			
Primiparous	472 (45.3)	1,242 (33.5)	
Multiparous	566 (54.4)	2,465 (66.4)	<0.001
Not stated	3 (0.3)	5 (0.1)	
Smoking status			
Smoked	19 (1.8)	574 (15.5)	<0.001
Did not smoke	1022 (98.2)	3,126 (84.2)	
Not stated	0 (0.0)	12 (0.3)	
Type of labour			
Spontaneous	192 (18.4)	1,001 (27.0)	
Induction of labour	510 (49.0)	1,572 (42.3)	<0.001
No labour	339 (32.6)	1,139 (30.7)	
Method of birth			
Spontaneous vaginal[a]	403 (38.7)	1,580 (42.6)	
Instrumental vaginal	114 (11.0)	286 (7.7)	0.002
No labour CS	339 (32.6)	1,139 (30.7)	
Labour CS	185 (17.8)	707 (19.0)	
Episiotomy			
Yes	139 (13.4)	296 (8.0)	<0.001
No	901 (86.6)	3,416 (92.0)	
Not stated	1 (0.1)	0 (0.0)	
Gestational age			
37	149 (14.3)	673 (18.1)	
38	403 (38.7)	1,403 (37.8)	
39	321 (30.8)	973 (26.2)	<0.001
40	145 (13.9)	467 (12.6)	
41 or more	23 (2.2)	196 (5.3)	

a includes vaginal breech birth

Table 7.2: Characteristics and interventions for women with GDM 2002–2012

	Private (n=8034)	Public (n=38256)	p value
Maternal age (Years)			
Less than 20	8 (0.1)	455 (1.2)	
20-29	1,241 (15.4)	12,345 (32.3)	<0.001
30-39	6,001 (74.7)	22,521 (58.9)	
>= 40	781 (9.7)	2,933 (7.7)	
Not stated	3 (0)	2 (0)	
Born in Australia			
Yes	4,840 (60.2)	18,087 (47.3)	<0.001
No	3,138 (39.1)	20,077 (52.5)	
Not stated	56 (0.7)	92 (0.2)	
Parity			
Primiparous	3,699 (46)	14,780 (38.6)	<0.001
Multiparous	4,327 (53.9)	23,461 (61.3)	
Not stated	8 (0.1)	15 (0)	
Smoking status			
Smoked	136 (1.7)	4,081 (10.7)	<0.001
Did not smoke	7,896 (98.3)	34,000 (88.9)	
Not stated	2 (0.0)	175 (0.5)	
Type of labour			
Spontaneous	2,308 (28.7)	15,508 (40.5)	
Induction of labour	3,314 (41.2)	15,722 (41.1)	<0.001
No labour	2,404 (29.9)	7,025 (18.4)	
Not stated	8 (0.1)	1 (0)	
Method of birth			
Spontaneous vaginal[a]	3,256 (40.5)	21,727 (56.8)	
Instrumental vaginal	1,167 (14.5)	3,860 (10.1)	<0.001
No labour CS	2,404 (29.9)	7,025 (18.4)	
Labour CS	1,198 (14.9)	5,639 (14.7)	
Not stated	9 (0.1)	5 (0)	
Episiotomy			
Yes	1,428 (17.8)	4,182 (10.9)	<0.001
No	6,605 (82.2)	34,074 (89.1)	
Not stated	1 (0.0)	0 (0.0)	
Gestational age (weeks)			
37	752 (9.4)	3,498 (9.1)	
38	2,757 (34.3)	10,364 (27.1)	
39	2,772 (34.5)	13,193 (34.5)	<0.001
40	1,544 (19.2)	8,292 (21.7)	
41 or more	209 (2.6)	2,909 (7.6)	

a includes vaginal breech birth

Table 7.3 presents a multivariate analysis of maternal outcomes by hospital sector for both women with pre-existing diabetes and women with GDM. Among women with GDM, there was a significant increase in the odds of third- and fourth-degree perineal tear among women who gave birth in public hospitals compared with women who gave birth in private hospitals (AOR 3.58, 95% CI (2.55-5.01)). There was no significant difference in the odds of postpartum haemorrhage between women who gave birth in public hospitals and those who gave birth in private hospitals.

Table 7.3: Maternal outcomes in private and public hospitals, women with pre-existing diabetes and women with GDM 2007–2012

	Private[a] n (%)	Public n (%)	OR (95% CI)	AOR (95% CI)
			Pre-existing diabetes	
Third- and fourth-degree perineal tear[bc]	**Total = 326**	**Total =1,030**		
	4 (1.2)	22 (2.1)	1.76 (0.60-5.14)	1.74 (0.51-5.88)
Postpartum haemorrhage[d]	**Total = 643**	**Total =2,116**		
	2 (0.3)	23 (1.1)	3.51 (0.83-14.94)	3.6 (0.76-16.96)
			GDM	
Third- and fourth-degree perineal tear[bc]	**Total = 2,708**	**Total =15,831**		
	38 (1.4)	648 (4.1)	3 (2.16-4.17)	3.58* (2.55-5.01)
Postpartum haemorrhage[d]	**Total = 5,059**	**Total =23,935**		
	57 (1.1)	273 (1.1)	1.01 (0.76-1.35)	1.05 (0.78-1.41)

a Reference group
b Odds ratios for third and fourth degree perineal tear were adjusted for women age groups, parity, smoking during pregnancy, method of birth, last birth by caesarean section, maternal country of birth, birthweight groups, episiotomy, maternal- and pregnancy-associated hypertension.
c Vaginal birth only
d Odds ratios for postpartum haemorrhage were adjusted for women age groups, parity, smoking during pregnancy, method of birth, last birth by caesarean section, maternal country of birth, birthweight groups, maternal- and pregnancy-associated hypertension.
* Significant

There were three (0.8/1000) neonatal deaths among term singleton babies born to women with pre-existing diabetes in public hospitals. There were no neonatal deaths among those born in private hospitals.

Neonatal outcomes for live-born term singleton babies by hospital sector are shown in Table 7.4. For live-born term singleton babies born to women with pre-existing diabetes, there was a significant increase in the odds of admission to NICU/SCN among live-born term singleton babies born in public hospital compared with those born in private hospitals (AOR 2.44, 95% CI (2.08-2.87)). There was a 77% increase in the likelihood for transfer to another hospital among those born in public hospitals compared to those born in private hospitals (AOR 1.77, 95% CI (1.11-2.84)) (Table 7.4). There was no significant increase in the odds of the needs for high-level neonatal resuscitation or Apgar score less than seven. However, there was a significant decrease in the odds of the need for any neonatal resuscitation among live-born term singleton babies born in public hospitals compared to those born in private hospitals (AOR 0.58, 95% CI (0.5-0.69)). This decrease is due to the lower rate of suction and oxygen therapy.

Live-born term singleton babies born to women with GDM in public hospitals had two-and-a-half times the increase in the likelihood of a five minute Apgar score less than seven compared to those born in private hospitals (AOR 2.49, 95% CI (1.84-3.38)). The odds of both the need for high-level neonatal resuscitation and the admission to NICU/SCN were higher among live-born term singleton babies born to women with GDM in public hospitals than those born in private hospitals (AOR 1.45, 95% CI (1.30-1.63), and AOR 1.35, 95% CI (1.27-1.43), respectively). However, there was a 50% decrease in the odds of the need for any resuscitation among live-born term singleton babies born in public hospitals compared to those born in private hospitals (AOR 0.50, 95% CI (0.47-0.53)). This decrease is due to the lower rate of suction and oxygen therapy.

Live-born term singleton babies born in public hospitals were four times more likely to transfer to another hospital than those born in private hospitals (AOR 4.44, 95% CI (3.40-5.79)) (Table 7.4). The total perinatal death rate was 5.5/1000 among women with pre-existing diabetes and 2.2/1,000 among women with GDM. There was statistically significant increase in the odds of perinatal death among live-born term singleton babies born to women with GDM in public hospitals compared to those born in the private hospitals (AOR 2.16, 95% CI (1.03-4.54)).

Table 7.4: **Neonatal outcomes of term singletons born to women with diabetes by hospital sector[a] 2002–2012**

	Private[b] n (%)	Public n (%)	OR (95% CI)	AOR[c] (95% CI)
			Pre-existing diabetes	
	1038	**3672**		
5 min Apgar score <7[d]	10 (1.0)	59 (1.6)	1.69 (0.86-3.31)	1.81 (0.88-3.72)
High-level resuscitation[d]	4 (0.4)	24 (0.7)	1.71 (0.59-4.93)	2.08 (0.57-7.61)
Admission to NICU/SCN	391 (37.7)	2040 (55.9)	2.10 (1.82-2.42)	2.44* (2.08-2.87)
Transferred to a higher level facility[d]	24 (2.3)	145 (4)	1.75 (1.13-2.71)	1.77* (1.11-2.84)
Perinatal death	1 (1.0)[e]	25 (6.8)[e]	7.07[f] (0.96-52.18)	5.07[f] (0.63-41.06)
Stillbirth	*1 (1.0)[e]*	*22 (6.0)[e]*	1.01[f] (0.94-1.08)	1.00[f] (0.93-1.08)
Neonatal deaths[d]	*0 (0.0)*	*3 (0.8)[e]*	-	-
			GDM	
	8009	**38053**		
5 min Apgar score <7[d]	48 (0.6)	512 (1.3)	2.27 (1.68-3.05)	2.49* (1.84-3.38)
High-level resuscitation[d]	15 (0.2)	228 (0.6)	3.20 (1.90-5.40)	3.19* (1.87-5.43)
Admission to NICU/SCd	2003 (25)	11238 (29.6)	1.26 (1.19-1.33)	1.35* (1.27-1.43)
Transferred to a higher level facility[d]	60 (0.8)	1016 (2.7)	3.64 (2.8-4.73)	4.44* (3.40-5.79)
Perinatal death	8 (1.0)[e]	95 (2.5)[e]	2.50[f] (1.21-5.14)	2.16[f]*(1.03-4.54)
Stillbirth	*8 (1.0)[e]*	*80 (2.1)[e]*	1.00[f] (0.98-1.03)	1.00[f] (0.98-1.03)
Neonatal deaths [d]	*0 (0.0)[e]*	*15 (0.4)[e]*	-	-

a Excludes babies who admitted to NICU due to one or more congenital anomalies.
b Reference group.
c Odd ratios adjusted for method of birth, parity, maternal age group, maternal country of birth, smoking during pregnancy, birthweight groups, maternal- and pregnancy-induced hypertension.
d live-birth only
e Per 1000
f Poisson regression
* Significant

7.6 Discussion

This study is the first population-based study in the literature to compare adverse perinatal outcomes between public and private hospitals for women with diabetes during pregnancy and their babies. The results show that among women with GDM the rate of no-labour caesarean section was significantly higher among women who gave birth in private hospitals than those who gave birth in public hospitals, while this rate was comparable among women with pre-existing diabetes. The rate of induction of labour was similar among women with GDM who gave birth in private hospitals and those who gave birth in public hospitals. Women with GDM who gave birth in public hospitals had higher odds of third- and four-degree perineal tear. The odds of admission to NICU/SCN and transfer to a higher-level facility were higher in term singleton babies born to women with GDM in public hospitals than those born in private hospitals. Being born in a public hospital was associated with increased likelihood of adverse neonatal outcomes for term singleton babies born to women with GDM.

The study results confirm previously published results from population-based studies conducted using Australian National Perinatal Data Collection (Robson, Laws & Sullivan 2009) and population-based studies conducted in NSW (Dahlen et al. 2012; Dahlen et al. 2014) and WA (Einarsdóttir et al. 2013) that the rate of obstetric interventions is higher in private hospitals than in public hospitals. However, the study results show that among women with pre-existing diabetes, the rate of no-labour caesarean section in private hospitals was marginally higher than in public hospitals (private 32.6% vs public 30.7%). Although this increase was statistically significant, it may not be clinically significant. The similar rate of no-labour caesarean section among women with pre-existing diabetes in both public and private hospitals may reflect the level of obstetric complications among women with pre-existing diabetes.

The odds of third- and fourth-degree perineal tear were three times higher among women with GDM who gave birth in public hospitals compared to those who gave birth in private hospitals. This association remained significant after adjusting for episiotomy, birthweight and other potential confounders. Similar results were published by Robson et al. (2009) (Robson, Laws & Sullivan 2009). In a previously published study on the NSW general population, Dahlen et al. (2014) found that the rate of third- and fourth-degree perineal tear was 5.4% among primiparous women who gave birth in public hospitals compared to 4.7% among those who gave birth in private hospitals. However, the rate of third- and fourth-degree perineal tear was similar among multiparous women who gave birth in public and private hospitals (0.9%) (Dahlen et al. 2014).

Consistent with previously published studies on NSW (Dahlen et al. 2014), WA (Einarsdóttir et al. 2013) and the Australian general populations (Robson, Laws & Sullivan 2009), this study found that live-born term singleton babies born to women with GDM in public hospitals had an increase in the likelihood of five minute Apgar score less than seven.

As for term singleton babies in the Australian general population (Robson, Laws & Sullivan 2009), the likelihood of the need for high-level neonatal resuscitation was higher among term singleton babies born to women with GDM in the public hospitals compared to those born in private hospitals. This study's analysis investigating 'any neonatal resuscitation' found that being born in public hospitals was associated with about a 50% decrease in the odds of the need for any neonatal resuscitation. This result is similar to the findings published by Dahlen et al. (2014), who found a significant decrease of any type of neonatal resuscitation among term singleton babies born to low-risk women in NSW public hospitals compared to those born in private hospitals. For example, there was twice the rate of routine suctioning among babies born in private hospitals compared to those who born in public hospitals (Dahlen et al. 2014). Among this study's population, the increase in any type of neonatal resuscitation was due to a higher rate of suction and oxygen therapy in private hospitals compared to public hospitals. Among low-risk women, (Einarsdóttir et al. 2013) found that there was no significant difference in the rate of the need for endotracheal intubation or external cardiac massage between babies born in private hospitals and those who born in public hospitals in WA (Einarsdóttir et al. 2013).

For both live-born term singleton babies born to women with pre-existing diabetes and those who born to women with GDM, the odds of admission to NICU/SCN was higher among live-born term singleton babies born in public hospitals than those born in private hospitals. Although this study's result is similar to the findings published by Robson et al. (2009) (Robson, Laws & Sullivan 2009), it is inconsistent with those of Einarsdóttir et al. (2013) (Einarsdóttir et al. 2013) who found a significant reduction in admission to SCN among term singleton babies born in public hospitals. Similarly, the study results are inconsistent with those of Dahlen et al. (2014) (Dahlen et al. 2014) who did find a significant difference in the odds of admission to NICU/SCN between singletons born to-risk women in public and private hospitals. These differences can be explained by the differences in population and in policies adopted across the sector institutions. Babies born to women with diabetes during pregnancy are routinely admitted to NICU due to asymptomatic hypoglycaemia and other conditions (NICE 2015). The total perinatal death rate among term singleton babies born to women with GDM was similar to the Australian national rate of perinatal death among term babies to the period from 2006 to 2012, which ranged from 1.8/1,000 in 2012 (Hilder L et al. 2014) to 2.2/1,000 in 2009 (Li et al. 2011). In contrast, the total perinatal death rate among term singleton babies born to women with pre-existing (5.5/1000) diabetes was significantly higher when compared to the national Australian rate for term babies.

By using Perinatal Data Collection, a population-based validated dataset of NSW births (Roberts et al. 2009), this study provides high-level population evidence on the association of birth hospital sector (public, private) and perinatal outcomes for women with diabetes during pregnancy and their babies. The use of large population data allows for the adjustment of important factors such as birthweight, episiotomy, parity, maternal and obstetric hypertension, and other socio-demographic factors.

The study has some limitations. Adjustment for obesity or shoulder dystocia was not done due to the unavailability of data in the NSW PDC. To reduce the effect of not being able to investigate obesity and shoulder dystocia the analysis adjusted for birthweight groups. As well, no adjustment was possible for other maternal socio-demographic factors such as Indigenous status, remoteness and socio-economic status due to the lack of extraction of this information. This may affect the analysis as hospitalisation in public hospitals is higher in remote and very remote areas than in major cities and with higher lower socio-economic groups than with higher socio-economic groups; his contrasts with the private hospitals profile, where hospitalisation is higher in major cities than in remote and very remote areas and higher among areas classified as having the highest socio-economic status (AIHW 2017b). Another limitation is the lack of NSW PDC data about the reasons for admission to NICU. Information on patient's insurance status is not available in NSW PDC, but this would have affected the analysis minimally because in Australia only 4.8% of privately insured women give birth in public hospitals and 1.1% uninsured women gave birth in private hospitals (Robson, Laws & Sullivan 2009). This study's database does not include information on management and treatment of diabetes during pregnancy, and therefore did not allow the determination of the severity of the diabetes and whether it was well controlled or not during pregnancy; this too may affect the results of the study.

