

Accuracy of estimated fetal weight using ultrasound at term
in pregnant women diagnosed with gestational and pre-
gestational diabetes at Groote Schuur Hospital



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DECLARATION BY APPLICANT

I, Mareli Venter, declare that the work contained in this dissertation is my original work and work by others has been acknowledged as such.

The study was carried out while I was a registrar in the Department of Obstetrics and Gynaecology at the University of Cape Town as required for the MMed (O&G).

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ABSTRACT

Background

The incidence of diabetes is rising globally. Similarly, there has also been a rise in the incidence of diabetes in pregnancy, both pre-gestational as well as gestational. These patients are at risk of multiple perinatal complications, including macrosomia. There is an increased risk of perinatal complications with a fetal weight at birth of more than 4 000 g, especially if macrosomia occurs in the context of diabetes. In order to predict fetal macrosomia, fetal weight estimation remains an important component of antenatal surveillance. Despite the relative inaccuracy of ultrasound fetal weight estimation, the current National Institute for Health and Care Excellence (NICE) guideline on the care of diabetic patients, recommends offering 4 weekly ultrasound scans from 28 to 36 weeks to assess fetal growth and wellbeing. In addition, the Western Cape guidelines recommend offering an elective caesarean section to diabetic patients with an estimated fetal weight of 4 000 g or more at term with a fetal abdominal circumference greater than the 90th percentile. This practice has subsequently resulted in a large number of caesarean deliveries performed to prevent fetal and maternal complications related to presumed macrosomia.

Objectives

The aim of this study was to assess the accuracy of ultrasound fetal weight estimation performed in diabetic women at term, as well as to determine the incidence of macrosomia in the study population and the accuracy of ultrasound identification of macrosomia.

Methods

A retrospective audit was undertaken in women who attended antenatal services at Groote Schuur Hospital (GSH). This study reviewed women with an abnormal glucose tolerance test (GTT) during pregnancy or with known diabetes preceding pregnancy attending GSH during a 12-month period were included. Women with a singleton pregnancy at 36 weeks or more that underwent a documented ultrasound for fetal weight estimation within 7 days of delivery were included in this audit.

Results

A total of 97 women in the study population met the inclusions criteria. Seventy patients (72%) had gestational diabetes and 22 (18%) had pre-gestational diabetes. Ultrasound weight estimations were accurate to within 10% of birth weight in 70,1% of all patients. Eleven (11,3%) patients had macrosomic (> 4 000 g) babies. In these patients only 54,5% of fetal weight estimations were accurate to within 10% of birth weight. Ultrasound for detection of macrosomia had a sensitivity of 58,3% (CI: 36-82%) and a specificity of 96,5% (CI: 93-99%).

Conclusion

The accuracy of ultrasound fetal weight estimation performed in diabetic patients at GSH appears similar to that of other international studies. Ultrasound estimations become increasingly inaccurate in extremes of fetal weight. One in four fetal weight estimations had an estimation error of > 10% with a tendency towards underestimation in macrosomic fetuses. Ultrasound fetal weight estimation as a predictor for fetal macrosomia should therefore remain under scrutiny, especially in the context of the high perinatal morbidity associated with macrosomia and shoulder dystocia as well as the rising litigation related to birth complications.

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ABBREVIATIONS

ACOG	American College of Obstetricians and Gynaecologists
BMI	Body mass index
BW	Birth weight
DM	Diabetes Mellitus
EFW	Estimated fetal weight
GDM	Gestational diabetes
GSH	Groote Schuur Hospital
GTT	Glucose tolerance test
HAPO	Hyperglycaemia and adverse pregnancy outcomes
IADPSG	International association of diabetes and pregnancy study group
IDF	International Diabetes Federation
IGT	Impaired glucose tolerance
MOU	Midwife Obstetric Unit
NICE	National institute for health and care excellence
RCOG	Royal College of Obstetricians and Gynaecologists
USA	United States of America

CHAPTER 1

Background and Literature Review

Introduction

Diabetes mellitus (DM) has a rapidly rising global incidence with an estimated 366 million people affected in 2011. This is according to global estimates compiled by the International Diabetes Federation (IDF), based on data from 170 selected data sources from 110 countries. The global incidence is expected to rise by 50.7% with an expected 552 million people affected by DM in 2030. An alarming increase in incidence of 92% is predicted for low-income countries. The African continent is expected to have the largest proportional increase in numbers by 2030. In South Africa, the IDF estimated the incidence of DM to be 7% among adults between the age of 20 and 79 years in 2011. The incidence is amongst the highest in Africa and is expected to rise to 7,9% in 2030. ^[1]

Motala et al. conducted a cross sectional survey in a rural South African community of Zulu descent, using the 1998 World Health Organization criteria for disorders of glycaemia. They found a moderate age-adjusted prevalence of 3,9% for DM. The age-adjusted prevalence for total disorders of glycaemia (including impaired glucose tolerance and impaired fasting glycaemia) was as high as 10,2%. Eighty-four percent of the cases of DM were newly diagnosed during the survey. ^[2]

Diabetes in pregnancy

With the rising burden of DM globally, hyperglycaemia in pregnancy poses a major threat to maternal health worldwide. Global estimates presented by the IDF indicate a high prevalence. An estimated 21,4 million live births, with a rate of 170 cases per 1 000 live births, were affected by hyperglycaemia in pregnancy in 2013. More than 90% of these cases occurred in low- and middle-income countries. ^[1]

