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ASSESSMENT OF MATERNAL AND NEONATAL OUTCOMES OF PREGNANT WOMEN WITH GESTATIONAL DIABETES MELLITUS AT KING ABDULAZIZ MEDICAL CITY – JEDDAH

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Abstract:

This retrospective cohort study presented the factual findings on the maternal and neonatal outcomes of women diagnosed with Gestational Diabetes Mellitus (GDM) in King Abdulaziz Medical City – Jeddah (KAMC-J). Differences in between women with GDM (n=214) to non-diabetic women (n=225) were assessed based on their pre-pregnancy status, delivery status and presented maternal and neonatal outcomes. Association of GDM to pre-pregnancy maternal characteristics, maternal and neonatal outcomes were also determined.

This study found out that women with GDM had no significant difference in terms of adverse maternal and neonatal outcomes as compared to non-diabetic. However, although the study findings represents the effective diabetes control and management as observed among GDM women managed in KAMC-J, still it's undeniable that cases of adverse maternal and neonatal outcomes are still presented in this study population and carries risks for the mother and neonate; and has been documented in local and international studies. It is therefore shown that the exact utility of diabetic control and management to eradicate completely the occurrence of associated maternal and neonatal outcomes is still undetermined. This study therefore recommended that multi-center study in a national perspective of this country is indeed necessary. To further evaluate the effectiveness of GDM management and to determine effective measures to prevent completely the maternal and neonatal adverse outcomes associated with GDM.

Keywords:*Gestational diabetes mellitus; Maternal outcomes; Neonatal outcomes; Perinatal outcomes; Saudi Arabia.*

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INTRODUCTION:

Gestational diabetes mellitus (GDM) is defined as any impaired glucose tolerance that is first recognized during pregnancy. In certain patients, GDM could be undiagnosed type 2 diabetes mellitus (DM). However, glucose intolerance returns to normal following delivery of the baby in many cases of GDM [1-3]. Nevertheless, GDM patients are at an increased risk of progressing to type 2 DM after delivery [4,5]. In Saudi Arabia, GDM has an alarming prevalence that ranging from 18.7 to 51% of all pregnant women which have become a major health concern in this country [6-8].

Untreated GDM is associated with several fetal and maternal outcomes. Hyperglycemia and Adverse Pregnancy Outcome (HAPO) was a prospective cohort study using blinded data, which took place in nine countries and included 25,505 patients. This study found a continuous linear association between maternal glycemia and numerous poor maternal and fetal outcomes, including pre-eclampsia, primary cesarean sections, prematurity, birth weight above the 90th percentile, neonatal hypoglycemia, shoulder dystocia, intensive care, and others [9]. However, there are randomized controlled trials proved that treatment of GDM as compared to usual care found significant reduction in serious maternal and neonatal outcomes including shoulder dystocia, increased frequency of induction of labor, lower birth weights, lower rates of macrosomia and fewer cesarean section. This also improved health-related quality of life of women during pregnancy up to the period of three months postpartum, and decreased incidence of postpartum depression [10,11]. However, although there is increasing evidences on effective treatments of GDM in reducing adverse maternal and neonatal outcomes, there remains a need for evaluating the effectiveness of management in treating GDM and it is still underrepresented in this country.

Therefore, this study aimed to assess the maternal and neonatal outcomes as the basis for evaluation of the effectiveness in the management of GDM in a specialized hospital in Saudi Arabia. Moreover, the study results were compared against national and international studies.

METHODS:

Study Design and Setting

This is a retrospective cohort study that assessed the maternal and neonatal outcomes of GDM women as compared to non-diabetic women in the combined endocrine–obstetric clinic at King Abdulaziz Medical City in Jeddah (KAMC-J), Saudi Arabia. All medical records of pregnant women were retrieved from the department of medical record of the institution, and reviewed for data collection, which extended from January 1, 2015 to December 31, 2016. Data collection was performed with permission obtained from the Medical Records Department.

Study Population and Sampling Technique Used

A total of 6894 pregnant women medical records identified. Medical codes were used to categorize the GDM women to non-diabetic women. Of those, 1086 were GDM women and 5808 were the non-diabetic women.

Based on the means of birth weights reported in a similar local study,[6] sample size inputs were a mean difference of 100g, a standard deviation of 400, an alpha error of 0.05 and a power of 80%. The study would require 252 samples for each group. Computerized simple sampling technique was also applied using Microsoft Excel (2014 version; Microsoft Corporation, USA) to obtain the definite sample size of 480 for women with GDM and 750 for non-diabetic women. These patients were then assessed for their eligibility to enter the study.

Inclusion and exclusion criteria

Inclusion criteria for this study were as follows; the mother must be in the age range of 20–40 years old, has been pregnant for a single baby for at least 28 or more gestational weeks at the time of delivery, and not known to be diagnosed with type 1 DM or type 2 DM prior to pregnancy. However, those who had two or more previous cesarean sections, loss of follow-up that resulted in unknown delivery outcomes, diagnosis made outside of our institution and its primary care centers, uncertain diabetic status, diagnosed with significant comorbidities prior to or during pregnancy, use of diabetogenic or teratogenic drugs, substance abuse (alcohol, cocaine, etc.), and active smoking were excluded in this study.