Conclusion

Although some obstetric interventions are higher in private hospitals than in public hospitals, for women with diabetes during pregnancy who gave birth in private hospital their babies have lower adverse maternal and neonatal outcomes than those in public hospitals. However, there are a number of factors that cannot be accounted for in this analysis. Further research is needed to investigate the reason behind this decrease in adverse outcomes in private hospitals.

7.7 Chapter summary

This chapter examined interventions for women with diabetes during pregnancy in public and private hospitals. It also compared the rates of adverse perinatal outcomes between women with diabetes during pregnancy who gave birth in public and those who gave birth in private hospitals. The key points of this chapter are:

- Spontaneous vaginal births were higher among women with diabetes (pre-existing and GDM) who gave birth in public hospitals than those who gave birth in private hospitals.
- No-labour caesarean sections were slightly higher among women with pre-existing diabetes in private hospitals than those who gave birth in public hospitals.
- Rates of induction of labour were similar among women with GDM who gave birth in public hospitals and those who gave birth in private hospitals.
- Term singleton babies born to women with pre-existing diabetes in public hospitals had a significant increase in the odds of admission to NICU/SCN and therefore were more likely to be transferred to a higher-level facility.
- Term singleton babies born to women with GDM in public hospitals had a statistically significant increase in the odds of an Apgar score less than seven, were more likely to need high-level resuscitation, and more likely to be admitted to NICU/SCN and to be transferred to a higher-level facility.

Chapter 8: Discussion, recommendation and conclusion

8.1 About this chapter

This thesis analysed the NSW PDC to explore the research questions outlined in each of Chapters 4 to 7. This chapter builds upon the discussion of the major findings of these four chapters and concludes with recommendations for future research.

8.2 Why conduct this research

Diabetes in pregnancy is an increasing public health problem world-wide and in Australia. There is a limited information in the literature on the association on method of birth and perinatal outcomes of women with diabetes during pregnancy and their babies. Since 2010, there have been published population-based studies that investigate the association of method of birth with perinatal outcome for women with diabetes during pregnancy, three of these studies emerged from this thesis and the fourth is the study by Stuart, Matthiesen & Källén (2011). This thesis aimed to investigate the association between method of birth and perinatal outcomes for women with diabetes during pregnancy and their babies. This includes (1) identifying the main contributing factor for caesarean section, (2) investigating the neonatal outcomes by method of birth, (3) investigating the rate OASIs among women with and without GDM investigating the association of episiotomy with method of birth and its association with OASI, and lastly (4) compares the perinatal outcomes by public private and hospital sector.

This thesis includes four population-based studies that have significantly added to the literature to address the gap in information on method of birth among women with diabetes during pregnancy.

8.3 Main findings of this research

The results of this thesis highlights that the main contributing factor for caesarean section among women with and without diabetes was a previous caesarean section. Instrumental vaginal birth and labour caesarean sections were associated with adverse neonatal outcomes such as the need for resuscitation for babies born to women with diabetes during pregnancy. For women with GDM who gave birth to macrosomic babies, instrumental vaginal birth was associated with a significant increase in the odds of OASIs when indicated episiotomy is protective against OASIs among primiparous women with GDM and all women without GDM. Giving birth in private hospitals was associated with higher rates of obstetric interventions than giving birth in public hospitals. The rate of OASIs was higher among women gave birth in public hospitals than in private hospitals. Babies born in public hospitals were less likely to need neonatal resuscitation than those born in private hospitals.

8.4 Implication of this thesis on the practice

Little information is available in the public domain in NSW regarding the method of birth for women with diabetes during pregnancy and the associated perinatal outcomes. Findings from this thesis can be used to provide information for women with diabetes during pregnancy thus informing the choice of method of birth. they can be used to develop educational pamphlets and web materials to help women in the decision-making process regarding mode of birth. In addition to benefiting women with diabetes during pregnancy, results from this thesis can inform maternity clinicians, policy makers and the government regarding the method of birth for women with diabetes during pregnancy.

8.5 Main results and discussion based on each four results chapters

Study one: Caesarean section and diabetes during pregnancy: An NSW population study using the Robson classification

In study one the Robson Classification for caesarean section was used to examine the rate of caesarean section among women with diabetes during pregnancy and to determine the main contributor to the caesarean section rate among women with diabetes and women without diabetes who gave birth in NSW between 2002 and 2012. The study also compared the rate of caesarean section among women with diabetes and women without diabetes during pregnancy. This study created baseline information for monitoring and benchmarking caesarean sections among women with diabetes during pregnancy. This is the first population-based study in the literature that applied the Robson classification to women with diabetes during pregnancy.

The study found that applying the Robson classification for caesarean section to women with diabetes during pregnancy shows that nulliparous women with diabetes are most likely to give birth by caesarean section following induction of labour or prior to labour. This group (Robson group 2) represents more than 20% of women with diabetes. In contrast, nulliparous women without diabetes are more likely (23.3%) to give birth after a spontaneous onset of labour.

Study one results reflect recent Australian maternity care practice among women with diabetes and confirms what is known from the Australian and international literature that women with diabetes have a higher rate of birth interventions than women without diabetes (Farrar et al. 2016; Shand et al. 2008).

Caesarean sections among women with diabetes in Robson group 2a (nulliparous women who had induction of labour) represented 14.5% and 17.1% of the total caesarean sections among women with pre-existing diabetes and women with GDM respectively. Caesraean sections among nulliparous women with diabetes who had spontaneous onset of labour (Robson group 1) represented only 2.7% of the total caesarean sections among women with pre-existing diabetes and 6.1% of the total caesarean sections among women with GDM. To date, there is no clear evidence that induction of labour is actually associated with an increase in the risk of caesarean section. The recently published Cochrane systematic review (Biesty et al. 2018) showed that there was no difference in the rate of caesarean section among women with GDM who had an induction of labour at 38^{+0} or 39^{+0} weeks' gestation compared to those who had expectant management. Similarly, several observational studies did not find a significant increase in the risk of caesarean section after induction of labour for women with diabetes during pregnancy (Alberico et al. 2010; Levy et al. 2002; Melamed et al. 2016; Sutton et al. 2014). Study one results also showed that nulliparous women with pre-existing diabetes who had induction of labour (Robson group 2a) had double the odds of having a caesarean section compared to women without diabetes in the same group. Although this increase was statistically significant among women with GDM compared to women without diabetes, the proportion of caesarean sections among women with GDM in group 2a was only marginally higher than that among women without diabetes (34.7% vs 31.7%).

Irrespective of having a diagnosis of diabetes during pregnancy, a history of a previous caesarean section is the main contributor to the caesarean section rates. More than a third of the total caesarean sections among women with diabetes and among women without diabetes were among multiparous women with a history of caesarean section

(Robson group 5). The main indication for caesarean section among this group of women was elective repeat caesarean section. The high rate of repeat caesarean section indicates that preventive strategies for primary caesarean section could significantly contribute to the reduction of the total number of caesarean sections among women with diabetes during pregnancy.

Study one provides an overall picture of caesarean sections among women with diabetes during pregnancy and demonstrates the utility and value of routinely auditing caesarean section using the Robson classification to monitor practice.

Study two: Neonatal outcomes of live-born term singletons in vertex presentation born to mothers with diabetes during pregnancy by mode of birth: A New South Wales population-based retrospective cohort study.

Study two provides population evidence of the association between method of birth and poorer neonatal outcomes for babies born to women with diabetes during pregnancy compared with women with normal glucose tolerance. This study investigated the neonatal outcomes of live-born term singleton babies with a vertex presentation born to women with diabetes during pregnancy. Three neonatal outcomes were used as a proxy for neonatal morbidity: five minutes Apgar score of less than seven; admission to NICU/SCN; and the need for neonatal resuscitation.

Macrosomia is an important factor that influences birth management and is an important risk factor affecting neonatal outcomes (ACOG 2016). For this reason, the analyses in study two were done separately for macrosomic and non-macrosomic babies. This study showed that spontaneous vaginal birth was associated with a reduction in the risk of adverse neonatal outcomes for babies born to women with diabetes compared to other methods of birth. This study also showed that 38.3% of women with pre-existing diabetes and 31.5% of women with GDM who laboured gave birth by instrumental vaginal birth or caesarean section. The highest rates of caesarean section (37.3%) and instrumental vaginal birth (10.6%) were for the 378 women with pre-existing diabetes who gave birth to macrosomic babies after induction of labour. Of the 200 women who gave birth to macrosomic babies after spontaneous onset of labour, 73 (36.5%) women gave birth by labour caesarean section. In contrast, the group with the highest proportion of spontaneous vaginal births (74.2%) were women with GDM who gave birth to non-macrosomic babies after spontaneous onset of labour.

Study two results showed that babies born after instrumental vaginal birth or labour caesarean section had a significant increase in the odds of poorer neonatal outcomes, including admission to NICU/SCN and the need for neonatal resuscitation. This increase in the poorer neonatal outcomes after instrumental birth and labour caesarean section could be due to two additional factors: (1) instrumental vaginal birth and labour caesarean section are indicated when fetal compromise is suspected or in the case of prolonged second stage of labour; and (2) instrumental vaginal birth and labour caesarean section (especially if performed in second the stage of labour) are per se associated with neonatal morbidity (RANZCOG 2016; RCOG 2011a).

There are several serious risks with instrumental vaginal birth, including an increased risk of shoulder dystocia and its complications, especially in women with macrosomic babies (Athukorala et al. 2007; Kolderup, Laros Jr & Musci 1997), facial nerve palsy, corneal abrasion, retinal haemorrhage (O'Mahony, Hofmeyr & Menon 2010), and skull fracture and/or intracranial haemorrhage (Towner et al. 1999).

Macrosomia is associated with an increased risk of unsuccessful instrumental vaginal birth, which may result in an increase in the incidence of in-labour caesarean section among women who gave birth to babies with birthweight ≥4000g (RANZCOG 2016). This is evident in the study two results among women with pre-existing diabetes who gave birth to macrosomic babies, with 36.5% of women who had a spontaneous onset of labour and 37.3% of those who had an induction of labour giving birth by labour caesarean section.

Study three: Obstetric anal sphincter injuries among women with gestational diabetes and women without gestational diabetes: A NSW population-based cohort study.

Following from the findings of study two that provided evidence of adverse neonatal outcomes, study three investigated serious maternal morbidity. Study three demonstrated the association between GDM and women experiencing obstetric anal sphincter injuries (OASIs) by method of birth and birthweight. It also examined whether the combination of an episiotomy with method of birth was associated with a reduction in the odds of OASIs. Instrumental vaginal birth and high birthweight have been reported to be risk factors for OASIs (Baghestan et al. 2010; Dahlen et al. 2007); consequently, the analysis for this study was stratified by method of birth and birthweight.

The association of instrumental vaginal birth and birthweight with the risk of OASIs was clearly shown in the results, with women with GDM who gave birth to macrosomic babies by instrumental vaginal birth having a significant increase in the odds of OASIs compared to women without GDM. This increase was evident in both forceps and vacuum extraction birth. In contrast, there was no significant increase in odds of OASIs among women who gave birth to macrosomic babies by spontaneous vaginal birth.

The second aim of this study was to investigate whether the combination of an episiotomy with a particular method of birth was associated with a reduction in the odds of OASIs. There is controversy in the literature and between guidelines regarding whether performing an episiotomy with instrumental vaginal birth is a protective factor for preventing OASIs. According to the guideline “The Management of Third- and Fourth-Degree Perineal Tears” published by the Royal College of Obstetricians and Gynaecologists (RCOG 2015) there is evidence that mediolateral episiotomy with instrumental vaginal birth has a protective effect on OASIs and performing an episiotomy with an instrumental vaginal birth is therefore recommended. However, the guideline “Instrumental Vaginal Birth” published by the Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG 2016) states that there is not enough evidence to support routine episiotomy with instrumental vaginal birth. Study three found that among primiparous women with GDM, the combination of episiotomy with a forceps birth was associated with lower odds of OASIs than forceps alone. However, there was no significant difference in the odds of OASIs between multiparous women with GDM who had an episiotomy combined with forceps and those who had an episiotomy alone.

For primiparous women without GDM, the combination of episiotomy with forceps was associated with lower odds of OASIs than forceps alone. In addition, among this group of women, the combination of episiotomy with a vacuum extraction was also associated with lower odds of OASIs than vacuum extraction alone. However, this reduction in the odds ratio was only from 1.99, 95% CI (1.85-2.14) to 1.44, 95% CI (1.33-1.55). Unlike multiparous women with GDM, those without GDM had lower odds of OASIs when episiotomy was combined with forceps than forceps alone.

The results of study three provide additional population evidence that episiotomy with a forceps birth is a protective factor on OASIs.

Study four: Birth interventions, maternal and neonatal outcomes for women with diabetes during pregnancy giving birth in public and private hospitals.

Study four compared the level of birth interventions and associated perinatal outcomes of women with diabetes during pregnancy who gave birth to term singleton babies in NSW public hospitals with those who gave birth in NSW private hospitals. This study is the first population-based study that has investigated birth interventions and perinatal outcomes for women with diabetes during pregnancy by hospital sector (public/private). The results show that the rates of spontaneous vaginal birth were higher in the public hospitals than in the private hospitals (public 42.6% vs private 38.7% for women with pre-existing diabetes, and public 56.8 vs private 40.5% for women with GDM). There were fewer birth interventions for women with diabetes during pregnancy in the public hospitals.

Interestingly, the proportion of no labour caesarean section was only marginally higher among women with pre-existing diabetes who gave birth in private hospitals than among those who gave birth in public hospitals (private 32.6 vs public 30.7%, p=0.002). Although the difference is statistically significant, it may not be clinically significant. The high proportion of no labour caesarean section in both public and private hospitals may reflect the increased incidence of obstetric complications affecting women with pre-existing diabetes. The proportion of induction of labour was similar among women who gave birth in public hospitals and those who gave birth in private hospitals. However, the gestational age at induction of labour differed. Ten per cent of women with GDM who had induction of labour in public hospitals were induced after 40 weeks gestation while only 3.9% of women with GDM who had induction of labour were induced after 40 weeks gestation in private hospitals. Although, this study examined births up to 2012 in NSW, reflecting maternity care prior to the publication of the 2015 National Institute for Health and Clinical Excellence (NICE) guidelines, the practice of induction of labour of women with GDM in private hospitals was in line with the recommendations of NICE guideline that recommended induction of labour or no-labour caesarean section for women with GDM no later 40^{+6} weeks of gestation (NICE 2015).

Study four showed that giving birth in NSW public hospitals was associated with increased odds of poorer perinatal outcomes. However, this can be partially explained by the socio-demographic differences of women who give birth in Australian public and private hospitals. The literature shows that women with diabetes during pregnancy are more likely to give birth in public hospitals than those in general population (Shand et al. 2008). This reflects the greater prevalence of diabetes, including both pre-existing and GDM among women residing in low-socioeconomic areas and among women born overseas (Abouzeid et al. 2015; AIHW, Thow & Waters 2005). Both groups of women are more likely to give birth in public hospitals (Dahlen et al. 2013). In the statistical analysis for study four, adjustment was made for some of these socio-demographic factors, including maternal age, maternal country of birth, and smoking during pregnancy. The results of this analysis showed that being born in public hospitals was associated with poorer neonatal outcomes as measured by five minute Apgar score less than seven, the need for a high level of neonatal resuscitation, admission to NICU and high rate of third- and fourth-degree perineal tear. These results should be interpreted with caution as the study was not able to adjust for obesity, Indigenous status, place of residence and potential disadvantage that could have contributed to differences shown in perinatal outcomes observed in public and private hospitals. Such data were not available in our research extract.

8.6 Strengths and limitations

This thesis included four population-based studies. These studies are the first population-based studies in Australia and the largest internationally, that investigated the association between method of birth and perinatal outcomes for women with diabetes during pregnancy. The use of population data provides high level of evidence that hospital-based research cannot achieve. NSW PDC is a large validated population data base with a high level of accuracy. As described in chapter three, NSW PDC has been validated by several studies. These studies found that NSW PDC reported perinatal outcomes including birth by caesarean section with high accuracy and high sensitivity (Ampt et al. 2013; Chen et al. 2010). A limitation of the study is that NSW PDC lacks some risk and outcome variables related to diabetes such as maternal BMI and shoulder dystocia which limited our ability to adjust for these variables. Another limitation is the under reporting of GDM in the PDC. A published validation study on NSW PDC found that compared to the APDC, the PDC reported diabetes with lower sensitivity and accuracy (Bell et al. 2008). Stregths and limitations of this study are presented in detail in Chapter three (Research methods).

8.7 Directions for future research:

In this thesis the Robson classification for caesarean section was used to benchmark caesarean section among women with diabetes during pregnancy. This provides useful information for reviewing maternity care and for the counselling of women with diabetes during pregnancy regarding method of birth. This auditing of method of birth for this high-risk group should be incorporated into routine maternity health information systems. Further research is also needed to use the Robson classification for monitoring perinatal outcomes for women with diabetes during pregnancy. The Robson classification can be used to routinely provide audited data for caesarean section across other chronic non-communicable disease in pregnancy such as hypertension, renal disease, and epilepsy.