It is postulated that the DM epidemic is driven by lifestyle changes attributed to urbanization and development. Inadequate nutrition as well as a low level of physical activity leads to central obesity and an increased risk of metabolic disorders including DM. In high-income and upper-middle income countries changing fertility patterns are also

affecting the prevalence of hyperglycaemia in pregnancy as women often opt to have children later in their lives. The prevalence of hyperglycaemia in pregnancy is estimated to be as high as 39,2% at the age of 40 years or older. ^[3]

Approximately 5% of pregnancies in England and Wales are complicated by diabetes. It is estimated that 87,5% of these patients have gestational diabetes, 7,5% Type 1 diabetes and 5% Type 2 diabetes. ^[4] In the United States, when using the traditional diagnostic criteria, the incidence of diabetes in pregnancy is 6 to 7%. ^[5]

There is a paucity of available literature on the incidence of diabetes in pregnancy in South Africa. One study conducted by Mamabolo et al. in the Limpopo province, found an 8,8% rate of gestational diabetes. This study included 262 women and screening was done in the third trimester of pregnancy. ^[6]

Diagnostic criteria

The International Association of Diabetes and Pregnancy Study Group (IADPSG) proposed new criteria to diagnose diabetes in pregnancy in 2010. This was based on the findings of the landmark hyperglycaemia and adverse pregnancy outcomes (HAPO) study. This multi-center cross sectional study found strong evidence to suggest that maternal glucose levels lower than the diagnostic levels for diabetes in pregnancy, is also associated with adverse pregnancy outcomes. The IADPSG suggests two phase screening in pregnancy. This consists of early screening, aimed at diagnosing women with pre-existing diabetes not previously diagnosed, as well as an oral glucose tolerance test (GTT) at 24 to 28 weeks' gestation in all women not previously found to have diabetes. If the fasting blood glucose is 7,0 mmol/l or more, diabetes is diagnosed. Gestational diabetes is diagnosed if the fasting blood sugar is > 5,1 mmol/l, the 1-hour blood sugar > 10,0 mmol/l or the 2-hour blood sugar > 8,5 mmol/l. These values are much lower than those used previously. If these criteria are adopted, this will lead to a marked increase in the incidence of diabetes in pregnancy. When using these criteria, the global incidence is estimated at 17%. ^[3,7] These criteria have not yet been widely adopted in the South African setting.

Pregnancy complications

In pregnancy, diabetes is associated with multiple perinatal complications. The diabetic mother is at an increased risk of pre-eclampsia and preterm labour. The fetus of the diabetic mother is at an increased risk of congenital malformations, perinatal mortality and stillbirth, as well as macrosomia and its associated morbidity. ^[4]

The exact definition of macrosomia remains contentious. The Royal College of Obstetricians and Gynaecologists (RCOG) defines macrosomia as a fetal weight at birth of 5 000 g or more in normal pregnancies or a fetal weight at birth of 4 500 g or more in pregnancies affected by diabetes. ^[8] The American College of Obstetricians and Gynecologists (ACOG) is more conservative, with macrosomia defined as a fetal weight at birth greater than 4 500 g as both fetal and maternal morbidity shows a sharp increase at this cut off. It is, however, recognized that the risk is already increased with a fetal weight at birth of more than 4 000 g. ^[9]

Maternal risks specifically associated with a macrosomic fetus include prolonged or obstructed labour, operative vaginal delivery, increased risk of caesarean delivery, perineal trauma, post-partum haemorrhage and uterine rupture. The macrosomic fetus is at risk of shoulder dystocia with or without trauma e.g. brachial plexus injury or fractures. There is also an increased risk of birth asphyxia, meconium aspiration and the need for assisted ventilation. The risk of mortality increases proportionately to weight and rises sharply in infants who weigh 5 000 g or more. ^[10, 11]

Langer et al. examined a cohort of 75 979 women who delivered vaginally and stratified them into a diabetic and a non-diabetic group. In the non-diabetic group, 7,6% of the women delivered a baby with a birth weight of 4 000 g or more, compared to 20,6% of the women in the diabetic group. The rate of shoulder dystocia in the non-diabetic group was 0,3%, compared to a 3,2% rate in the diabetic patients. There was a 3-fold higher risk for shoulder dystocia in diabetic patients with a macrosomic fetus. ^[12] The increased risk of shoulder dystocia in macrosomic fetuses in the diabetic population can be explained by the different patterns of fat distribution in the non-diabetic and diabetic fetus. In the fetus of a non-diabetic mother, large fetal size is generally genetically determined with the fat distribution similar to that of smaller fetuses. In diabetic patients the fetus is exposed to

high plasma glucose levels during pregnancy, leading to fetal hyper-insulinaemia. Insulin acts as a growth factor and increased levels lead to a disproportionate deposition of fat in the fetal trunk and shoulders, as well as organomegaly. This results in an increased abdominal and shoulder circumference, which in turn leads to an increased risk for shoulder dystocia. ^[12]

Nassar et al., in their work across a 12-year period between 1984 and 1996, described a 7,7% risk of fetal trauma in patients who delivered a macrosomic fetus weighing more than 4 500 g vaginally. ^[13]

Rouse et al., in their review of qualitative data, described the risk of brachial plexus injury with shoulder dystocia to be 9% in fetuses weighing less than 4 000 g, 18% if the fetal weight is between 4 000 g and 4 499 g and 26% with a fetal weight of 4 500 g or more. Many of these injuries recovered over time, although the probability of a brachial plexus injury resulting in permanent disability was 6,7% in their review. ^[14]

Fetal weight estimation in the diabetic population, therefore, remains an important component of antenatal surveillance, especially in the late third trimester.