This thesis analysed the NSW PDC to explore the research questions. However, there were limitations in the reported perinatal outcomes available in this PDC dataset. More research is needed using linked population health datasets to investigate the association of method of birth with other perinatal outcomes such as shoulder dystocia and other birth trauma, including brachial plexus injury and other perinatal outcomes that are recorded using ICD10-AM classification system in the NSW Admitted Patient Data Collection (APDC) (CHeReL 2018). Using the APDC can also provide information on congenital anomalies. Other data sources would be the Perinatal Death Review Database, which provides information on the obstetric cause of death; the Perinatal Society of Australia and New Zealand perinatal death classification; and the hospital where the death occurred (CHeReL 2018).

8.8 Concluding remarks:

The care of women whose pregnancies are complicated by diabetes is challenging and associated with high rates of birth interventions in both the public and private sectors. Birth interventions including induction of labour, caesarean section and instrumental birth are becoming increasingly prevalent in complicated pregnancies such those involving pre-existing diabetes and with suspected fetal macrosomia.

This research found the Robson classification for caesarean section to be a simple and clinically informative classification that can be used to examine and benchmark caesarean section for women with medically and obstetrically complicated pregnancies caused by diabetes during pregnancy. It can be potentially used to benchmark all methods of birth for women with complicated pregnancies.

This research found that giving birth by spontaneous vaginal birth is associated with lower odds of adverse perinatal outcomes for women with diabetes during pregnancy and their babies. On the other hand, birth interventions such as instrumental vaginal birth and labour caesarean section are associated with an increase in the odds of adverse perinatal outcomes.

As part of a comprehensive package of antenatal education, counselling should routinely be provided for women with diabetes during pregnancy to advise about the onset of labour and method of birth, and how these are associated with different risks and perinatal complications for the women and their babies. Importantly women should also be informed of interventions that can potentially reduce the risk of the adverse outcomes such as the protective effect of episiotomy with instrumental vaginal birth on OASIs.

Appendices

Appendix 1: Glossary

Apgar score[1]**:** A numerical scoring system routinely administered one and 5 minutes after birth to evaluate the condition of the baby. The score ranges from 0–10 (10 being perfect). It takes account of 5 physical signs, each of which is assigned a component score of 0, 1 or 2: heart rate, respiration, muscle tone, reflexes, and colour.

Birth weight1[1]**:** The newborn infant's first bare weight in grams. Low birth weight: birth weight less than 2,500 grams. Very low birth weight: birth weight less than 1,500 grams. Extremely low birth weight: birth weight less than 1,000 grams.

Caesarean section[1]**:** Birth of the fetus through an abdominal incision.

Cephalic presentation: Fetal head presentation in labour which includes vertex, face or brow presentation.

Episiotomy[1]**:** An incision of the perineum and vagina to enlarge the vulval orifice.

Gestational age[1]**:** The duration of pregnancy in completed weeks from the first day of the last normal menstrual period. Where accurate information on the date of the last menstrual period is not available, a clinical estimate of gestational age may be obtained from ultrasound during the first half of pregnancy or by examination of the newborn infant.

Induction of labour[1]**:** Oxytocics–prostaglandins: the initiation of labour by the use of oxytocic agents, prostaglandins, or their derivatives (oral, intravaginal or intravenous).

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[1]As defined by the Centre for Epidemiology and Evidence, Population and Public Health Division, NSW Ministry of Health
Source: Centre for Epidemiology and Evidence 2015, New South Wales Mothers and Babies 2013, NSW Ministry of Health, Sydney. http://www.health.nsw.gov.au/hsnsw/Publications/mothers-and-babies-2013.pdf

ARM only: the initiation of labour by artificial rupture of membranes. Oxytocics–prostaglandins and ARM: both medical and surgical induction as defined above (combined medical and surgical induction).

Instrumental vaginal birth: Assisted vaginal birth either by forceps or vacuum.

Labour caesarean section (intrapartum caesarean section): Caesarean section after onset of labour.

Live birth[1]**:** The complete expulsion or extraction from its mother of a baby who, after being born, breathes or shows any evidence of life such as a heartbeat.[2]

Macrosomia: Birthweight ≥ 4000g.

No labour caesarean section (pre-labour caesarean section): Caesarean section without labour.

Parity[1]**:** The total number of live births and stillbirths of the mother before the pregnancy or birth under consideration.

Perinatal death[1]**:** A stillbirth or neonatal death.

Perineal status[1]**:** *1st degree tear:* a perineal graze–laceration–tear involving: the fourchette, hymen, labia, skin, vagina, or vulva. *2nd degree tear:* a perineal laceration or tear involving the pelvic floor or perineal muscles or vaginal muscles. *3rd degree tear:* a perineal laceration–tear involving the anal sphincter or rectovaginal septum. *4th*

[1]As defined by the Centre for Epidemiology and Evidence, Population and Public Health Division, NSW Ministry of Health
Source: Centre for Epidemiology and Evidence 2015, New South Wales Mothers and Babies 2013, NSW Ministry of Health, Sydney. http://www.health.nsw.gov.au/hsnsw/Publications/mothers-and-babies-2013.pdf

degree tear: a third-degree perineal laceration or tear which also involves the anal mucosa or rectal mucosa.

Plurality[1]**:** The number of fetuses in utero at 20 weeks gestation that are subsequently born separately. On this basis pregnancy may be classified as single or multiple.

Primary caesarean section[1]**:** First caesarean section.

Spontaneous vaginal birth (non-instrumental vaginal birth): Unassisted vaginal birth.

Stillbirth[1]**:** The complete expulsion or extraction from its mother of a product of conception of at least 20 weeks gestation or 400 grams birth weight who did not, at any time after birth, breathe, or show any evidence of life such as a heartbeat.[3]

Vertex presentation: Crown presentation of the fetal head at labour.

[1]As defined by the Centre for Epidemiology and Evidence, Population and Public Health Division, NSW Ministry of Health
Source: Centre for Epidemiology and Evidence 2015, New South Wales Mothers and Babies 2013, NSW Ministry of Health, Sydney. http://www.health.nsw.gov.au/hsnsw/Publications/mothers-and-babies-2013.pdf

Appendix 2: Authors' contributions and signatures

Cesarean section and diabetes during pregnancy: An NSW population study using the Robson classification

Authors' contributions

Reem Zeki (First author): Contributed to the conception and design of the study, performed the data analysis, interpretation of the results, and drafting of the manuscript and revising it for critically important intellectual content, and final approval of the manuscript to be submitted for publication.

Jeremy J N Oats (Co-supervisor): Contributed to the conception and design of the study, interpretation of the results, revising the manuscript for critically important intellectual content, and approval of the manuscript to be submitted for publication.

Alex Y Wang (Co-supervisor): Contributed to the conception and design of the study, provided support for data analysis, interpretation of the results, revising the manuscript for critically important intellectual content, and approval of the manuscript to be submitted for publication.

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Caroline S E Homer (Co-supervisor): Provided interpretation of the results, revising the manuscript for critically important intellectual content, and approval of the manuscript to be submitted for publication.

Elizabeth A Sullivan (Principal supervisor): Contributed to the conception and design of the study, interpretation of the results, revising the manuscript for critically important intellectual content, and approval of the manuscript to be submitted for publication.

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Neonatal outcomes of live-born term singletons in vertex presentation born to mothers with diabetes during pregnancy by mode of birth: a New South Wales population-based retrospective cohort study

Authors' contributions

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Obstetric anal sphincter injuries among women with gestational diabetes and women without gestational diabetes: a NSW population-based cohort study.

Authors' contributions

Reem Zeki (First author): Contributed to the conception and design of the study, performed the data analysis, interpretation of the results, and drafting the manuscript and revising it for critically important intellectual content, and final approval of the manuscript to be submitted for publication.

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Appendix 3: Published articles

Zeki, R., Oats, J.J.N., Wang, A.Y., Li, Z., Homer, C.S.E. & Sullivan, E.A. 2018, 'Cesarean section and diabetes during pregnancy: An NSW population study using the Robson classification', *Journal of Obstetrics and Gynaecology Research*.

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Cesarean section and diabetes during pregnancy: An NSW population study using the Robson classification

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Abstract

Aim: The aim of this study was to identify the main contributors to cesarean section (CS) among women with and without diabetes during pregnancy using the Robson classification and to compare CS rates within Robson groups.

Methods: A population-based cohort study was conducted of all women who gave birth in New South Wales, Australia, between 2002 and 2012. Women with pregestational diabetes (types 1 and 2) and gestational diabetes mellitus (GDM) were grouped using the Robson classification. Adjusted odd ratios (AOR) and 95% confidence intervals (CI) were calculated using multivariable logistic regression.

Results: The total CS rate was 58.6% for women with pregestational diabetes, 36.8% for women with GDM and 28.5% for women without diabetes. Previous CS contributed the most to the total number of CS in all populations. For preterm birth, the contribution to the total was 20.5% for women with pregestational diabetes and 5.7% for women without diabetes. Compared to women without diabetes, for nulliparous with pregestational diabetes, the odds of CS was 1.4 (95% CI, 1.1–1.8) for spontaneous labor and 2.0 (95% CI, 1.7–2.3) for induction of labor.

Conclusion: A history of CS was the main contributor to the total CS. Reducing primary CS is the first step to lowering the high rate of CS among women with diabetes. Nulliparous women were more likely to have CS if they had pregestational diabetes. This increase was also evident in all multiparous women giving birth. The high rate of preterm births and CS reflects the clinical issues for women with diabetes during pregnancy.

Key words: cesarean section, gestational diabetes, pregnancy, pregnancy in diabetics, Robson classification.

Introduction

Diabetes during pregnancy is an increasing problem worldwide.[1] In Australia, 0.5% of women have pregestational diabetes (type 1 and type 2 diabetes), and up to 13.0% of women develop gestational diabetes mellitus (GDM).[2,3] Pregestational diabetes occurs before pregnancy and continues after pregnancy.[4] GDM is defined as pregnancy-induced hyperglycemia or glucose abnormality that existed previously but was undiagnosed prior to pregnancy.[5]

The rate of cesarean sections (CS) is positively associated with an increase in plasma glucose level during pregnancy.[6] The Hyperglycemia and Adverse Pregnancy Outcomes study showed an increase of 8–11% in the odds of CS, with one standard deviation increase in plasma glucose level.[6] The 2005–2007 Australian data show that 59.2% of women with

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pregestational diabetes and 40.1% of women with GDM gave birth by CS, compared with 30.0% for women without diabetes.[2]

In order to better understand current clinical practice around the method of birth for women with and without a diagnosis of diabetes during pregnancy, a clinically relevant classification system of CS is required. In 2015, the World Health Organization (WHO) recommended that the Robson classification be used as a global standard for evaluating, monitoring and comparing CS rates.[7] The Robson classification is 'mutually exclusive and totally inclusive' and is based on women's parity, plurality, presentation, gestational age, history of previous CS and onset of labor.[8] To date, three hospital-based studies have applied the Robson classification to women with diabetes during pregnancy.[9–11] However, there have not been any population-based studies applying the Robson classification to pregestational diabetes and GDM, despite suggestions by the classification users.[9,12]

Our study, using New South Wales (NSW) population data, had two aims. The first was to use the Robson classification to identify the main contributors to CS among women with pregestational diabetes, women with GDM and women without diabetes during pregnancy. The second part of the study aimed to compare CS rates between women with diabetes during pregnancy and those without within each Robson classification group.

Methods

Study design and outcome

A population-based retrospective cohort study was conducted. The main outcome of the study was CS.

Data source

This study used data and definitions from the NSW Perinatal Data Collection (PDC). The PDC is a population-based surveillance system of all births in NSW, Australia. It contains information about NSW public and private hospital births and home births and information about all women who have had live births and stillbirths of at least 20 weeks' gestational age or at least 400 g birthweight.[13] NSW is the most populous state, with a third of the total Australian population and more than 95 000 women giving birth every year.[14]

PDC information is collected from the electronic notification form that is completed by the attending midwife or doctor at birth. It includes information on maternal demographics, health, pregnancy, labor and birth, as well as perinatal outcomes. The completed forms are sent to NSW Ministry of Health, where the information is validated and compiled into the PDC.[13]

Study population

This study included all women (n = 1 007 843) who gave birth in NSW between January 1, 2002 and December 31, 2012. Of these, 6030 (0.6%) women had pregestational diabetes (type 1 and type 2 diabetes), 51 135 (5.1%) had GDM, and 950 678 (94.3%) did not have diabetes during pregnancy.

Diagnosis of GDM

During the study period, only one guideline used in NSW for the diagnosis of GDM. This was the Australasian Diabetes in Pregnancy Society (ADIPS) guideline that recommended screening for GDM at 26–28 weeks' gestation using the glucose challenge test (GCT). If the non-fasting GCT measured at 1 h postload plasma glucose level was ≥7.8 mmol/L after 50 g glucose load or ≥8.0 mmol/L after 75 g glucose load, a 75 g 2-h oral glucose tolerance test (OGTT) was recommended.[15] GDM was then diagnosed if the fasting venous plasma glucose level was ≥5.5 mmol/L and/or if the load was ≥8.0 mmol/L at 2 h following the 75 g glucose.[15]

Pregestational diabetes and GDM have different effects on pregnancy outcomes, with pregestational diabetes being associated with more complicated outcomes.[2,6,16] In addition, pregestational diabetes poses considerable challenges in clinical management.[17] For this reason, statistical analysis was performed separately for pregestational diabetes and GDM.

Statistical analysis

The sociodemographic factors of women with pregestational diabetes and women with GDM were compared with women without diabetes using a Chi-square test for categorical variables and an Independent Sample t-test for continuous variables. Women were classified according to Robson criteria into 10 groups correlating with their obstetric history (Table 1).

Six variables inform the classification: parity, plurality, presentation, gestational age, history of previous CS and type of labor. Women in groups 2 and 4 were further grouped according to their onset of labor into those who had an induction of labor and those who had a CS with no labor.

Table 1 Extended Robson 10 groups[8]

1	Nulliparous, single cephalic, gestational age ≥ 37 weeks, spontaneous labor
2	Nulliparous, single cephalic, gestational age ≥ 37 weeks, induction of labor or no labor CS
2(a)	Nulliparous, single cephalic, gestational age ≥ 37 weeks, induction of labor
2(b)	Nulliparous, single cephalic, gestational age ≥ 37 weeks, no labor CS
3	Multiparous, without previous CS, single cephalic, gestational age ≥ 37 weeks, spontaneous labor
4	Multiparous, without previous CS, single cephalic, gestational age ≥ 37 weeks, induction of labor or no labor CS
4(a)	Multiparous, without previous CS, single cephalic, gestational age ≥ 37 weeks, induction of labor
4(b)	Multiparous, without previous CS, single cephalic, gestational age ≥ 37 weeks, no labor CS
5	All multiparous, with at least one previous CS, single cephalic, gestational age ≥ 37 weeks
6	All nulliparous, single breech pregnancy
7	All multiparous, single breech, including women with previous CS
8	All women, multiple pregnancies including women with previous CS
9	All women, single transverse, oblique or other lie including women with previous CS
10	All women, single cephalic, gestational age ≤ 36 weeks, including women with previous CS

CS, cesarean section.

Summary statistics were produced using the extended Robson classification for 10 groups stratified by diabetes status. These include:

1. the proportion of the obstetric population of each group
2. the rate of CS within each group
3. the relative contribution of each group to the total CS rate (the proportion of CS in each Robson group according to the total number of CS)
4. the absolute contribution of each group to the total CS rate (rate of CS in each Robson group in relation to the total population).

Multivariable logistic regression was used to investigate the likelihood of CS for women with diabetes compared with women without diabetes. Adjusted odds ratios (AOR) and 95% confidence intervals (95% CI) were calculated. Adjustment was made for maternal age, maternal country of birth (Australian born – yes/no), smoking status, birthweight (<2500, 2500–3999 and ≥4000 g) and pregestational and maternal hypertension.

The analysis was performed using the Statistical Package for the Social Sciences (SPSS) software Version 22.0 (IBM Corporation, Armonk, NY). A P value less than 0.05 was considered statistically significant.

Details of ethics approval

The use of deidentified data was approved by the Executive Director, Centre for Epidemiology and Evidence, NSW Ministry of Health. Ethics approval was granted by the University of Technology Sydney Human Research Ethics Committee (UTS HREC ETH16-0219).

Results

There were significant differences in maternal sociodemographic factors between women with diabetes during pregnancy and women without diabetes (Table 2). A higher proportion of women aged ≥35 years was observed among women with diabetes during pregnancy – 32.5% of women with pregestational diabetes and 34.9% of women with GDM – compared to 21.3% among women without diabetes. Multiparous women represented 63.0% of women with pregestational diabetes and 59.7% of women with GDM, compared with 57.4% of women without diabetes (Table 2).

Table 3 presents the extended Robson classifications for women with pregestational diabetes, women with GDM and women without diabetes. Nulliparous women who had an induction of labor or a CS with no labor (Robson group 2) represented the largest percentages of women in both pregestational diabetes and GDM categories – 20.8% and 21.4%, respectively – compared to only 14.4% of women without diabetes. Group 3 (multiparous who went into spontaneous labor), which was the largest group of women without diabetes, comprised 27.3% of the total population. The second largest group of women with diabetes during pregnancy was multiparous women who had induction of labor. Although the percentages of women with diabetes during pregnancy in groups 4 and 2 were relatively similar to each other, the contribution of group 4 to the total number of CS was significantly lower than the contribution of group 2. Among women with and without diabetes during pregnancy, the highest contribution to the total number of CS was from multiparous women who had a

Table 2 Women's sociodemographic factors by diabetes status 2002–2012.

	Pregestational diabetes n = 6030 n (%)	P value[†,‡]	Gestational diabetes n = 51 135 n (%)	P value[†,§]	No diabetes n = 950 678 n (%)
Age					
Mean (SD)	31.7 (5.6)	<0.001[¶]	32.2 (5.3)	<0.001[¶]	29.9 (5.6)
<20	96 (1.6)	<0.001	511 (1.0)	<0.001	36 205 (3.8)
20–24	584 (9.7)		3398 (6.6)		135 636 (14.3)
25–29	1353 (22.4)		11 440 (22.4)		263 235 (27.7)
30–34	2033 (33.7)		17 957 (35.1)		312 697 (32.9)
35–39	1499 (24.9)		13 607 (26.6)		168 304 (17.7)
≥40	463 (7.7)		4217 (8.2)		34 359 (3.6)
Not stated	2 (0.0)		5 (0.0)		242 (0.0)
Parity					
Nulliparous	2222 (36.8)	<0.001	20 570 (40.2)	<0.001	403 372 (42.4)
Multiparous	3799 (63.0)		30 540 (59.7)		545 804 (57.4)
Not stated	9 (0.1)		25 (0.0)		1502 (0.2)
Plurality					
Singleton	5912 (98.0)	0.004	50 130 (98.0)	<0.001	936 428 (98.5)
Multiple	118 (2.0)		1005 (2.0)		14 250 (1.5)
Country of birth					
Australian	4036 (66.9)	<0.001	25 527 (49.9)	<0.001	672 362 (70.7)
Overseas born	1979 (32.8)		25 436 (49.7)		275 022 (28.9)
Not stated	15 (0.2)		172 (0.3)		3294 (0.3)
Smoking					
Smoked	840 (13.9)	0.111	4769 (9.3)	<0.001	125 787 (13.2)
Did not smoke	5172 (85.8)		46 159 (90.3)		821 935 (86.5)
Not stated	18 (0.3)		207 (0.4)		2956 (0.3)

†Excludes not stated values; ‡P-value for pregestational diabetes compared to no diabetes; §P-value for GDM compared to no diabetes; ¶Using independent samples t-test.

history of previous CS (group 5). This group contributed to 30.9% of all CS performed among women with pregestational diabetes, 34.8% among women with GDM and 34.8% among women without diabetes (Table 3). The main indication for CS in this group was elective repeat CS. The rate of the elective repeat CS was 69.5% among women with pregestational diabetes, 61.3% among women with GDM and 74.1% among women without diabetes.

The rates of vaginal birth after CS (VBAC) among women in group 5 was 8.6% among women with pregestational diabetes, 14.1% among women with GDM and 19.5% among women without diabetes.

Women who had experienced preterm births (Robson group 10) represented 16.8% of the total number of women with pregestational diabetes. This percentage was significantly larger than the percentage of group 10 women without diabetes (4.9%). Group 10 women contributed to 20.5% of the total number of CS among women with pregestational diabetes, 7.4% among women with GDM and 5.7% of the total number of CS among women without diabetes (Table 3); 46% of women with pregestational diabetes in group 10 had a no labor CS, and 21.6% had induction of labor, respectively contributing to 14.5% and 2.5% of the total number of CS among women with pregestational diabetes.

Table 4 shows that the total CS rate was significantly higher among women with pregestational diabetes than among women without diabetes (AOR 2.4, 95% CI, 2.3–2.6). With the exception of women in Robson groups 6, 7 and 9 (women who had noncephalic pregnancies), the rate of CS was significantly higher among women with pregestational diabetes compared to women without diabetes across all other Robson groups.

For women with pregestational diabetes, the highest rate of CS was among women with a history of previous CS (group 5). This rate was significantly higher among women with pregestational diabetes than women without diabetes (91.4% and 80.5%, respectively) (AOR 2.5, 95% CI, 2.0–3.1). Half (49.6%) of the nulliparous women who had induction of labor (group 2(a)) had a CS compared to 31.7% of women without diabetes in the same group (AOR 2.0, 95% CI, 1.7–2.3) (Table 4).

Table 3 Summary statistics for cesarean section by diabetes, 2002–2012

Robson groups	Pregestational diabetes				Gestational diabetes				No diabetes			
		CS				CS				CS		
	Women, n (%)	n	Relative† %	Absolute rate‡, % (95% CI)	Women, n (%)	n	Relative† %	Absolute rate‡, % (95% CI)	Women, n (%)	n	Relative† (%)	Absolute rate‡, % (95% CI)
1	384 (6.4)	88	2.7	1.5 (1.2–1.8)	6777 (13.3)	1139	6.1	2.2 (2.1–2.4)	218 798 (23.3)	32163	12.0	3.4 (3.4–3.5)
2	1244 (20.8)	771	24.1	12.9 (12.0–13.8)	10 860 (21.4)	4842	25.9	9.5 (9.3–9.8)	135 580 (14.4)	58 986	22.0	6.3 (6.2–6.3)
2(a)	938 (15.7)	465	14.5	7.8 (7.1–8.5)	9212 (18.1)	3194	17.1	6.3 (6.1–6.5)	11 2146 (11.9)	35 548	13.3	3.8 (3.7–3.8)
2(b)	306 (5.1)	306	9.5	5.1 (4.5–5.7)	1648 (3.2)	1648	8.8	3.2 (3.1–3.4)	23 438 (2.5)	23 438	8.8	2.5 (2.5–2.5)
3	604 (10.1)	36	1.1	0.6 (0.4–0.8)	9044 (17.8)	331	1.8	0.7 (0.6–0.7)	25 6210 (27.3)	5936	2.2	0.6 (0.6–0.6)
4	1167 (19.5)	250	7.8	4.2 (3.7–4.7)	9923 (19.5)	1590	8.5	3.1 (3.0–3.3)	111 002 (11.8)	17 904	6.7	1.9 (1.9–1.9)
4(a)	1030 (17.2)	113	3.5	1.9 (1.5–2.2)	8982 (17.7)	649	3.5	1.3 (1.2–1.4)	98 401 (10.5)	5303	2.0	0.6 (0.5–0.6)
4(b)	137 (2.3)	137	4.3	2. 3 (1.9–2.7)	941 (1.9)	941	5.0	1.9 (1.7–2.0)	12 601 (1.34)	12 601	4.7	1.3 (1.3–1.4)
5	1082 (18.1)	989	30.9	16.5 (15.5–17.6)	7562 (14.9)	6494	34.8	12.8 (12.5–13.1)	115 954 (12.4)	93 305	34.8	9.9 (9.9–10.0)
6	127 (2.1)	115	3.6	1.9 (1.6–2.3)	883 (1.7)	861	4.6	1.7 (1.6–1.8)	18 594 (2.0)	17 127	6.4	1.8 (1.8–1.9)
7	169 (2.8)	145	4.5	2.4 (2.0–2.8)	1031 (2.0)	957	5.1	1.9 (1.8–2.0)	15 456 (1.6)	13 350	5.0	1.4 (1.4–1.4)
8	118 (2.0)	90	2.8	1.5 (1.2–1.8)	1005 (2.0)	692	3.7	1.4 (1.3–1.5)	14 290 (1.5)	8914	3.3	0.9 (0.9–1.0)
9	75 (1.3)	64	2.0	1.1 (0.8–1.3)	455 (0.9)	389	2.1	0.8 (0.7–0.8)	6701 (0.7)	4859	1.8	0.5 (0.5–0.5)
10	1007 (16.8)	657	20.5	11.0 (10.2–11.8)	3259 (6.4)	1388	7.4	2.7 (2.6–2.9)	46 033 (4.9)	15 304	5.7	1.6 (1.6–1.7)
Total§	5977 (100.0)	3205	100.0	53.6 (51.8–55.5)	50 799 (100.0)	18 683	100.0	36.8 (36.3–37.3)	938 581 (100.0)	267 848	100.0	28.5 (28.4–28.6)

CS, cesarean section; †Relative contribution: proportion of CS in each Robson group according to the total number of CS; ‡Absolute contribution: rate of CS in each Robson group in relation to the total population; §Excludes 12 486 (1.2%) women with no stated Robson classification.

Table 4 Rate of CS within each Robson group for women with pregestational diabetes compared to women who did not have diabetes, 2002–2012

Robson groups	Pregestational diabetes		No diabetes†
	CS%	AOR‡ (95% CI)	CS%
1	22.9	1.4* (1.1–1.8)	14.7
2	62.0	2.0* (1.7–2.2)	43.5
2(a)	49.6	2.0* (1.7–2.3)	31.7
2(b)	100.0	–	100.0
3	6.0	2.1* (1.5–2.9)	2.3
4	21.4	1.3* (1.1–1.5)	16.1
4(a)	11.0	1.8* (1.5–2.2)	5.4
4(b)	100.0	–	100.0
5	91.4	2.5* (2.0–3.1)	80.5
6	90.6	0.9 (0.4–1.7)	92.1
7	85.8	0.8 (0.5–1.3)	86.4
8	76.3	1.8* (1.2–2.8)	62.6
9	85.3	1.8 (0.9–3.5)	72.5
10	65.2	3.1* (2.7–3.5)	33.2
Total	53.6	2.4* (2.3–2.6)	28.5

AOR, adjusted odd ratios; CS, cesarean section; †Reference group; ‡AOR, odd ratio was adjusted for maternal age, maternal country of birth (Australian born yes/no), smoking status, birthweight (<2500, 2500–3999 and ≥4000 g) and maternal and obstetric hypertension; *Significant.

Table 5 shows that 36.8% of women with GDM gave birth by CS compared to 28.5% of women without diabetes (AOR 1.3, 95% CI, 1.2–1.3). The highest rate of CS was for women with GDM (97.5%) and women without diabetes (92.1%) among group 6 nulliparous, who had a breech presentation.

For both nulliparous and multiparous women with GDM who had an induction of labor (groups 2(a) and 4(a)), there was an increase in the rate of CS compared with women without diabetes in the same groups ((AOR 1.1, 95% CI, 1.0–1.1 for nulliparous women) and (AOR 1.2, 95% CI, 1.1–1.3 for multiparous women)) (Table 5).

Discussion

Our study is the first population-based study to use the Robson classification to compare CS rates among women with and without diabetes during pregnancy. Previous published studies that used the Robson classification to analyze CS rates among women with diabetes during pregnancy are hospital-based studies with limited sample size and generalizability.[9–11] Our study provides population data and confirms these hospital studies' results.[9–11]

We found that previous CS was the main driver for CS, regardless of whether the women had diabetes during pregnancy or not. A previous study that used the Robson classification on the Australian general population also found that previous CS was the highest contributor to the total number of CS.[18] Our results also confirm results from international studies that found group 5 to be the main contributor to the total number of CS.[19–22]

Among women in the Robson group 5 (women with a history of CS), we found that the CS rate was significantly higher among women with pregestational diabetes and women with GDM compared with women without diabetes. One explanation may be that women with diabetes during pregnancy have lower rates of successful VBAC than women without diabetes.[23,24] This is supported by data demonstrating that the rate of unsuccessful VBAC among women who trialed labor is 38% among women with pregestational diabetes [24] and 36% among women with GDM,[23] compared to 24% among women without diabetes. Among our study population, women without diabetes had more than double the rate of successful VBAC than women with pregestational diabetes and were five percentage points more likely to have a successful VBAC compared with women with GDM. This indicates that primary CS among

Table 5 Rate of CS within each Robson group for women who had gestational diabetes compared to women who did not have diabetes, 2002–2012.

Robson groups	Gestational diabetes		No diabetes†
	CS%	AOR‡ (95% CI)	CS%
1	16.8	1.1 (1.0–1.1)	14.7
2	44.6	0.9* (0.9–1.0)	43.5
2(a)	34.7	1.1* (1.0–1.1)	31.7
2(b)	100.0	–	100.0
3	3.7	1.4* (1.3–1.6)	2.3
4	16.0	0.9* (0.8–0.9)	16.1
4(a)	7.2	1.2* (1.1–1.3)	5.4
4(b)	100.0	–	100.0
5	85.9	1.4* (1.3–1.5)	80.5
6	97.5	4.2* (2.6–6.8)	92.1
7	92.8	1.7* (1.3–2.1)	86.4
8	68.9	1.2* (1.0–1.3)	62.6
9	85.5	1.7* (1.3–2.2)	72.5
10	42.6	1.2* (1.1–1.3)	33.2
Total	36.8	1.3* (1.2–1.3)	28.5

AOR, adjusted odd ratios; CS, cesarean section; †Reference group; ‡AOR, odd ratio was adjusted for maternal age, maternal country of birth (Australian born yes/no), smoking status, birthweight (<2500, 2500–3999 and ≥4000 g) and maternal and obstetric hypertension; *Significant.

women with diabetes during pregnancy has a greater effect on consecutive methods of birth than among women without diabetes. There is compelling evidence, therefore, to suggest that reducing the rate of the primary CS can help to reduce the overall rate of CS.

The second highest contributor to the total number of CS was group 2 (nulliparous who had induction of labor or no-labor CS), regardless of whether women had diabetes or not. However, within this group, the contribution of CS relative to the total population rate was significantly higher among women with diabetes during pregnancy than women without diabetes. This is due in part to the overrepresentation of women with diabetes during pregnancy in this group (20.8% of women with pregestational diabetes and 21.4% of women with GDM, compared to 14.4% of women without diabetes) (Table 3).

In addition, previously published research shows that women with diabetes during pregnancy who had induction of labor are at a higher risk of CS than women without diabetes.[25] In our population, nulliparous women with pregestational diabetes who had induction of labor had double the odds of having a CS compared to women without diabetes. Half (49.6%) of these women had a CS, which is consistent with the rate of 48.5% among women with type 1 diabetes published by Carroll *et al*.[10] The evidence, therefore, suggests that a more judicious approach to inducing labor in nulliparous women with diabetes may help reduce the primary CS rate.

In women with pregestational diabetes, the rate of preterm labor is high.[7,16,26,27] Among our population, group 10 women with preterm birth represented 16.8% of women with pregestational diabetes. The high rate of preterm birth is likely related to iatrogenic interventions among women with pregestational diabetes.[27,28] In our study only one third (32.2%) of these women with pregestational diabetes in group 10 had a spontaneous preterm birth, while the majority of them had either no labor CS (46.2%) or induction of labor (21.6%) before 37 weeks gestation. CS among women in group 10 contributed 20.5% of the total number of CS among women with pregestational diabetes. Our research is consistent with the findings of a 2009 Brazilian tertiary hospital study using the Robson classification to investigate the rate of CS among women with diabetes during pregnancy, which found that 21.0% of the total CS was contributed by women in group 10.[9] Among our study population in group 10, women with pregestational diabetes had double the rate of CS than among women without diabetes.

We found that the rates of CS among women with diabetes during pregnancy were higher than those among women without diabetes across most Robson groups. This is consistent for both women with pregestational diabetes and women with GDM. Although the difference in CS rates between women with GDM and women without diabetes was statistically significant, it is difficult to draw definitive conclusions regarding the clinical significance of this finding due to the large sample size.

Strength and limitations

The use of the WHO-recommended Robson classification with large population data provides population-based information on the rate of CS among women with diabetes during pregnancy and the contribution of each group to the total number of CS. Hospital-based studies have provided the impetus for this study, but they have not delivered results of sufficient scope, reliability and generalizability to inform clinical decision making. By using population data that reports childbirth-related diagnosis and procedures with high levels of accuracy,[29] our results can be used as a reference population for other studies investigating the method of birth and diabetes during pregnancy.

There were no data items on the management of diabetes during pregnancy or maternal body mass index (BMI) in the NSW PDC dataset. This is a limitation of the study because a large proportion of women with diabetes during pregnancy have high BMI, which is associated with increases in the risk of CS among women with diabetes during pregnancy.[30] Further studies are required to evaluate the impact of maternal BMI on CS.