Methods of estimating fetal weight

Prior to real-time ultrasound being widely accessible, clinical fetal weight estimation was the gold standard. A retrospective cohort study by Goetzinger et al. evaluated the accuracy of clinical fetal weight estimation in 3 797 patients at term. The correlation between clinical estimation and actual birth weight was poor, with an absolute error in clinical estimate of more than 500 g in 24,8% of patients. Body mass index (BMI), fetal station and admission diagnosis did not play a statistically significant role. Clinical weight estimations had a very low detection rate for fetal macrosomia (fetal weight > 4 000 g) with only 18,1% of macrosomic fetuses correctly identified antenatally. ^[15]

The initial assumption was that ultrasound fetal weight estimation would be superior to clinical estimates. A number of studies have subsequently compared different methods of fetal weight estimation including clinical palpation, maternal estimation and ultrasound estimation. In 2002 in the USA, Diase and Monga found no statistically significant

difference in the accuracy of fetal weight estimation when comparing these 3 different methods in 32 diabetic patients at term. ^[16] A larger study, including 200 patients, by Baum et al. directly compared clinical palpation with ultrasound fetal weight estimation. Patients with singleton pregnancies at 37 to 42 weeks' gestation were included in this study. They concluded that ultrasound was not superior to clinical estimation, with 64% of clinical estimates compared to 62,5% of ultrasound estimates being within 10% of actual birth weight. ^[17]

At the extremes of fetal weight clinical estimates become less accurate. In low birth weight fetuses (< 2 500 g), ultrasound estimation of fetal weight has been shown to be more accurate than clinical estimation. In the macrosomic group (> 4 000 g) both ultrasound and clinical estimates become more inaccurate, with ultrasound underestimating and clinical palpation overestimating the number of macrosomic fetuses according to a Nigerian study by Shittu et al. ^[18] A systematic underestimation of fetal weight in diabetic patients was noted in a New Zealand study by Colman et al. ^[19] Wong et al. reported similar findings in a study in 2001 and the authors suggested that diabetes in pregnancy could lead to an increase in soft tissue mass and liver size in these fetuses. The ultrasound formulae might therefore be less accurate as it does not account for this difference. ^[20]

However, a study by Alsulyman et al. found no statistically significant difference in the mean absolute percent error and therefore in the accuracy of fetal weight prediction between the diabetic and non-diabetic population when matched for maternal body mass index and birth weight ($9,0\% \pm 7,1\%$ vs. $8,4\% \pm 6,3\%$). They concluded that a birth weight of more than 4 500 g rather than maternal diabetes influenced the accuracy of ultrasound fetal weight estimation. Hadlock's formula for fetal weight prediction demonstrates a mean absolute error of 13% when the birth weight is > 4 500 g compared to only 8% with a birth weight below 4 500 g. ^[21]

A study conducted by Ben-Haroush et al. in Israel consisted of 840 women with singleton pregnancies who had an ultrasound fetal weight estimation within 3 days of undergoing induction of labour. They demonstrated a good correlation between the sonographic estimated fetal weight and birth weight with an overall accuracy to within 10% of birth

weight in 74,4% of patients. They noted that independent factors that significantly reduced the accuracy of ultrasound estimation of fetal weight included prematurity, increased birth weight, anterior placental location, higher gravidity and younger maternal age, although this was not thought to have clinical significance. The study cohort included both diabetic and non-diabetic patients. Seventy-four (8,8%) of patients in this study had fetuses with a birth weight greater than 4 000 g. The sensitivity and specificity of ultrasound in the prediction of macrosomia in this group was 47% and 95% respectively, with a positive predictive value of 46% and a negative predictive value of 95%. [22]

Ultrasound fetal weight estimation

The earliest method of ultrasound fetal weight estimation included only an abdominal circumference method. Further attempts to improve the accuracy led to the use of multiple growth parameters in different regression equations or volumetric formulae. A systematic review published by the International Society of Ultrasound in Obstetrics and Gynaecology in 2004 compared multiple different methods. They concluded that there was no statistically significant difference between the accuracy of these different methods. [23]

In the systematic review by the International Society of Ultrasound in Obstetrics and Gynaecology, inter- and intra-observer variability remained a significant factor affecting the accuracy of ultrasound fetal weight estimation. The proposed methods to minimize this include:

- multiple measurements
- optimal image quality
- uniform equipment calibration
- appropriate measurement methods. [23]

Ultrasound in pregnancies complicated by diabetes

Despite these previous studies, the current National Institute for Health and Care Excellence (NICE) guideline on the care of diabetic patients recommends offering ultrasound 4 weekly from 28 to 36 weeks to assess fetal growth and wellbeing. [4]

The South African national guidelines recommend a dating ultrasound for all patients. In addition, it is recommended that diabetic patients have a nuchal translucency scan as well as a detailed fetal anomaly scan done at a specialist level hospital. ^[24] The current protocol for management of diabetic patients at Groote Schuur Hospital (GSH) goes further and recommends that ultrasound to measure growth be done at 4 weekly intervals commencing at 28 weeks. In addition, the Western Cape guidelines recommend offering an elective caesarean section to diabetic patients with an estimated fetal weight of 4000 g or more at term with a fetal abdominal circumference greater than the 90th centile. ^[25] This is also the practice at the Maternity Centre at GSH and has subsequently resulted in a large number of caesarean deliveries performed to prevent fetal and maternal morbidity related to presumed macrosomia.