A further limitation of our study was the possible underestimation of the number of women with diabetes. In our study, the proportion of GDM from the NSW PDC data was 5.1%, which is marginally lower than that found in an earlier validation study based on two datasets – the Admitted Patient Data Collection (APDC) and PDC – which found 5.6% of primiparous and 6.1% of multiparous had GDM, respectively.[31] However, that study reassuringly found that, irrespective of the data source of GDM status, the odds ratio of CS among women with GDM compared with women without GDM was consistent at 1.4 (95% CI, 1.3–1.5) for PDC versus 1.5 (95% CI, 1.4–1.6) from the combined data of the PDC and

APDC for primiparous and 1.4 (95% CI, 1.3–1.5) versus 1.5 (95% CI, 1.4–1.6) for multiparous women.[31]

The Robson classification is a clinically informative and simple classification system for examining CS among women with medical conditions and obstetric complications such as diabetes during pregnancy. It provides a granularity around a set of actions leading to CS.

In our population-based study, the highest contributing factor to having a CS was from women with a history of CS, whether or not they had diabetes during pregnancy. For women with diabetes during pregnancy, the CS is high across most Robson groups compared with women without diabetes. Focusing on the primary prevention of CS would help in reducing the overall rate of CS among women with diabetes during pregnancy.

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Disclosure

None declared.

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Neonatal outcomes of live-born term singletons in vertex presentation born to mothers with diabetes during pregnancy by mode of birth: a New South Wales population-based retrospective cohort study

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ABSTRACT

Objectives To investigate the association between the mode of birth and adverse neonatal outcomes of macrosomic (birth weight ≥4000 g) and non-macrosomic (birth weight <4000 g) live-born term singletons in vertex presentation (TSV) born to mothers with diabetes (pre-existing and gestational diabetes mellitus (GDM)).

Design A population-based retrospective cohort study.

Setting New South Wales, Australia.

Patients All live-born TSV born to mothers with diabetes from 2002 to 2012.

Intervention Comparison of neonatal outcomes by mode of birth (prelabour caesarean section (CS) and planned vaginal birth resulted in intrapartum CS, non-instrumental or instrumental vaginal birth).

Main outcome measures Five-minute Apgar score <7, admission to neonatal intensive care unit (NICU) or special care nursery (SCN) and the need for resuscitation.

Results Among the 48 882 TSV born to mothers with diabetes, prelabour CS was associated with a significant increase in the rate of admission to NICU/SCN compared with planned vaginal birth. For TSV born to mothers with pre-existing diabetes, compared with non-instrumental vaginal birth, instrumental vaginal birth was associated with increased odds of the need for resuscitation in macrosomic (adjusted ORs (AOR) 2.6; 95% CI (1.2 to 7.5)) and non-macrosomic TSV (AOR 3.3; 95% CI (2.2 to 5.0)). For TSV born to mothers with GDM, intrapartum CS was associated with increased odds of the need for resuscitation compared with non-instrumental vaginal birth in non-macrosomic TSV (AOR 2.3; 95% CI (2.1 to 2.7)). Instrumental vaginal birth was associated with increased likelihood of requiring resuscitation compared with non-instrumental vaginal birth for both macrosomic (AOR 2.3; 95% CI (1.7 to 3.1)) and non-macrosomic (AOR 2.5; 95% CI (2.2 to 2.9)) TSV.

Conclusion Pregnant women with diabetes, particularly those with suspected fetal macrosomia, need to be aware of the increased likelihood of adverse neonatal outcomes following instrumental vaginal birth and intrapartum CS when planning mode of birth.

What is already known on this topic?

- Diabetes during pregnancy is associated with adverse neonatal and long-term baby outcomes.
- There is no agreement in the national and international guidelines about the best mode of birth for women with diabetes during pregnancy.

What this study hopes to add?

- Diabetic women gave birth to macrosomic term singletons in vertex presentation are likely to give birth by intrapartum caesarean section (CS) and those who gave birth to non-macrosomic by instrumental birth.
- Intrapartum CS and instrumental vaginal birth are associated with increased likelihood of adverse neonatal outcomes.

INTRODUCTION

Diabetes during pregnancy is associated with increased incidence of adverse baby outcomes.[1] Babies born to mothers with diabetes during pregnancy are at higher risk of perinatal mortality and morbidity including preterm birth, congenital abnormality, neonatal hypoglycaemia and macrosomia.[2]

There is little consistency internationally regarding recommendations on the mode of birth for women with diabetes during pregnancy. Variations are seen in both national and professional society guidelines and recommendations.[2] The American College of Obstetricians and Gynecologists guidelines recommend caesarean section (CS) for women with diabetes during pregnancy with an estimated birth weight >4500 g.[3 4] The National Institute for Health and Care Excellence (NICE) guideline in the UK recommends induction of labour or elective CS if indicated, between 37^{+0} and 38^{+6} weeks of gestation for women with pre-existing diabetes.[5] For women with gestational diabetes mellitus (GDM), the NICE guideline recommends elective birth no later than 40^{+6} weeks of gestation.[5] The Australasian Diabetes in Pregnancy Society (ADIPS) guidelines advise that for women with pre-existing diabetes, elective CS should be considered if estimated birth weight exceeds 4250–4500 g.[6] For women with uncomplicated GDM, ADIPS guideline does not recommend birth before term unless there is an obstetric indication.[7]

The rate of CS is high among women with diabetes during pregnancy in Australia.[8] The leading reasons for a planned CS (prelabour CS) are for the prevention of stillbirth and the reduction of birth complications associated with macrosomia.[2 9] Currently, there are no population-based studies in Australia that have evaluated the neonatal outcomes of babies born to mothers with diabetes according to the mode of birth.

Our study aimed to compare adverse neonatal outcomes for live-born term singletons in vertex presentation (TSV) born to mothers with diabetes during pregnancy (pre-existing diabetes and GDM) by mode of birth-stratified macrosomia (macrosomic and non-macrosomic TSV).

MATERIALS AND METHODS

Data source

A population-based retrospective cohort study was conducted using the New South Wales (NSW) Perinatal Data Collection (PDC).[10] The PDC is a population-based surveillance system. It includes all births occurring in NSW public and private hospitals as well as home births. Women giving birth to live births and stillbirths of at least 20 weeks or at least 400 g birth weight are included in the database. Around 32% of the Australian population lives in NSW, and more than 95 000 women give birth in this state annually.[11 12]

The NSW PDC is based on electronic forms that are completed at birth by the attendants. Information on maternal demographics, maternal health, pregnancy, obstetric complications, labour and perinatal outcomes is included in the form. The forms are submitted to NSW Ministry of Health where the information is validated and compiled into the statewide PDC.[10]

Study population

There were 48 983 TSV born during the study period of which 101 are stillbirths (18 (0.4%) born to mothers with pre-existing diabetes and 83 (0.2%) born to mothers with GDM). Due to our inability to identify times of stillbirth (antepartum or intrapartum), these stillbirths were excluded from the study. The study includes all live-born TSV (n=48 882) born in NSW to mothers with diabetes during pregnancy between 1 January 2002 and 31 December 2012. Of these, 4501 (9.2%) were born to mothers with pre-existing diabetes and 44 381 (90.8%) were born to mothers with GDM.

Of our study population, 276 (0.4%) TSV were excluded from the multivariate logistic regression due to admission to neonatal intensive care unit (NICU) or special care nursery (SCN) with one or more diagnosed birth defects, and 71 (0.1%) were excluded because of missing data (mode of birth, birth weight and admission to NICU or SCN due to birth defect). A total of 4458 live-born TSV born to mothers with pre-existing diabetes and 44 148 born to mothers with GDM were included in the multivariate logistic regression.

Study factors and outcome measurements

Pre-existing diabetes includes type I and type II. GDM is defined as glucose intolerance that is diagnosed for the first time during pregnancy which may include hyperglycaemia induced by pregnancy or previously undiagnosed existing abnormalities of glucose tolerance.[13]

Modes of birth include non-instrumental and instrumental vaginal births, prelabour CS (often known as an elective CS) and intrapartum CS. Planned vaginal births are births that were primarily intended to be non-instrumental vaginal births, although they might end with intrapartum CS, instrumental vaginal birth or non-instrumental vaginal birth.

The definition for macrosomia adopted by the International Association of Diabetes in Pregnancy Study Group of birth weight ≥4000 g was used.[14] 'Large for gestational age' was defined as a birth weight greater than the 90th percentile for gestational age and 'small for gestational age' is birth weight less than the 10th percentile.[14]

Adverse neonatal outcomes were 5 min Apgar score <7, neonate admission to NICU or SCN, and the need for resuscitation which included resuscitation by intermittent positive pressure respiration by bag and mask, intubation, and intermittent positive pressure respiration, external cardiac massage and ventilation.

Statistical analysis

Maternal characteristics and baby outcomes were compared by mode of birth using X^2 test. Trend analysis was used to compare the rate of prelabour CS by year using Mantel-Haenszel test for trend analysis.

Multivariate logistic regression was used to investigate the likelihood of adverse neonatal outcomes by mode of birth. Two analyses were conducted; the first compared TSV born by prelabour CS with TSV born by all other modes of birth combined as planned vaginal births. This first analysis was performed to inform the decision of performing prelabour CS or proceed to planned vaginal birth. The second compared TSV born by non-instrumental vaginal birth, TSV who were planned as vaginal births but for whom resorting to instrumental birth and intrapartum CS, and TSV born by prelabour CS. The second analysis was performed to

Table 1 Maternal characteristics and birth outcomes for TSV born to women with pre-existing diabetes, 2002–2012

	Prelabour caesarean section		Non-instrumental vaginal birth		Instrumental vaginal birth		Intrapartum caesarean section	
	n=1286	(%)	n=1969	(%)	n=397	(%)	n=849	(%)
Age (years)								
<20	11	0.9	33	1.7	10	2.5	9	1.1
20–24	85	6.6	185	9.4	57	14.4	91	10.7
25–29	246	19.1	436	22.1	89	22.4	209	24.6
30–34	434	33.7	675	34.3	143	36.0	271	31.9
35–39	391	30.4	502	25.5	71	17.9	207	24.4
≥40	119	9.3	138	7.0	27	6.8	62	7.3
Parity								
Primiparae	304	23.6	487	24.7	280	70.5	553	65.1
Multiparae	980	76.2	1480	75.2	115	29.0	296	34.9
Not stated	2	0.2	2	0.1	2	0.5	0	0.0
Number of previous caesarean section*								
None	136	13.9	1380	93.2	96	83.5	149	50.3
One	602	61.4	67	4.5	19	16.5	115	38.9
Two or more	239	24.4	4	0.3	0	0.0	31	10.5
Not stated	3	0.3	29	2.0	0	0.0	1	0.3
Country of birth								
Australian born	862	67.0	1204	61.1	256	64.5	586	69.0
Overseas born	420	32.7	760	38.6	140	35.3	262	30.9
Not stated	4	0.3	5	0.3	1	0.3	1	0.1
Smoking during pregnancy								
Smoked	142	11.0	288	14.6	43	10.8	84	9.9
Did not smoke	1140	88.6	1677	85.2	352	88.7	764	90.0
Not stated	4	0.3	4	0.2	2	0.5	1	0.1
Birth weight (g)								
Less than 4000	888	69.1	1659	84.3	342	86.1	635	74.8
4000 and over	397	30.9	310	15.7	54	13.6	214	25.2
Not stated	1	0.1	0	0.0	1	0.3	0	0.0
Small for gestational age	62	4.8	151	7.7	23	5.8	50	5.9
Large for gestational age	508	39.5	332	16.9	70	17.6	291	34.3
Sex								
Male	682	53.0	962	48.9	208	52.4	446	52.5
Female	604	47.0	1007	51.1	189	47.6	403	47.5
Gestational age (weeks)								
37	290	22.6	241	12.2	59	14.9	177	20.8
38	610	47.4	599	30.4	153	38.5	328	38.6
39	321	25.0	605	30.7	103	25.9	202	23.8
40	54	4.2	369	18.7	59	14.9	117	13.8
Greater than 40	11	0.9	155	7.9	23	5.8	25	2.9

*For multipara mothers only.
TSV, term singletons in vertex presentation.

help inform the decision in the situation where vaginal birth is planned.

Adjusted OR (AOR) and 95% CI were presented. The adjustment was made for maternal age, maternal country of birth (Australian-born mothers, overseas-born mothers), parity (no previous pregnancies; one, two, three or more previous pregnancies), smoking during pregnancy (smoked, did not smoke), essential and

Table 2 Maternal characteristics and birth outcomes for TSV born to women with gestational diabetes, 2002–2012

	Prelabour caesarean section		Non-instrumental vaginal birth		Instrumental vaginal birth		Intrapartum caesarean section	
	n=7958	(%)	n=24 946	(%)	n=5017	(%)	n=6447	(%)
Age (years)								
<20	22	0.3	300	1.2	49	1.0	73	1.1
20–24	276	3.5	1882	7.5	374	7.5	518	8.0
25–29	1227	15.4	6067	24.3	1274	25.4	1539	23.9
30–34	2690	33.8	8849	35.5	1899	37.9	2219	34.4
35–39	2734	34.4	6161	24.7	1142	22.8	1570	24.4
≥40	1008	12.7	1684	6.8	279	5.6	527	8.2
Not stated	1	0.0	3	0.0	0	0.0	1	0.0
Parity								
Primiparae	1644	20.7	7747	31.1	3877	77.3	4329	67.1
Multiparae	6309	79.3	17 191	68.9	1138	22.7	2114	32.8
Not stated	5	0.1	8	0.0	2	0.0	4	0.1
Number of previous caesarean section*								
None	939	14.9	16 086	93.6	922	81.0	978	46.3
One	3820	60.5	844	4.9	195	17.1	965	45.6
Two or more	1534	24.3	21	0.1	5	0.4	157	7.4
Not stated	16	0.3	240	1.4	16	1.4	14	0.7
Country of birth								
Australian born	4353	54.7	12 323	49.4	2172	43.3	3131	48.6
Overseas born	3587	45.1	12 546	50.3	2824	56.3	3291	51.0
Not stated	18	0.2	77	0.3	21	0.4	25	0.4
Smoking during pregnancy								
Smoked	607	7.6	2549	10.2	299	6.0	554	8.6
Did not smoke	7315	91.9	22 308	89.4	4695	93.6	5872	91.1
Not stated	36	0.5	89	0.4	23	0.5	1	0.0
Birth weight (g)								
Less than 4000	6628	83.3	22 400	89.8	4588	91.4	5494	85.2
4000 and over	1327	16.7	2544	10.2	428	8.5	953	14.8
Not stated	3	0.0	2	0.0	1	0.0	0	0.0
Small for gestational age	496	6.2	2590	10.4	667	13.3	651	10.1
Large for gestational age	1652	20.8	2502	10.0	402	8.0	930	14.4
Sex								
Male	4194	52.7	12 471	50.0	2709	54.0	3665	56.8
Female	3762	47.3	12 470	50.0	2305	45.9	2782	43.2
Not stated	2	0.0	5	0.0	3	0.1	0	0.0
Gestational age (weeks)								
37	921	11.6	2133	8.6	379	7.6	572	8.9
38	3271	41.1	6337	25.4	1138	22.7	1639	25.4
39	3000	37.7	8503	34.1	1695	33.8	2044	31.7
40	597	7.5	6118	24.5	1367	27.2	1580	24.5
Greater than 40	169	2.1	1855	7.4	438	8.7	612	9.5

*For multipara mothers only.
TSV, term singletons in vertex presentation.

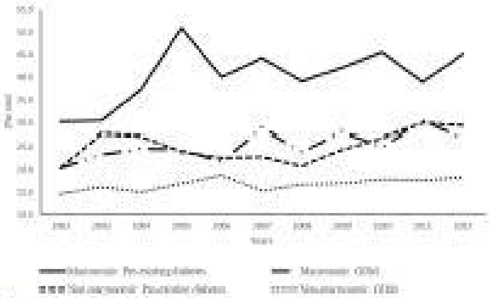

Figure 1 Rates of prelabour caesarean section. GDM, gestational diabetes mellitus.

pregnancy-induced hypertension, and hospital sector (public, private). The analysis was performed using Statistical Package for Social Science (SPSS) software V.22.0 (IBM). P value <0.05or CI not including 1 was considered statistically significant.

RESULTS

Maternal characteristics and baby outcomes are presented in tables 1 and 2. Among mothers who went into labour, 38.8% with pre-existing diabetes and 31.5% with GDM gave birth by instrumental vaginal birth or intrapartum CS. The highest proportion of mothers aged <25 years were among mothers with pre-existing diabetes who gave birth by instrumental vaginal birth (16.9%, P<0.001) (table 1). The proportion of primipara mothers were higher among those who had instrumental vaginal birth (70.5% and 77.3% among mothers with pre-existing diabetes and mothers with GDM, respectively) (tables 1 and 2). There were 17 neonatal deaths of which 2 (0.4 per 1000 live-born TSV) were born to women with pre-existing diabetes and 15 (0.3 per 1000 live-born TSV) were born to women with GDM.

Figure 1 shows an increasing trend in prelabour CS for both macrosomic and non-macrosomic TSV. The largest increase was seen among macrosomic TSV (P=0.048), followed by non-macrosomic TSV born to mothers with pre-existing diabetes (P=0.032).

Among mothers with pre-existing diabetes in the planned vaginal birth group, the highest rate of instrumental vaginal birth was among those who gave birth to non-macrosomic TSV who had induction of labour (13.2%) (online supplementary figure 1). Mothers with GDM who had induction of labour and gave birth to non-macrosomic TSV had the highest rate of instrumental vaginal birth (15.2%) (online supplementary figure 2).

There were no significant changes in the rate of admission to NICU/SCN for TSV born to mothers with pre-existing diabetes and for macrosomic TSV born to mothers with GDM from 2002 to 2012. There was a significant increase in the rate of high-level resuscitation for non-macrosomic TSV born to mothers with GDM between 2002 and 2012.

Prelabour CS compared with planned vaginal birth

For TSV born to mothers with pre-existing diabetes by prelabour CS, there was a significant increase in the odds of admission to NICU/SCN compared with TSV born by planned vaginal birth (AOR 2.3, 95% CI (1.7 to 3.2) for macrosomic TSV; AOR 1.6, 95% CI (1.4 to 1.9) for non-macrosomic TSV) (table 3).

Non-instrumental vaginal birth compared with other modes of birth

TSV born to mothers with pre-existing diabetes

For non-macrosomic TSV, prelabour CS, instrumental vaginal birth and intrapartum CS were associated with increased odds of admission to NICU/SCN compared with non-instrumental vaginal birth (AOR 2.1, 95% CI (1.8 to 2.5) for prelabour CS; AOR 1.8, 95% CI (1.4 to 2.3) for instrumental vaginal birth; AOR 2.4, 95% CI (2.0 to 3.0) for intrapartum CS). Both instrumental vaginal birth and intrapartum CS were associated with a significant increase in the odds of requiring resuscitation compared with non-instrumental vaginal birth (AOR 3.3, 95% CI (2.2 to 5.0) for instrumental vaginal birth; AOR 2.3, 95% CI (1.6 to 3.4) for intrapartum CS) (table 4).

For macrosomic TSV, instrumental vaginal birth was associated with a significant increase in the odds of requiring resuscitation (AOR 2.6, 95% CI (1.2 to 5.7)) and admission to NICU/SCN (AOR 2.1, 95% CI (1.1 to 3.9)) compared with non-instrumental vaginal birth (table 4).

TSV born to mothers with GDM

Among non-macrosomic TSV, compared with non-instrumental vaginal birth, all other modes of birth were associated with increased odds of admission to NICU/SCN (AOR 1.5, 95% CI (1.4 to 1.6) for instrumental vaginal birth; AOR 1.9, 95% CI (1.7 to 2.0) for intrapartum CS; AOR 1.6, 95% CI (1.5 to 1.7) for prelabour CS) and need for resuscitation (AOR 2.5, 95% CI (2.2 to 2.9) for instrumental vaginal birth; AOR 2.3, 95% CI (2.1 to 2.7) for intrapartum CS; AOR 1.5, 95% CI (1.3 to 1.7) for prelabour CS) (table 4).

Among macrosomic TSV born to GDM mothers, compared with non-instrumental vaginal birth, the rate of requiring resuscitation was higher after instrumental vaginal birth (AOR 2.3, 95% CI (1.7 to 3.1)) and lower after prelabour CS (AOR 0.7, 95% CI (0.6 to 0.9)) (table 4).

DISCUSSION

To our knowledge, this Australian study is the largest population-based investigation of neonatal outcomes related to mode of birth in live-born TSV born to mothers with diabetes during pregnancy. The study results showed that, among TSV born to mothers with diabetes during

Table 3 Adjusted ORs for adverse neonatal outcomes of TSV born to women with diabetes during pregnancy after prelabour CS and planned vaginal birth, 2002–2012

	Planned vaginal birth†		Prelabour caesarean section		
	n	(%)	n	(%)	AOR‡ (95% CI)
			Pre-existing diabetes		
Birth weight less than 4000 g	2613		880		
5 min Apgar score <7	37	1.4	10	1.1	0.8 (0.4 to 1.6)
Admitted to NICU/SCN	1180	45.2	495	56.3	1.6* (1.4 to 1.9)
Need for resuscitation§	183	7.0	51	5.8	0.9 (0.6 to 1.2)
Birth weight 4000 g and over	574		391		
5 min Apgar score <7	16	2.8	1	0.3	0.1* (0.0 to 0.9)
Admitted to NICU/SCN	329	57.3	285	72.9	2.3* (1.7 to 3.2)
Need for resuscitation§	76	13.2	32	8.2	0.7 (0.4 to 1.1)
			Gestational diabetes		
Birth weight less than 4000 g	32 330		6590		
5 min Apgar score <7	362	1.1	62	0.9	1.0 (0.7 to 1.3)
Admitted to NICU/SCN	8613	26.6	2107	32.0	1.4* (1.3 to 1.4)
Need for resuscitation§	1752	5.4	326	4.9	1.1 (0.9 to 1.2)
Birth weight 4000 g and over	3911		1317		
5 min Apgar score <7	76	1.9	22	1.7	1.0 (0.6 to 1.6)
Admitted to NICU/SCN	1288	32.9	610	46.3	1.8* (1.7 to 2.2)
Need for resuscitation§	423	10.8	99	7.5	0.7* (0.5 to 0.9)

*P<0.05.
†Reference group.
‡ORs were adjusted for maternal age, maternal country of birth, the number of previous pregnancies, smoking during pregnancy, essential and pregnancy-induced hypertension and hospital sector.
§Need for resuscitation includes intermittent positive pressure respiration by bag and mask, intubation and intermittent positive pressure respiration as well as external cardiac massage and ventilation.
AOR, adjusted OR; CS, caesarean section; NICU, neonatal intensive care unit; SCN, special care nursery; TSV, term singletons in vertex presentation.

pregnancy, prelabour CS was associated with a significant increase in the rate of admission to NICU/SCN compared with planned vaginal birth. Both instrumental vaginal birth and intrapartum CS were associated with increased odds of requiring resuscitation compared with non-instrumental vaginal birth.

The use of a large validated population-based data set with high accuracy[15] generates a high level of evidence that cannot be achieved in hospital settings. Our study provides population-level evidence on the association between mode of birth and neonatal outcomes of TSV born to mothers with diabetes during pregnancy in NSW. Our study also provides information about clinical practice for mothers with diabetes during pregnancy. The validation study by Ampt *et al* on the NSW PDC shows that the PDC had high sensitivity (>94.7%) and high positive predictive value (>96.1%) in reporting dichotomised outcome variables such as 5 min Apgar score <7 and neonatal resuscitation.[16]

The limitation of the study is the lack of information on reasons for NICU/SCN admissions as macrosomic TSV are routinely admitted to NICU/SCN for expected hypoglycaemia without clinical necessity which increases the rate of admission to NICU/SCN. Some services do have a routine policy of admitting babies born to mothers with diabetes to an NICU/SCN, hence the numbers could be higher. Another limitation is the lack of information on maternal body mass index and on umbilical artery pH and lactate levels. To remove the confounding related to birth defects, we excluded TSV admitted to NICU/SCN because of birth defects from our multivariable logistic regression. However, we are unable to adjust for maternal body mass index, an independent risk factor for adverse pregnancy outcomes such as low Apgar score and a higher rate of admission to NICU.[17] We used stratification by estimated fetal macrosomia using birth weight to limit the impact of maternal body mass index on the mode of birth and neonatal outcomes. We are also unable to adjust for shoulder dystocia as it was not captured in NSW PDC. We also lack information on second-stage CS which did not allow us to compare between intrapartum CS and instrumental vaginal birth.

There was no significant difference in the odds of 5 min Apgar score <7 between TSV born after prelabour CS and those born after planned vaginal birth for mothers who had pre-existing diabetes or GDM. Stuart *et al* found a

Table 4 Adjusted ORs for adverse neonatal outcomes of TSV born to women with diabetes during pregnancy by mode of birth, 2002–2012

	Non-instrumental vaginal birth†		Instrumental vaginal birth			Intrapartum caesarean section			Prelabour caesarean section		
	n	(%)	n	(%)	AOR‡ (95% CI)	n	(%)	AOR‡ (95% CI)	n	%	AOR‡ (95% CI)
Pre-existing diabetes											
Birth weight less than 4000 g	1647		338			628			890		
5 min Apgar score <7	19	1.2	6	1.8	1.7 (0.6 to 4.5)	12	1.9	1.6 (0.7 to 3.6)	10	1.1	0.9 (0.4 to 2.1)
Admitted to NICU/SCN	633	38.4	170	50.3	1.8* (1.4 to 2.3)	377	60.0	2.4* (2.0 to 3.0)	495	56.3	2.1* (1.8 to 2.5)
Need for resuscitation§	74	4.5	46	13.6	3.3* (2.2 to 5.0)	63	10.0	2.3* (1.6 to 3.4)	51	5.8	1.3 (0.9 to 1.9)
Birth weight 4000 g and over	310		54			210			391		
5 min Apgar score <7	12	3.9	3	5.6	0.8 (0.2 to 3.7)	1	0.5	0.1* (0.0 to 0.5)	1	0.3	0.1* (0.0 to 0.5)
Admitted to NICU/SCN	137	44.2	34	63.0	2.1* (1.1 to 3.9)	158	75.2	3.9* (2.6 to 5.9)	285	72.9	4.1* (2.9 to 5.7)
Need for resuscitation§	32	10.3	14	25.9	2.6* (1.2 to 5.7)	30	14.3	1.3 (0.7 to 2.3)	32	8.2	0.8 (0.5 to 1.4)
Gestational diabetes											
Birth weight less than 4000 g	22 304		4565			5461			6590		
5 min Apgar score <7	177	0.8	87	1.9	2.4* (1.8 to 3.1)	98	1.8	2.1* (1.6 to 2.7)	62	0.9	1.3 (0.9 to 1.7)
Admitted to NICU/SCN	5299	23.8	1354	29.7	1.5* (1.4 to 1.6)	1960	35.9	1.9* (1.7 to 2.0)	2107	32.0	1.6* (1.5 to 1.7)
Need for resuscitation§	822	3.7	433	9.5	2.5* (2.2 to 2.9)	497	9.1	2.3* (2.1 to 2.7)	326	4.9	1.5* (1.3 to 1.7)
Birth weight 4000 g and over	2539		426			946			1317		
5 min Apgar score <7	49	1.9	14	3.3	1.8 (0.9 to 3.5)	13	1.4	0.7 (0.3 to 1.3)	22	1.7	1.0 (0.6 to 1.7)
Admitted to NICU/SCN	752	29.6	138	32.4	1.3* (1.0 to 1.7)	398	42.1	1.9* (1.6 to 2.3)	610	46.3	2.3* (2.0 to 2.7)
Need for resuscitation§	259	10.2	76	17.8	2.3* (1.7 to 3.1)	88	9.3	1.0 (0.7 to 1.3)	99	7.5	0.7* (0.6 to 0.9)

*P<0.05.
†Reference group.
‡ORs were adjusted for maternal age, maternal country of birth, the number of previous pregnancies, smoking during pregnancy, essential and pregnancy-induced hypertension and hospital sector.
§Need for resuscitation includes intermittent positive pressure respiration by bag and mask, intubation and intermittent positive pressure respiration as well as external cardiac massage and ventilation.
AOR, adjusted OR; NICU, neonatal intensive care unit; SCN, special care nursery; TSV, term singletons in vertex presentation.

significant reduction in the odds of 5 min Apgar score <7 among TSV born to mothers with diabetes during pregnancy who were born after prelabour CS at 38 weeks' gestation compared with those born after planned vaginal birth at 39 weeks' gestation.[18]

TSV born to mothers with diabetes during pregnancy can be affected by a number of morbidities including respiratory distress syndrome, hypoglycaemia and hypocalcaemia that can lead to an increase in the likelihood of admission to NICU/SCN.[5] In addition, CS is associated with increased odds of neonatal respiratory morbidity.[19] The NICE guideline recommended admission to NICU if babies who were born to mothers with diabetes had one of the following symptoms: hypoglycaemia, respiratory distress or jaundice, signs of cardiac decompensation, neonatal encephalopathy or polycythaemia, the need for tube feeding or who were born preterm.[5]

Our study found that instrumental vaginal birth and intrapartum CS were associated with an increase in the odds of the need for resuscitation and admission to NICU/SCN compared with non-instrumental vaginal birth. One indication for instrumental vaginal birth and intrapartum CS is fetal compromise,[20] which is also an indication for neonatal resuscitation.[21] Thus, requiring resuscitation might have been associated with fetal compromise, not the use of instrumental vaginal birth or intrapartum CS. However, instrumental vaginal birth alone is also considered a risk factor for requiring neonatal resuscitation.[21]

Our study found that women with diabetes have a low rate of non-instrumental vaginal birth and high rate of giving birth by intrapartum CS and instrumental birth. This is consistent with previous studies.[18 22] Among our population of mothers who went into labour, 38.8% of those with pre-existing diabetes and 31.5% of those with GDM gave birth by instrumental vaginal birth or intrapartum CS compared with 29.4% of women in the NSW general population.[23] One in four mothers (25.9%) with planned vaginal birth gave birth to a macrosomic TSV by intrapartum CS, and one in five mothers (20.5%) with planned vaginal birth gave birth to a non-macrosomic TSV by instrumental vaginal birth. Given that both intrapartum CS and instrumental birth are associated with increased odds of adverse neonatal outcomes, the high proportion of resorting to instrumental vaginal birth for non-macrosomic TSV or intrapartum CS for macrosomic TSV should be considered when planning vaginal births.

Although prelabour CS was associated with a reduction in some adverse neonatal outcomes, specifically requiring resuscitation for macrosomic TSV, prelabour CS is associated with adverse maternal outcomes. In the general population, CS is associated with immediate risk to the mother of infection, haemorrhage, anaesthetic risks and mortality.[24] It is also associated with an increased likelihood of repeat elective CS in future pregnancies and increased risk of stillbirth and placenta praevia and accreta, uterine rupture, and peripartum hysterectomy.[24] The risk of adverse maternal outcomes following CS might be escalated for women with diabetes during pregnancy since they are at higher risk of adverse maternal outcomes (such as infection and impaired wound healing) than women without diabetes.[25]

CONCLUSION

Of mothers with planned vaginal birth, one in four gave birth to a macrosomic TSV by intrapartum CS and one in five gave birth to a non-macrosomic TSV by instrumental vaginal birth. The potential risk of adverse neonatal outcomes associated with intrapartum CS and instrumental vaginal birth should be considered when planning for birth of women with diabetes. Close monitoring and readiness to intervene are needed when planning labour for TSV, particularly when the baby is macrosomic as CS is often required to expedite birth.