Caesarean section for suspected macrosomia

Rouse et al. found a rate of 489 caesarean sections done for infants with a suspected birth weight greater than 4 000 g in diabetic patients to prevent one case of permanent brachial plexus injury. ^[14]

There has been much debate on an acceptable caesarean section rate globally with a wide range in both developed and developing countries. The national caesarean section rate is 23% as published in the Saving Mothers report (2011 – 2013). Haemorrhage remains an important cause of maternal mortality both in South Africa and worldwide. The high number of maternal deaths related to haemorrhage associated with caesarean delivery has also been highlighted in the latest confidential enquiries, with caesarean delivery having a 2,8-fold higher risk of mortality when compared to vaginal delivery. ^[26] When comparing the maternal morbidity and mortality associated with caesarean section with the fetal benefit and number needed to treat, one has to question the current practice of caesarean delivery in mothers with suspected macrosomic fetuses.

As such, ultrasound fetal weight estimation as a predictor for fetal macrosomia should remain under scrutiny in the context of the high morbidity associated with caesarean section. The focus needs to remain on improving both the accuracy of fetal weight estimation and the detection of macrosomic fetuses.

Aims

The aim of this study is to assess the accuracy of ultrasound fetal weight estimation, performed in diabetic women with a singleton pregnancy at 36 weeks or more, at Groote Schuur Hospital, over the period of 1 September 2010 to 31 August 2011.

Primary objectives:

- To evaluate the institutional accuracy of ultrasound fetal weight estimation in singleton term pregnancies in women with gestational and pre-gestational diabetes, compared to birth weight.
- To determine the incidence of macrosomia in our study population.
- To assess the rate of accurate identification of macrosomia in diabetic patients.

Secondary objectives:

- To compare the accuracy of ultrasound fetal weight estimation in diabetic patients at our institution to that of international study results.
- To review the practice of routine ultrasound fetal weight estimation at term in diabetic patients to guide decisions with regard to mode of delivery.

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CHAPTER 2

Title: Accuracy of estimated fetal weight using ultrasound at term in pregnant women diagnosed with gestational and pre-gestational diabetes at Groote Schuur Hospital

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Abstract

Background

The incidence of diabetes in pregnancy is rising globally. These patients are at risk of multiple perinatal complications, including macrosomia. In order to predict fetal macrosomia, fetal weight estimation remains an important component of antenatal surveillance.

Objectives and methods

This retrospective audit assessed the accuracy of ultrasound fetal weight estimation and the identification of macrosomia in diabetic women at term. Our study reviewed women with diabetes in pregnancy who attended antenatal services at Groote Schuur Hospital (GSH) during a 12-month period. Patients at ≥ 36 weeks that underwent ultrasound fetal weight estimation within 7 days of delivery were included.

Results

Ninety-seven women in the study population met the inclusion criteria. Ultrasound weight estimations were accurate to within 10% of birth weight in 70,1% of patients. Eleven patients (11,3%) had macrosomic ($> 4\,000$ g) babies. In these patients, only 54,5% of fetal weight estimations were accurate to within 10% of birth weight. Ultrasound for

detection of macrosomia had a sensitivity of 58,3% (CI: 36-82%) and a specificity of 96,5% (CI: 93-99%).

Conclusion

The accuracy of ultrasound fetal weight estimation in diabetic patients at GSH appears similar to that of other international studies. Ultrasound estimations become increasingly inaccurate in extremes of fetal weight. One in four weight estimations had an estimation error of > 10% with a tendency towards underestimation in macrosomic fetuses.

Ultrasound fetal weight estimation as a predictor for macrosomia should remain under scrutiny, especially in the context of the high perinatal morbidity associated macrosomia and shoulder dystocia as well as the rising litigation associated with birth complications.

Introduction

Diabetes mellitus has a rapidly rising global incidence with an alarming estimate of a 90% increase in incidence in Africa. The number of pregnancies complicated by diabetes is also on the rise. ^[1,2]

In pregnancy, diabetes is associated with multiple perinatal complications. The diabetic mother is at an increased risk of pre-eclampsia and preterm labour. The fetus of the diabetic mother is at an increased risk of congenital malformations, perinatal mortality and stillbirth as well as fetal overgrowth (macrosomia) and its associated complications. ^[2]

The exact definition of macrosomia remains contentious. The Royal College of Obstetricians and Gynaecologists (RCOG) defines macrosomia as a fetal weight at birth of 5 000 g or more in normal pregnancies or a fetal weight at birth of 4 500 g or more in pregnancies affected by diabetes. ^[3] The American College of Obstetricians and Gynecologists (ACOG) is more conservative, with macrosomia defined as a fetal weight at birth greater than 4 500 g. Both fetal and maternal morbidity show a sharp increase at this cut off. It is, however, recognized that there is a somewhat increased risk with a fetal weight at birth of more than 4 000 g, especially if the pregnancy is complicated by diabetes. ^[4]

Maternal risks specifically associated with a macrosomic fetus include prolonged or obstructed labour, assisted vaginal delivery, increased risk of caesarean delivery, perineal trauma, post-partum haemorrhage and uterine rupture. The macrosomic fetus is at risk of shoulder dystocia, which can cause trauma to the fetus e.g. nerve injury or fractures. There is also an increased risk of birth asphyxia. ^[5]

In order to predict fetal macrosomia, fetal weight estimation remains an important component of antenatal surveillance, especially in the late third trimester. Prior to real-time ultrasound being widely accessible, clinical fetal weight estimation was the gold standard but the accuracy was found to be relatively poor. ^[6]

The initial assumption was that ultrasound fetal weight estimation would be superior to clinical estimates. Ultrasound fetal weight estimation was compared to clinical examination to estimate fetal birth weight as well as maternal fetal weight estimation. A number of studies have subsequently shown no significant difference between the accuracy of these different methods to estimate fetal weight. ^[7,8] However, at the extremes of fetal weight, clinical methods of fetal weight estimation become less accurate. In low birth weight fetuses (< 2 500 g), ultrasound estimation of fetal weight has been shown to be more accurate than clinical estimation. In the macrosomic (> 4 000 g) group both ultrasound and clinical estimates become more inaccurate. ^[9]

Despite the relative inaccuracy of ultrasound fetal weight estimation, the current National Institute for Health and Care Excellence (NICE) guideline on the care of diabetic patients, recommends offering 4 weekly ultrasound scans from 28 to 36 weeks to assess fetal growth and wellbeing. ^[2]

The South African national guidelines recommend a dating ultrasound for all patients. In addition, it is recommended that diabetic patients have a screening ultrasound to exclude fetal abnormalities at 12 to 14 weeks, as well as a detailed fetal anatomy scan performed at 18 to 22 weeks at a specialist level hospital. ^[10]

The current protocol for management of diabetic patients at Groote Schuur Hospital goes further and recommends growth scans at 4 weekly intervals starting at 28 weeks. In

addition, the Western Cape guidelines recommend offering an elective caesarean section to diabetic patients with an estimated fetal weight of 4 000 g or more at term with a fetal abdominal circumference greater than the 90th percentile. ^[11] This is also the practice at the Maternity Centre at Groote Schuur Hospital and has subsequently resulted in a large number of caesarean deliveries performed to prevent fetal and maternal complications related to presumed macrosomia.

There has been much debate on an acceptable caesarean section rate globally, with a wide range in both developed and developing countries. The national caesarean section rate is 23% as published in the Saving Mothers report (2011– 2013). Haemorrhage remains an important cause of maternal mortality both in South Africa and worldwide. The high number of maternal deaths related to haemorrhage associated with caesarean delivery has also been highlighted in the latest confidential enquiries, with caesarean delivery having a 2,8-fold higher risk of mortality when compared to vaginal delivery. ^[12]

As such, ultrasound fetal weight estimation as a predictor for fetal macrosomia should remain under scrutiny in the context of the multiple perinatal complications associated with macrosomia as well as the high morbidity associated with caesarean section. The focus needs to remain on improving both the accuracy of fetal weight estimation and the detection of macrosomic fetuses. It is also imperative to continuously audit the accuracy of ultrasound fetal weight estimation at our institution as well as assess the current practice in the light of restricted resources.

Methods

This is a retrospective descriptive study for the 12-month period from 1 September 2010 to 31 August 2011. All women diagnosed with an abnormal glucose tolerance test (GTT) during pregnancy or known to have pre-existing diabetes attending the antenatal clinic services at Groote Schuur Hospital during the year in question, were included in the diabetic database. Patients who had undergone a documented ultrasound fetal weight estimation at term (36 to 40 weeks) and delivered within 7 days from the ultrasound were

selected from this pre-existing approved database. The exclusion criteria for this study were multiple pregnancies, intra-uterine fetal death and fetal abnormalities.

Groote Schuur Hospital in Cape Town, South Africa is a Tertiary Level Hospital providing obstetric and neonatal services to a large drainage area consisting of multiple Midwife Obstetric Units (MOU's), Level 1 as well as Level 2 Hospitals. Patients with risk factors undergo screening GTT's and patients with abnormal results (fasting glucose > 5,5 mmol/l or 2-hour glucose > 7,7 mmol/l) are then referred to either a Level 2 or a Level 3 care facility. All patients who need medical intervention for diabetes diagnosed in pregnancy and all patients with pre-existing diabetes receive their antenatal care at a Level 3 Facility.

It is routine practice at Groote Schuur Hospital to do an ultrasound fetal weight estimation in diabetic patients prior to delivery. The investigation is done at 37 weeks' gestation. All ultrasounds were performed within the fetal medicine unit at Groote Schuur Hospital. At this unit fetal weight estimations were done by various categories of staff that included ultrasonographers, medical officers, fetal maternal specialists and registrars.

This study was undertaken to evaluate the institutional accuracy of ultrasound fetal weight estimation when compared to actual birth weight in singleton term pregnancies in women with gestational and pre-gestational diabetes, as well as to determine the incidence of macrosomia in our study population and the rate of accurate identification of macrosomia in these patients. Secondary objectives were to compare the accuracy of ultrasound fetal weight estimation at our institution to that of international study results and to review the practice of routine ultrasound fetal weight estimation at term in diabetic patients to guide decisions with regards to mode of delivery.

Results

Of the 725 patients entered into the diabetic database, 596 had live born singleton pregnancies at 36 weeks or later gestation. Of those patients, 97 had a documented ultrasound fetal weight estimation done within 7 days of delivery.

In the index study, the average age was 31,2 years with a range of 19 to 45 years. The average parity was 1,6 with a range of 0 to 5. Twenty-five of the 97 patients (25,7%) included were nulliparous. The average weight was 87,7 kg with a range of 49 to 153 kg. Seventy-three (75,3%) had height captured and BMI calculated. The average BMI was 34,7 with a range of 18,7 to 52,4. Only 10 women (13,7%) had a normal BMI (18,5 – 25,0). Nineteen women (26%) are classified as morbidly obese with a BMI of > 40.