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Contributors All authors were involved in the conception and design of the work and interpretation of the data for the manuscript. RZ was involved in initial drafting of the work. RZ, JL and AFW were involved in analysing the data. ALL authors were involved in the critical revision of the manuscript for intellectual content and approved the paper as submitted. All authors agree to be accountable for all aspects of the work and in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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BMJ Paediatrics Open

Neonatal outcomes of live-born term singletons in vertex presentation born to mothers with diabetes during pregnancy by mode of birth: a New South Wales population-based retrospective cohort study

Reem Zeki, Alex Y Wang, Kei Lui, Zhuoyang Li, Jeremy J N Oats, Caroline S E Homer and Elizabeth A Sullivan

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Figure S1: Onset of labour and mode of birth for mothers with pre-existing diabetes who gave birth to macrosomic and non-macrosomic TSV

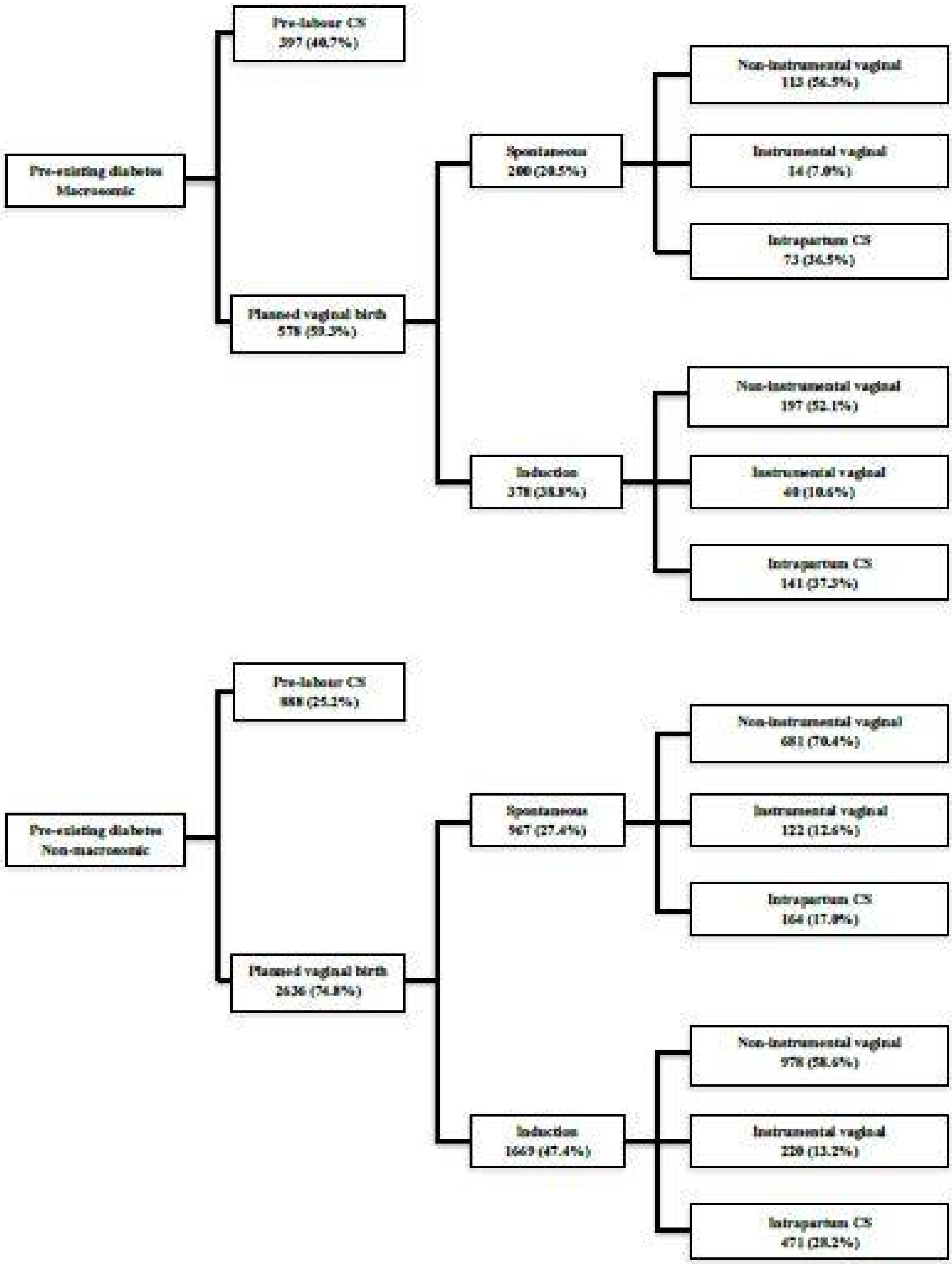
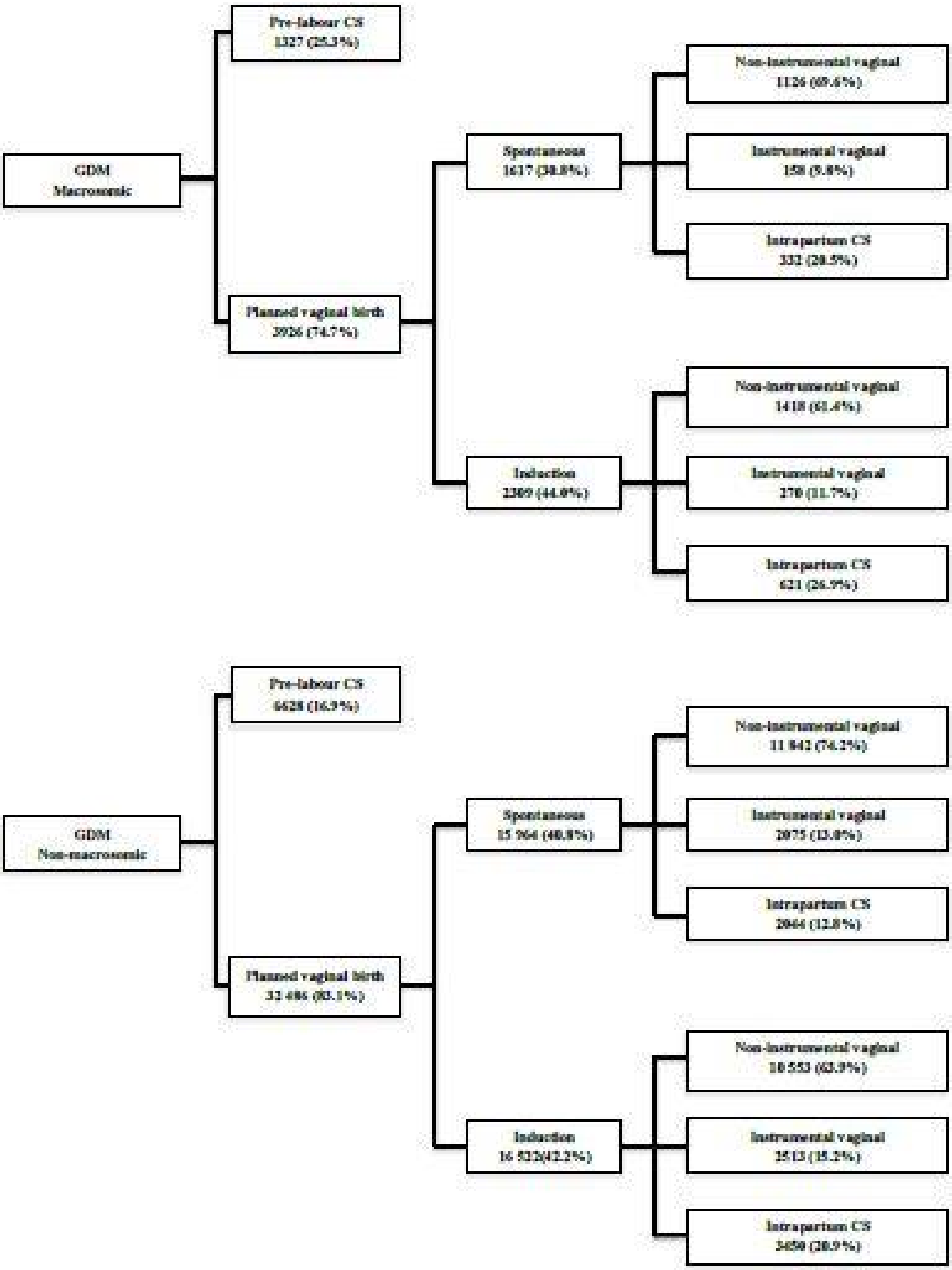


Figure S2: Onset of labour and mode of birth for mothers with GDM who gave birth to macrosomic and non-macrosomic TSV



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ANZJOG

ORIGINAL ARTICLE

Obstetric anal sphincter injuries among women with gestational diabetes and women without gestational diabetes: A NSW population-based cohort study

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Background: Obstetric anal sphincter injuries (OASIs) are associated with maternal morbidity; however, it is uncertain whether gestational diabetes (GDM) is an independent risk factor when considering birthweight mode of birth and episiotomy.

Aims: To compare rates of OASIs between women with GDM and women without GDM by mode of birth and birthweight. To investigate the association between episiotomy, mode of birth and the risk of OASIs.

Methods: A population-based cohort study of women who gave birth vaginally in NSW, from 2007 to 2013. Rates of OASIs were compared between women with and without GDM, stratified by mode of birth, birthweight and a multi-categorical variable of mode of birth and episiotomy. Adjusted odds ratios (aOR) and 95% confidence intervals (CI) were calculated by multivariable logistic regression.

Results: The rate of OASIs was 3.6% (95% CI: 2.6–2.7) vs 2.6% (95% CI: 3.4–2.8; $P < 0.001$) among women with and without GDM, respectively. Women with GDM and a macrosomic baby (birthweight ≥ 4000 g) had a higher risk of OASIs with forceps (aOR 1.76, 95% CI: 1.08–2.86, $P = 0.02$) or vacuum (aOR 1.89, 95% CI: 1.17–3.04, $P = 0.01$), compared with those without GDM. For primiparous women with GDM and all women without GDM, an episiotomy with forceps was associated with lower odds of OASIs than forceps only (primiparous GDM, forceps-episiotomy aOR 2.49, 95% CI: 2.00–3.11, forceps aOR 5.30, 95% CI: 3.72–7.54), (primiparous without GDM, forceps-episiotomy aOR 2.71, 95% CI: 2.55–2.89, forceps aOR 5.95, 95% CI: 5.41–6.55) and (multiparous without GDM, forceps-episiotomy aOR 3.75, 95% CI: 3.12–4.50, forceps aOR 6.20, 95% CI: 4.96–7.74).

Conclusion: Women with GDM and a macrosomic baby should be counselled about the increased risk of OASIs with both vacuum and forceps. With forceps birth, this risk can be partially mitigated by performing a concomitant episiotomy.

KEYWORDS
birth, birthweight, episiotomy, gestational diabetes, lacerations, obstetric anal sphincter injury, perineal trauma, perineum

INTRODUCTION

Obstetric anal sphincter injuries (OASIs) occurred in 4322 (2.1%) women who gave birth vaginally in Australia in 2012.[1] OASIs include both third- and fourth-degree perineal tears.[2] Third-degree tears are defined as perineal injury affecting the anal sphincter complex.[2] Fourth-degree perineal tears affect the anal mucosa and the anal sphincter complex.[2] Short- and long-term health problems have been reported to be associated with OASIs. Short-term complications can include perineal pain, oedema, bruising and urinary retention.[3,4] Long-term complications can include anxiety, depression, sexual dysfunction and anal incontinence, including flatal incontinence and leakage of stool.[3–5]

Several demographic factors have been identified as associating with OASIs. Asian ethnicity, maternal older age, first-time mother and giving birth in public hospitals are all associated with an increase in the risk of OASIs.[6–8] Instrumental vaginal birth, including forceps and vacuum births, has been identified as a major risk factor for OASIs.[7,9] Birthweight is associated with OASIs, with a New South Wales (NSW) population-based study showing a rate increase of 21% and 25% for every 200 g increase in birthweight, in primiparous and multiparous women, respectively.[6] For macrosomic babies (birthweight ≥ 4000 g), there was a significant increase with an adjusted odd ratio (aOR) of 2.64.[9] In addition to high birthweight, shoulder dystocia has been identified as an independent risk factor for OASIs.[10] Women with gestational diabetes mellitus (GDM) are at increased risk of OASIs due to the high birthweight baby compared to women without GDM.[6,7,11,12] Previously published research shows that among women with GDM, the OR of OASIs was 1.3 (95% CI: 1.1–1.6), compared to women without GDM.[7]

There is evidence that selective episiotomy can reduce the risk of OASIs.[2] A Cochrane systematic review shows that compared to routine episiotomy, selective episiotomy with spontaneous vaginal birth is associated with a slight reduction in the rate of OASIs.[13] The most recent Royal College of Obstetricians and Gynaecologists (RCOG) third and fourth degree tear green-top guideline recommended performing mediolateral episiotomy with instrumental vaginal birth, citing a significant reduction in OASI.[2] To date, no published population-based study has investigated the association between GDM and the risk of OASIs by both mode of birth and birthweight.

Our population-based study of women who gave birth vaginally in NSW has two aims:

1. to compare the rate of OASIs between women with or without GDM by mode of birth and birthweight and
2. to investigate the association between episiotomy, mode of birth and the risk of OASIs.

MATERIALS AND METHODS

Data source

The NSW Perinatal Data Collection (PDC) was used as the data source. The PDC is a population-based surveillance system that covers all births occurring in NSW public and private hospitals as well as home births. The PDC includes all live births and stillbirths of at least 20 weeks or at least 400 g birthweight.[14]

Information on maternal demographics, maternal health, pregnancy, obstetric complications, labour and birth as well as perinatal outcomes is included in the completed form. The NSW Ministry of Health receives the completed form, validates and compiles the information into a statewide PDC.[14]

Study population

All women who gave birth vaginally in NSW (465 124) from 1 January 2007 to 31 December 2013 were included. Women with pre-existing diabetes (2296, 0.5%) and women who had breech presentation (2518, 0.5%) were excluded from the analysis. Of the 460 310 women remaining in the analysis, 23 965 (5.2%) women had GDM and 436 345 (94.8%) women were without a diagnosis of GDM during pregnancy.

Study factors and outcome measurements

Gestational diabetes mellitus is defined as glucose intolerance that is diagnosed for the first time during pregnancy. It may include pregnancy-induced hyperglycaemia or undiagnosed hyperglycaemia that existed before pregnancy.[15]

Between 2007 and 2012, the Australian guidelines[16] recommended screening for GDM using the glucose challenge test (GCT) at 26–28 weeks gestation. A 75 g two-hour oral glucose tolerance test (OGTT) was recommended if the non-fasting GCT measured at one hour post-load plasma glucose level was:

- ≥7.8 mmol/L after 50 g glucose load, or
- ≥8.0 mmol/L after 75 g glucose load.

GDM was diagnosed if:

- fasting venous plasma glucose level was ≥5.5 mmol/L, and/or
- venous plasma glucose level was ≥8.0 mmol/L at two hours following the 75 g glucose load.

In 2013, a new guideline was published by the Australasian Diabetes In Pregnancy Society (ADIPS).[15] This guideline recommends routine testing for GDM at 24–28 weeks gestation using 75 g OGTT. GDM is diagnosed if:

- fasting glucose is ≥5.1 mmol/L or
- one-hour glucose is ≥10.0 mmol/L or
- two-hour glucose is ≥8.5 mmol/L.

The mode of birth includes spontaneous vaginal birth (vaginal birth which did not require instrumental assistance), and instrumental vaginal birth including both forceps and vacuum extraction. Episiotomy is recorded dichotomously as yes, no.

The outcome of the study was third- and fourth-degree perineal tears referred to as OASIs. In the PDC, perineal status is recorded as intact, first-degree tear/graze, second-degree tear, third-degree tear, fourth-degree tear, and 'other'. Third- and fourth-degree tears were combined, and all other types of tears were combined with 'intact'. A previously published validation study of the NSW PDC found third- and fourth-degree tears were adequately recorded in the PDC (Kappa value > 0.75).[17]

Statistical analysis

Maternal sociodemographic factors and obstetric characteristics were compared among women with GDM and women without GDM using a χ^2 test for categorical variables and an independent samples *t*-test for maternal age.

Two multivariate logistic regression models were employed. The first model investigated the ORs of OASIs for women with GDM compared with women without GDM. Data were stratified by macrosomia[18] and mode of birth (spontaneous vaginal birth, forceps delivery, and vacuum extraction). The second model investigated the likelihood of OASIs where an episiotomy was employed in the mode of birth.

Parity was included as an interaction term in the analysis to examine if it was an effect modifier. In model one (OASIs among women with GDM compared to women without GDM), parity was stratified into two groups: primiparous and multiparous for women who had a vacuum extraction and gave birth to macrosomic babies. For similar women who had either a spontaneous vaginal birth or forceps birth, the analysis was not stratified by parity as the interaction of parity with GDM was not significant. In model two (OASIs among women who had episiotomies and gave birth vaginally compared to women who had spontaneous vaginal birth without episiotomy), parity was found to be an effect modifier in the association between episiotomy and OASIs. For this reason, the analysis was stratified by parity. For model two, a multi-category variable was created for episiotomy and mode of birth, with spontaneous vaginal birth without episiotomy being the reference group.

Odds ratios, adjusted ORs (aOR), and 95% confidence intervals (CI) were produced. Variables associated with the outcomes in the univariate analysis ($P < 0.2$) and factors identified in the literature as potentially predictive were entered into the logistic regression model (univariate analysis for the covariate included in the model presented in Table S1). Adjustment for the first model was made for maternal age groups (<25 years, 25–34 years, and ≥35 years), maternal country of birth (Australian born, overseas born), parity (nullipara, multipara), plurality (singleton, multiple), last birth by caesarean section (yes, no), onset of labour (spontaneous, induction), episiotomy performed (yes, no), hospital sector (public, private), and baby sex (male, female), gestational age at birth (<37 weeks, ≥37 weeks). Adjustment for the second model was made for maternal age groups, maternal country of birth, plurality (singleton, multiple), last birth by caesarean section (yes, no), onset of labour (spontaneous, induction), hospital sector (public, private), baby sex (male, female), and birthweight (<4000 g, ≥4000 g). The percentages of combined episiotomy with mode of birth stratified by parity were calculated.

Details of ethics approval

The use of de-identified data was approved by the Executive Director, Centre for Epidemiology and Evidence, NSW Ministry of Health. Ethics approval was granted by University of Technology Sydney Human Research Ethics Committee (UTS HREC ETH16-0219).

RESULTS

During the period studied, 863 (3.6%) women with GDM had OASIs, and 11 561 (2.6%) women without GDM had OASIs ($P < 0.001$). The majority of women had third-degree perineal tears, 3.4% and 2.5% for women with and without GDM, respectively, with similar fourth-degree tear rates of 0.2% between the groups.