Seventy women (72,2%) in the study cohort had gestational diabetes of which 48 had impaired glucose tolerance and 22 had gestational diabetes. Twenty-seven (27,8%) had pre-gestational diabetes with 25 patients (25,7%) diagnosed with type 2 diabetes and 2 patients (2,1%) with type 1 diabetes.

The mean actual birth weight in the study cohort was 3 394 g (range 2 255 – 5 240 g). Eleven patients (11,3%) gave birth to macrosomic babies (birth weight >4 000 g). Four of these babies weighed more than 4 500 g and 1 more than 5 000 g. (Table 1)

	Mean Actual BW	< 2 500 g	2 500 – 3 999 g	4 000 – 4 500 g	> 4 500 g	Total:
IGT	3 332 g (range 2 255 – 5 240 g)	3	41	3	1	48
GDM	3 587 g (range 2 550 – 4 860 g)	0	19	1	2	22
DM2	3 295 g (range 2 500 – 4 575 g)	0	22	2	1	25
DM1	4 022 g (range 3 940 – 4 105 g)	0	1	1	0	2
Total	3 394 g (range 2 255 – 5 240 g)	3 (3,1%)	83 (85,6%)	7 (7,2%)	4 (4,1%)	97 (100%)

Table 1 – Birth weight distribution

BW = Birth Weight, IGT = Impaired glucose tolerance, GDM = Gestational diabetes, DM2 = Type 2 diabetes, DM1 = Type 1 diabetes

The average time interval between the ultrasound fetal weight estimation and delivery in the study cohort was 4,5 days. The average time interval between ultrasound and delivery for patients with IGT was 4,3 days, 4,0 days for patients with GDM, 4,9 days for patients with type 2 DM and 6,5 days for patients with type 1 DM.

When comparing estimated fetal weight to birth weight, ultrasound estimation was accurate to within 10% of birth weight in 68 out of 97 patients (70,1%). In macrosomic babies the distribution of error appears to be an underestimation of weight rather than an overestimation. There were no estimations in this weight category found to be more than 10% of actual birth weight. (Table 2)

	< 3 000 g n = 16 (16,5%)	3 000 – 3 999 g n = 70 (72,2%)	4 000 – 4 499 g n = 7 (7,2%)	> 4 500 g n = 4 (4,1%)	Total n = 97
Within 10% of BW	13 (81,2%)	49 (70%)	3 (42,9%)	3 (75%)	68 (70,1%)
>10% below BW	1 (6,3%)	13 (18,6%)	4 (57,1%)	1 (25%)	19 (19,6%)
>10% above	2 (12,5%)	8 (11,4%)	0 (0%)	0 (0%)	10 (10,3%)
Total	16 (100%)	70 (100%)	7 (100%)	4 (100%)	97 (100%)

Table 2 – Birth weight distribution

BW = Birth Weight

The accuracy of ultrasound estimation between the different diabetic groups varied from 54,5% to 100% (Table 3). However, the error distribution showed a tendency towards underestimation rather than overestimation of weight in the impaired glucose tolerance (IGT) and the gestational diabetes (GDM) subgroups. The accuracy of estimated fetal weight (EFW) to within 10% of birth weight among type 1 diabetics was 100% although numbers in this group were small (n=2).

	IGT n=48	GDM n=22	DM2 n=25	DM1 n=2	Total n = 97
Within 10% of BW	37 (77,1%)	12 (54,5%)	17 (68,0%)	2 (100%)	68
>10% below BW	7 (14,6%)	8 (36,4%)	4 (16,0%)	0 (0%)	19
> 10% above BW	4 (8,3%)	2 (9,1%)	4 (16,0%)	0 (0%)	10
Total	48	22	25	2	97

Table 3 - Error distribution per diabetic group

IGT = Impaired glucose tolerance, GDM = Gestational diabetes, DM2 = Type 2 diabetes, DM1 = Type 1 diabetes, BW = Birth weight

Of the 11 patients with macrosomia, 7 (63,6%) were correctly estimated by ultrasound to be more than 4 000 g. Therefore, 4 out of 11 patients (36,4%) with macrosomic infants were not accurately diagnosed. Ultrasound estimation incorrectly identified macrosomia in 3 patients (3,5%). When ultrasound prediction of birth weight is greater than 4 000 g, ultrasound had a sensitivity of 58,3% (CI: 36 - 82%), specificity of 96,5% (CI: 93 - 99%), positive predictive value of 70% (CI: 39 - 90%) and negative predictive value of 94,3% (CI: 92 - 98%).

In the 4 patients where macrosomia was not correctly identified by ultrasound estimation, the birth weight was underestimated by more than 10%, and two of these patients were delivered via emergency caesarean section for cephalo-pelvic disproportion (Table 4). In the 3 patients where ultrasound estimation incorrectly identified macrosomia, 2 patients had caesarean sections. These 3 patients had a maternal weight of more than 90 kg in common (Table 5).

	Age	Maternal weight	P	DM	EFW (g)	BW (g)	Weight difference (%)	US to Delivery (days)	US done by	MOD and indication
1	31	82	3	DM2	3 439	4 030	14,7	1	Registrar	CS - Macrosomia
2	27	153	0	DM2	3 530	4 120	14,3	5	Sonographe r	CS - CPD
3	27	100	0	GDM	3 795	4 255	10,8	7	Sonographe r	CS - Macrosomia
4	36	140	3	IGT	3 642	4 050	10,1	5	Sonographe r	CS - CPD

Table 4 - Macrosomia not correctly identified

P = Parity, DM = Diabetes Mellitus, EFW = Estimated fetal weight, BW = Birth weight, US = Ultrasound, MOD = Mode of delivery, DM2 = Type 2 diabetes, GDM = Gestational diabetes, IGT = Impaired glucose tolerance, CS = Caesarean section, CPD = Cephalo-pelvic disproportion

	Age	Maternal weight	P	DM	EFW (g)	BW (g)	Weight difference (%)	US to Delivery (days)	US done by	MOD and indication
1	41	94	5	DM2	4 287	3 850	11,4	4	Sonographer	CS - Macrosomia
2	40	99	4	GDM	4 024	3 580	12,4	0	Sonographer	NVD
3	27	102	2	DM2	4 041	3 500	15,5	5	Registrar	CS – Previous CS

Table 5 - Macrosomia incorrectly diagnosed

P = Parity, DM = Diabetes Mellitus, EFW = Estimated fetal weight, BW = Birth weight, US = Ultrasound, MOD = Mode of delivery, DM2 = Type 2 diabetes, GDM = Gestational diabetes, CS = Caesarean section, NVD = Normal vertex delivery

Delivery details were available for the entire cohort. Caesarean section was performed in 52 patients (53,6%). In 12 of the 52 patients, the indication for caesarean was macrosomia. The remaining 30 patients were delivered for other obstetric indications (Figure 1). In the 45 patients who delivered vaginally, no cases of shoulder dystocia were reported.

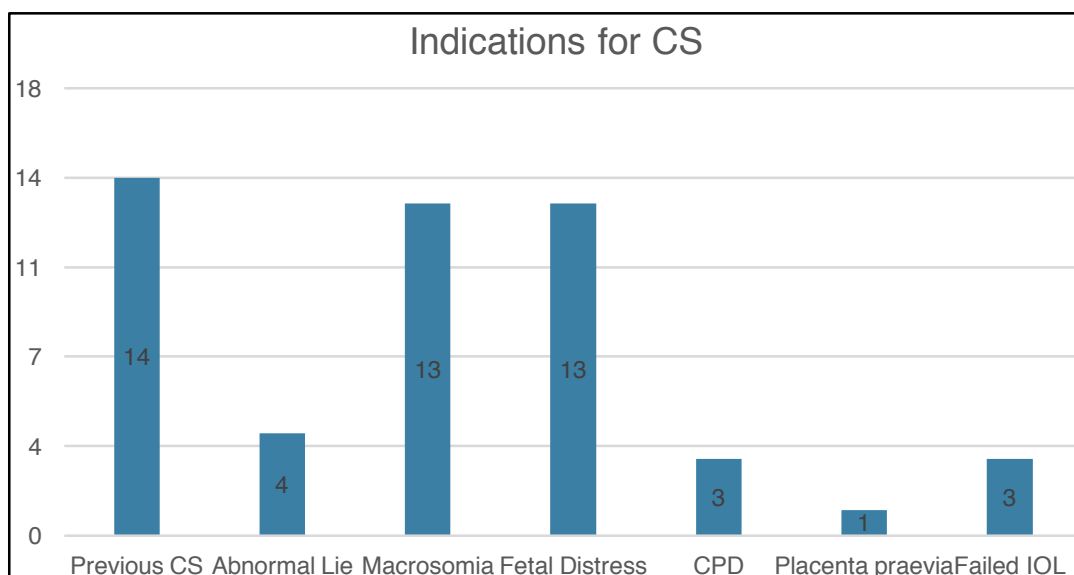


Figure 1 - Indications for CS

CS = Caesarean section, CPD = Cephalo-pelvic disproportion, IOL = Induction of labour

Discussion

Incidence of macrosomia in diabetic population

A review done by Chauhan et al. in the US in 2004 on the incidence of macrosomia (defined as > 4 000 g) in the general population, found a wide range worldwide. The incidence ranged from 1 – 28%. This wide range could be explained by a difference in the incidence of obesity and diabetes in different countries, as well as different ethnicity. No clear trend between low middle-income countries and high-income countries was found.

[13]

A study done by Wong et al. in Australia in 2001 found a 19% incidence of macrosomia in diabetic mothers included in the study. This study included both pre-gestational and gestational diabetics. There is limited data with respect to the incidence of macrosomia in the diabetic pregnant population in South Africa. ^[14]

The incidence of macrosomia in this study cohort was 11,3%. This compares well to the overall incidence of macrosomia in diabetic patients at Groote Schuur Hospital for this period (10,5%). As the incidence of diabetes in pregnancy increases, the rate of macrosomia is also expected to rise. This poses potential difficulty in maintaining a standard of care in a resource-limited setting, where ultrasound fetal weight estimations require operator expertise as well as advanced equipment.

Accuracy of EFW with US

In our retrospective review of 97 patients with diabetes in pregnancy, ultrasound fetal weight estimation at term done within 7 days of delivery correlated well with actual birth weight. Seventy percent of ultrasound estimations had an accuracy to within 10% of birth weight. This is comparable to that of similar international studies.