Table 1 presents the maternal and newborn characteristics of women with and without GDM. As seen in Table 1, regarding the baseline maternal and newborn characteristics, there were significant differences between women with and without GDM. Those with GDM were significantly older (≥35 years: 30.8% vs 19.5%, $P < 0.001$), more likely to be born overseas (51.4% vs 31.0%, $P < 0.001$), more likely to be induced (52.1% vs 28.6%, $P < 0.001$) and had a higher rate of episiotomy (20.5% vs 17.4%, $P < 0.001$). However, the GDM group had a lower rate of macrosomia (7.8% vs 11.4%, $P < 0.001$). Among women who gave birth to macrosomic babies, there was no significant difference in the percentage of instrumental vaginal birth between women with GDM (14.7%) and those without GDM (15.7%; $P = 0.29$).

The results of the multivariate analysis are shown in Table 2. For women who gave birth to macrosomic babies, the odds of OASIs were significantly higher among women with GDM who gave birth by forceps (aOR 1.76, 95% CI: 1.08–2.86) or vacuum (aOR 1.89, 95% CI: 1.17–3.04) compared to women without GDM. Women with GDM who gave birth to macrosomic babies by spontaneous vaginal birth did not have a significant increase in the odds of OASIs (aOR 1.07, 95% CI: 0.79–1.43) compared with those without GDM.

A subgroup analysis, by parity, of women with macrosomic babies, showed vacuum births in multiparous women with GDM had a significant increase in the odds of OASIs compared to women without GDM (aOR 2.66, 95% CI: 1.14–6.22). There was no statistically significant increase in the primiparous groups (aOR 1.67, 95% CI: 0.94–2.98).

Table 3 compares the rates of episiotomy, in women with and without GDM, analysed by parity and mode of birth. For primarous and multiparous women who had spontaneous vaginal birth, there was a statistically significant difference in rates of episiotomy, when comparing GDM status ($P < 0.001$). This difference was not statistically significant for primiparous ($P = 0.68$) and multiparous ($P = 0.05$)

TABLE 1 Maternal and newborn characteristics of women who had gestational diabetes mellitus (GDM) and women without GDM

	Without GDM (*n* = 436 345)	With GDM (*n* = 23 965)	
	n (%)	*n* (%)	*P*-value‡
Age, years			
Mean (SD)	29.5 (5.6)	31.7 (5.2)	<0.001
Less than 25	86 451 (19.8)	2090 (8.7)	<0.001
25-34	264 791 (60.7)	14 485 (60.4)	
35 or more	85 023 (19.5)	7389 (30.8)	
Not stated	80 (0.0)	1 (0.0)	
Country of birth			
Australian born	299 042 (68.5)	11 529 (48.1)	<0.001
Overseas born	135 364 (31.0)	12 326 (51.4)	
Not stated	1939 (0.4)	110 (0.5)	
Parity			
Nulliparous	183 742 (42.1)	9995 (41.7)	0.185
Multiparous	252 258 (57.8)	13 969 (58.3)	
Not stated	345 (0.1)	1 (0.0)	
Last birth by caesarean section†			
Yes	11 476 (4.5)	565 (4.0)	0.005
No	240 691 (95.4)	13 399 (95.9)	
Not stated	91 (0.0)	5 (0.0)	
Onset of labour			
Spontaneous	311 695 (71.4)	11 473 (47.9)	<0.001
Induced	124 601 (28.6)	12 491 (52.1)	
Not stated	49 (0.0)	1 (0.0)	
Mode of birth			
Spontaneous vaginal birth	366 255 (83.9)	19 595 (81.8)	<0.001
Forceps	24 634 (5.6)	1666 (7.0)	
Vacuum	45 456 (10.4)	2704 (11.3)	
Plurality			
Singleton	433 210 (99.3)	23 743 (99.1)	<0.001
Multiple	3135 (0.7)	222 (0.9)	
Episiotomy			
Yes	75 852 (17.4)	4923 (20.5)	<0.001
No	360 412 (82.6)	19 041 (79.5)	
Not stated	81 (0.0)	1 (0.0)	
Hospital sector			
Public	34 2317 (78.5)	20 287 (84.7)	<0.001
Private	89 257 (20.5)	3549 (14.8)	
Home birth/birth before arrival	4771 (1.1)	129 (0.5)	
Baby sex			
Male	221 297 (50.7)	12 157 (50.7)	0.988
Female	214 932 (49.3)	11 805 (49.3)	
Not stated	116 (0.0)	3 (0.0)	

(Continues)

TABLE 1 (Continued)

	Without GDM (n = 436 345)	With GDM (n = 23 965)	
	n (%)	n (%)	P-value‡
Birthweight, g			
Less than 3000	80 855 (18.5)	5831 (24.3)	<0.001
3000–3499	164 912 (37.8)	9951 (41.5)	
3500–3999	140 487 (32.2)	6310 (26.3)	
4000 and over	49 738 (11.4)	1863 (7.8)	
Not stated	354 (0.1)	10 (0.0)	
Gestational age (weeks)			
Less than 37	22 069 (5.1)	1507 (6.3)	<0.001
37 and over	414 206 (94.9)	22 456 (93.7)	
Not stated	70 (0.0)	2 (0.0)	

†Mutipara only.
‡Excludes not stated values.

TABLE 2 Obstetric anal sphincter injuries (OASIs) by mode of birth, birthweight and gestational diabetes mellitus (GDM)

	OASIs number (%)			
Mode of birth	Without GDM (reference group)	With GDM	OR (95% CI)	aOR† (95% CI)
Birthweight < 4000 g				
Spontaneous vaginal birth	5582/323 924 (1.7)	439/17 995 (2.4)	1.43 (1.29–1.57)	1.21* (1.09–1.34)
Forceps	2063/21 434 (9.6)	184/1546 (11.9)	1.27 (1.08–1.49)	1.13 (0.96–1.33)
Vacuum	1860/40 813 (4.6)	145/2550 (5.7)	1.26 (1.06–1.5)	1.15 (0.96–1.37)
Birthweight ≥ 4000 g				
Spontaneous vaginal birth	1273/41 922 (3.0)	50/1590 (3.1)	1.04 (0.78–1.38)	1.07 (0.79–1.43)
Forceps	413/3180 (13.0)	23/120 (19.2)	1.59 (1.00–2.53)	1.76* (1.08–2.86)
Vacuum	369/4618 (8.0)	22/153 (14.4)	1.93 (1.22–3.08)	1.89* (1.17–3.04)

*$P < 0.05$.
†aOR, odd ratios were adjusted for maternal age, maternal country of birth, parity, plurality, hospital sector, last birth by caesarean section, onset of labour, episiotomy, baby sex and gestational age.

TABLE 3 Percentage of women who had episiotomy by mode of birth, parity and gestational diabetes mellitus (GDM)

Parity	Without GDM n (%)	GDM n (%)	P-value
Primiparous			
Episiotomy and spontaneous vaginal birth	21 239 (16.5)	1332 (20.4)	<0.001
Episiotomy and forceps	16 973 (82.2)	1145 (82.7)	0.68
Episiotomy and vacuum	18 650 (54.1)	1172 (56.4)	0.04
Multiparous			
Episiotomy and spontaneous vaginal birth	13 143 (5.5)	871 (6.7)	<0.001
Episiotomy and forceps	2511 (63.0)	193 (68.9)	0.05
Episiotomy and vacuum	3303 (30.2)	209 (33.4)	0.083

women who had forceps-assisted birth and multiparous women who had vacuum extraction (P = 0.083). The percentage of episiotomy among primiparous women with GDM who had vacuum extraction was slightly higher than those without GDM (P = 0.04; Table 3).

Table 4 presents the ORs of OASIs by episiotomy and mode-of-birth, using the spontaneous vaginal birth without episiotomy, analysed by GDM status and parity. Primiparous women with GDM, who had a forceps-assisted birth, had the highest odds of OASIs (aOR 5.30, 95% CI: 3.72–7.54). This OR was reduced to 2.49 (95% CI: 2.00–3.11) when episiotomy was performed. For primiparous women without GDM, combined episiotomy with forceps birth or vacuum extraction significantly lowered the odds of OASIs (from 5.95, 95% CI: 5.41–6.55, to 2.71, 95% CI: 2.55–5.89 forceps) and (from 1.99, 95% CI: 1.89–2.14, to 1.44, 95% CI: 1.33–1.55 vacuum). A subgroup analysis was done for primiparous women who gave birth to macrosomic babies. Among women with GDM, episiotomy with forceps reduces the OR of OASIs from 5.38 (95% CI: 1.42–20.38) to 3.21 (95% CI: 1.47–7.05) compared to forceps alone. However, this reduction was not statistically significant. For primiparous women without GDM, the odds of OASIs were lower for women who had an episiotomy with forceps than women who did not have an episiotomy, (from 4.07, 95% CI: 3.15–5.26, to 1.86, 95% CI: 1.58–2.18).

TABLE 4 Obstetric anal sphincter injuries (OASIs) by mode of birth, episiotomy and gestational diabetes mellitus (GDM)

	OASIs number (%)	OR (95% CI)	aOR† (95% CI)
With GDM			
Primiparous			
Spontaneous vaginal birth-no episiotomy	258/5198 (5.0)	Reference	Reference
Spontaneous vaginal birth-episiotomy	66/1332 (5.0)	1.00 (0.76–1.32)	0.97 (0.73–1.29)
Forceps-no episiotomy	47/240 (19.6)	4.66 (3.31–6.57)	5.30* (3.72–7.54)
Forceps-episiotomy	141/1145 (12.3)	2.69 (2.17–3.34)	2.49* (2.00–3.11)
Vacuum-no episiotomy	71/907 (7.8)	1.63 (1.24–2.14)	1.79* (1.35–2.36)
Vacuum- episiotomy	79/1172 (6.7)	1.38 (1.07–1.80)	1.42* (1.09–1.86)
Multiparous			
Spontaneous vaginal birth-no episiotomy	143/12 192 (1.2)	Reference	Reference
Spontaneous vaginal birth-episiotomy	22/871 (2.5)	2.18 (1.39–3.44)	2.47* (1.55–3.93)
Forceps-no episiotomy	5/87 (5.7)	5.14 (2.05–12.86)	5.65* (2.21–14.43)
Forceps-episiotomy	14/193 (7.3)	6.59 (3.73–11.63)	5.23* (2.85–9.60)
Vacuum-no episiotomy	7/416 (1.7)	1.44 (0.67–3.10)	1.56 (0.72–3.38)
Vacuum-episiotomy	10/209 (4.8)	4.23 (2.20–8.16)	3.85* (1.94–7.64)
Without GDM			
Primiparous			
Spontaneous vaginal birth-no episiotomy	3822/107 332 (3.6)	Reference	Reference
Spontaneous vaginal birth-episiotomy	827/21 234 (3.9)	1.09 (1.01–1.18)	1.10* (1.02–1.19)
Forceps-no episiotomy	612/3664 (16.7)	5.44 (4.96–5.97)	5.95* (5.41–6.55)
Forceps-episiotomy	1620/16 972 (9.5)	2.87 (2.70–3.04)	2.71* (2.55–2.89)
Vacuum-no episiotomy	968/15 823 (6.1)	1.77 (1.64–1.90)	1.99* (1.85–2.14)
Vacuum- episiotomy	932/18 648 (5.0)	1.42 (1.32–1.53)	1.44* (1.33–1.55)
Multiparous			
Spontaneous vaginal birth-no episiotomy	1966/224 097 (0.9)	Reference	Reference
Spontaneous vaginal birth-episiotomy	237/13 142 (1.8)	2.07 (1.81–2.38)	2.06* (1.79–2.36)
Forceps- no episiotomy	97/1472 (6.6)	7.91 (6.40–9.76)	6.20* (4.96–7.74)
Forceps- episiotomy	147/2511 (5.9)	7.03 (5.93–8.35)	3.75* (3.12–4.50)
Vacuum-no episiotomy	226/7644 (3.0)	3.45 (3.00–3.96)	3.11* (2.69–3.59)
Vacuum- episiotomy	100/3302 (3.0)	3.61 (2.95–4.41)	2.34* (1.89–2.89)

*$P < 0.05$.
†aOR, odd ratios were adjusted for maternal age, maternal country of birth, plurality, hospital sector, last birth by caesarean section, the onset of labour, baby sex and birthweight.

DISCUSSION

Our study results show that women with GDM who gave birth to macrosomic babies and had an instrumental vaginal birth had an increase in the odds of OASIs compared to women without GDM. However, this association was not significant among women who gave birth to macrosomic babies by spontaneous vaginal birth. This study confirms that among primiparous women with GDM and all women without GDM, that when a forceps birth is indicated, performing an episiotomy is protective against OASIs.

Gestational diabetes is associated with an increase in birthweight[19] and the risk of shoulder dystocia when compared with women without GDM giving birth to babies within the same birthweight group.[20,21] In addition, among women with GDM, instrumental vaginal birth is associated with increased risk of shoulder dystocia compared to spontaneous vaginal birth.[22] The combination of these risk factors may explain why women with GDM who gave birth to macrosomic babies by instrumental vaginal birth had significantly higher odds of having OASIs compared to women without GDM. This interaction could be supported by our findings that there was no significant increase in odds of OASIs in GDM women who gave birth to macrosomic babies spontaneously or in women without GDM with instrumental birth to babies less that 4000 g. However, these non-significant results may be due to the small numbers in these subgroups.

Previously published studies show that an episiotomy with an instrumental vaginal birth is associated with reducing the risk of OASIs.[6,10,23] Guidelines published by both the Royal College of Obstetricians and Gynaecologists (RCOG) in 2011[24] and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists in 2016[25] state that in the absence of robust evidence, routine episiotomy with instrumental delivery cannot be recommended and that the use of an episiotomy should be at the decision of the operator. In contrast, the 2015 RCOG practice guideline (The Management of Third- and Fourth-Degree Perineal Tears) recommends performing an episiotomy with instrumental births.[2] Our results among primiparous women with GDM and all women without GDM confirm the results published by Ampt *et al.* (2013) and Gurol-Urganci *et al.* (2013) that an episiotomy with forceps birth reduces the odds of OASIs compared to forceps alone.[6,10] However, we found that episiotomy at the time of spontaneous vaginal birth increased the odds of OASIs among multiparous women with and without GDM. In contrast, among primiparous women with GDM having a spontaneous vaginal birth, there was no difference with episiotomy. Even though episiotomy with spontaneous vaginal birth was associated with statistically significant increase in the odds of OASIs among primiparous women without GDM, this increase may not be clinically significant as the difference in the percentage of OASIs was only 0.3% between spontaneous vaginal birth with and without episiotomy.

Strengths and limitations

A strength of this study is the use of the PDC, a statewide epidemiological collection of all births in NSW. We provide population-based evidence of an association between episiotomy and a reduction of OASIs among women with GDM. However, a validation study of the GDM detection in PDC shows a sensitivity of 63.3% (95% CI: 49.4–75.7).[26] This sensitivity suggests information bias as it reflects the period before the 2013 ADIPS guideline stating all women should have universal screening for GDM.[15] Therefore, our findings should be interpreted with this caveat.

A limitation of this study is that information on shoulder dystocia is not collected or available from the PDC; therefore, we were unable to adjust for this condition in the analysis. Country of birth was used as a proxy for the OASIs and GDM risk factor[10,27] ethnicity, which was not available in the PDC. There was no information available on the compliance of antenatal care providers to the ADIPS GDM screening and diagnosis guidelines.

CONCLUSION

There was a higher rate of OASIs among women with GDM. The risk of OASIs associated with instrumental births and birthweight ≥4000 g should be discussed with women with GDM. Our results among primiparous women with GDM and all women without GDM who have forceps birth provide evidence to support the RCOG's general recommendation to perform mediolateral episiotomy with instrumental vaginal birth.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1. Univariate analysis.

Table S1: Univariate analysis

	Crude OR (95%CI)	P value
Age (Years)		
less than 25	REF	REF
25 - 34	1.21(1.16-1.27)	<0.001
35 or more	0.73(0.68-0.78)	<0.002
Country of Birth		
Australian born	REF	REF
Overseas born	1.81(1.75-1.88)	<0.001
Parity		
Nulliparous	4.53(4.34-4.72)	<0.001
Multiparous	REF	REF
Last birth by caesarean section		
Yes	1.94 (1.78-2.11)	<0.001
No	REF	REF
Onset of labour		
Spontaneous	REF	REF
Induced	1.09 (1.05-1.13)	<0.001
Plurality		
Singleton	REF	REF
Multiple	0.45 (0.33-0.61)	<0.001
Episiotomy		
Yes	2.48 (2.38-2.57)	<0.001
No	REF	REF
Hospital sector		
Public	REF	REF
Private	0.44 (0.41-0.46)	<0.001
Baby sex		
Male	1.18 (1.14-1.22)	<0.001
female	REF	REF
Macrosomic		
Yes	1.68 (1.6-1.76)	<0.001
No	REF	REF
Term		
Yes	REF	REF
No	0.34 (0.29-0.8)	<0.001

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