Colman et al. found similar results in a study done in New Zealand in 2006 assessing ultrasound weight estimation accuracy. This study found that 74,8% of fetal weight estimations were within 10% of birth weight in the general population. This study included 1 177 women, of which only 48 women were diabetic. Upon analysis of women with diabetes, 71% of weight estimations were within 10% of birth weight. Similarly, the overall accuracy to within 10% of birth weight in the index study was 70,1%. ^[15]

Colman demonstrated that the underestimation of fetal weight was significantly more common in diabetic patients than non-diabetic patients. In his study the trend to underestimation in diabetic patients was similar in both the normal weight group (27%) and macrosomic group (31%). ^[15] This is similar to the findings in our study, which also shows a marked tendency towards underestimation in the macrosomic group. However, when analyzing only women with macrosomic infants, 54,5% were accurately estimated to within 10% of birth weight. There was a clear trend towards underestimation of fetal weight (45,5%). None of the macrosomic infants' weights were overestimated by more than 10%.

Accuracy of macrosomia identification

The reliability of prediction of fetal weight greater than 4 000 g is of specific importance in diabetic pregnancies at higher risk of macrosomia and its associated morbidity. Colman et al. found ultrasound to have a sensitivity of 61% (CI: 53–68%) and specificity of 96% (CI: 94 - 97%) in non-diabetic patients. ^[15] Our study cohort compared favourably with a sensitivity of 58,3% (CI: 36 - 82%) and specificity of 96,5% (CI: 93 - 99%). In our cohort ultrasound correctly diagnosed 2 out of every 3 cases of macrosomia.

On reviewing the above results, it would be reasonable to continue the current practice of doing an ultrasound fetal weight estimation in the diabetic patients within 7 days of delivery to screen for macrosomia and make recommendations regarding mode of delivery.

The strength of this study is that we now have data about the accuracy of ultrasound fetal weight estimation in our local population and our ultrasound service. Limitations of this study include the small sample size as well as it having been done retrospectively. A larger prospective study is recommended for future research.

Conclusion

The accuracy of ultrasound EFW performed in diabetic patients at GSH appears similar to that of other international studies. Ultrasound estimations become increasingly inaccurate in extremes of fetal weight and increased maternal BMI. One in four women undergoing ultrasound fetal weight estimation had an estimation error of >10% with a tendency towards underestimation of weight in macrosomic fetuses. Ultrasound fetal weight estimation as a predictor for fetal macrosomia should therefore remain under scrutiny, especially in the context of the high perinatal morbidity associated macrosomia and shoulder dystocia as well as the rising litigation associated with birth complications. The focus needs to remain on improving both the accuracy of fetal weight estimation and the detection of macrosomic fetuses. It is also imperative to continuously audit the accuracy of ultrasound fetal weight estimation at our institution as well as assess the current practice in the light of restricted resources.

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APPENDIX A

Approval letters



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



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05 June 2017

HREC REF: 350/2017

Dr L. Schoeman
Division of Obstetrics & Gynaecology
H45
OMB

Dear Dr Schoeman

PROJECT TITLE: ACCURACY OF ESTIMATED FETAL WEIGHT USING ULTRASOUND AT TERM IN PREGNANT IN WOMEN DIAGNOSED WITH GESTATIONAL AND PRE-GESTATIONAL DIABETES AT GROOTE SCHUUR HOSPITAL (Masters' candidate-Dr M Venter) sub-study linked to R010/2016

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 June 2018.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student, Dr M Venter will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

HREC 350/2017



UNIVERSITY OF CAPE TOWN
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18 March 2016

REF NO: R010/2016

Dr H van Zyl
Obstetrics and Gynaecology
H-Floor, OMB

Dear Dr van Zyl

PROJECT TITLE: Diabetic Audit Database - From 1 September 2010 - 31 August 2011

Thank you for your request to the Faculty of Health Sciences Human Research Ethics Committee.

The HREC has **approved** the registration of your database.

Please Note: All research, including that undertaken for a master's or doctoral degree, using registered databases, registries and repositories, requires submission as a new study. It requires an application form ([FHS013](#)) and a protocol which has undergone departmental review. The study will receive its own HREC REF number which will be linked to the main database or repository.

The registration of this database is valid until **30 March 2019**.

Please quote the HREC REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN ETHICS



Author Guidelines

Accepted manuscripts that are not in the correct format specified in these guidelines will be returned to the author(s) for correction, and will delay publication.

AUTHORSHIP Named authors must consent to publication. Authorship should be based on substantial contribution to: (i) conception, design, analysis and interpretation of data; (ii) drafting or critical revision for important intellectual content; and (iii) approval of the version to be published. These conditions must all be met (uniform requirements for manuscripts submitted to biomedical journals; refer to www.icmje.org).

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Scientific letters/short reports, which include case reports, side effects of drugs and brief or negative research findings should preferably be 1500 words or less, with 1 table or illustration and no more than 6 references. Please provide an accompanying abstract not exceeding 150 words.

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Review articles are rarely accepted unless invited.

Letters to the editor, for publication, should be about 400 words with only one illustration or table, and must include a correspondence address.

Obituaries should be about 400 words and may be accompanied by a photograph.

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preceded by a space (except for %), e.g. '40 kg' and '20 cm' but '50%'. Greater/smaller than signs (> and <) should be used for '40 years of age'. The same applies to ± and °, i.e. '35±6' and '19°C'.

Numbers should be written as grouped per thousand-units, i.e. 4 000, 22 160...

Quotes should be placed in single quotation marks: i.e. The respondent stated: '...'

Round **brackets** (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.

General formatting The manuscript must be in Microsoft Word or RTF document format. Text must be single-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes, with the exception of Tables).

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Journal references: Price NC, Jacobs NN, Roberts DA, et al. Importance of asking about glaucoma. *Stat Med* 1998;289(1):350-355. [<http://dx.doi.org/10.1000/hgjr.182>] [PMID: 2764753]

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