Screening, diagnosis, and management of GDM

All pregnant women who had their follow-up check-up at the institution and its covered primary care centers were screened for GDM at between 24 and 28 weeks of gestation by using the “two-step” approach adopted from the current American Diabetes Association (ADA) and American College of Obstetricians and Gynecologists (ACOG) guidelines [1-2]. In the initial screening, non-fasting 1-h 50 g glucose challenge test (GCT) was used. If the reading is ≥7.8 mmol/L, then the 100 g OGTT will then be performed while patient is fasting. However, those women for whom non-fasting 50 g GCT was tested after 28 weeks of gestation were also included in this study considering concern on

availability of appointments, and late presentation in a few cases.
Women considered to be at high risk of developing GDM were also screened for fasting blood glucose, random blood glucose, or non-fasting 50 g GCT at their first prenatal visit. Patients who tested negative for early GDM had their non-fasting 50 g GCT repeated at between 24 and 28 weeks of gestation.

GDM diagnosis is made when one of two conditions were met: 1) at least two readings of the 100 g OGTT were equal or higher than Carpenter/Coustan (CC) cut-offs (i.e. fasting: 5.3 mmol/L, 1h: 10.0 mmol/L, 2h: 8.6 mmol/L, 3h: 7.8 mmol/L), and 2) a reading for the non-fasting 50 g GCT ≥11.1 mmol/L was diagnostic thus did not require an additional 100 g OGTT to confirm. GDM diagnosis was ruled out when the non-fasting 50 g GCT done after 24 weeks of gestation was <7.8 mmol/L, or when a maximum of one reading was higher than the aforementioned CC diagnostic thresholds for the 100 g OGTT done after 24 weeks of gestation.

After a diagnosis of GDM was reached, the patient was started on a diet and referred to a dietician. Additionally, she was admitted to the maternal–fetal medicine unit (MFMU) for three-point blood glucose profiling (fasting, 2 hours after breakfast, and 2 hours after lunch), or admitted to the ward if there was no available slot in MFMU for four-point blood glucose profiling (fasting, 2 hours after breakfast, 2 hours after lunch, and 2 hours after dinner). After that, the patient was given an appointment with MFMU for 1–2 weeks later for two-point blood glucose profiling (fasting and postprandial) to observe the effect of the management. GDM patients were followed every 2–4 weeks thereafter, subject to the availability of appointments or complexity of the case. GDM monitoring was achieved by self-monitoring blood glucose, two-point blood glucose profiling, random blood glucose, and HgA1c levels. Blood sugar targets were: fasting, ≤5.3 mmol/L; 2 hours postprandial, ≤6.7 mmol/L, and HgA1c, 6–6.5% [12]. If the patient was found to have uncontrolled GDM, she was admitted to the ward for blood glucose monitoring, and referred to endocrinology for possible initiation of insulin. If the patient was started on insulin, basal insulin (detemir or NPH) and pre-prandial insulin (aspart or HRI) were used for management. The dose of insulin was calculated according to the degree of hyperglycemia by an endocrinology consultant or fellow. Moreover, patients on insulin were followed in the GDM specialized clinic in addition to the obstetric clinic, and were referred to a diabetic educator and a dietician. In addition, for GDM patients on insulin, a biophysical profile was taken at weekly follow-up after 34 weeks. Lastly, elective induction of labor was offered and scheduled at 38–39 weeks for patients on insulin, and at 40 weeks for patients on diet.

Data collection
All eligible pregnant women medical records that met the inclusion criteria were reviewed to collect the data necessary for the study purpose. Maternal characteristics were collected such as maternal age, gravidity, parity, previous miscarriages, living children, occupation, presence of previous history of GDM, presence of first-degree family history of DM, height, first weight measurement during pregnancy and the gestational week in which it was taken, pre-pregnancy weight (calculated using a weight-gain-for-gestational-age z score chart developed by Hutcheon et al. [13] pre-pregnancy BMI, non-fasting 50 g GCT reading, and 100 g OGTT (fasting, 1, 2, and 3 hour) readings. Gestational age was calculated based on the last missed menstrual period or from an early ultrasound finding. For patients with GDM, specific variables were collected including the treatment of GDM (diet or insulin), gestational week in which the initial test was done, and gestational week in which the diagnosis of GDM was obtained.

Data on maternal outcomes collected were gestational age at the time of delivery, type of delivery (vaginal, instrumental including ventouse or forceps, cesarean section including elective or emergency), documented indication of the route of delivery (except for vaginal), induction of labor (mechanical or using medications), and recorded reason for induction of labor.

Data on neonatal outcomes collected were gender, birth weight, head circumference, length, Apgar score at 1 and 5 minutes, and presence of intrauterine fetal death.

Studied maternal and neonatal outcomes
Maternal outcomes studied for correlation were the induction of labor, vaginal delivery, emergency and elective cesarean section, and instrumental delivery; while age of gestation (term or preterm), birth weight, macrosomia (defined as birth weight ≥4000 g), low birth weight (<2500 g), and Apgar score of <7 at 5 minutes were under the neonatal outcomes.

Statistical analysis
Data were analyzed using Statistical Packages of Social Sciences or SPSS (version 23; IBM, USA). Simple descriptive statistics were used to determine the distribution of maternal characteristics. Counts and percentages were calculated for the categorical

and nominal variables, and means and standard deviations for continuous variables. To assess whether any relationship existed between categorical variables, the Chi-square (X^2) test was used. An independent t-test was used to compare the means of two groups. These tests were done under the assumption of normal distribution. Alternatively, Welch's t-test was used for two group means. Lastly, binary logistic regression was calculated to determine association between maternal characteristics (Independent Variables) and studied maternal and neonatal clinical outcomes (dependent variable). Statistical significance was defined by the 5% level of probability with 95% reliability.

RESULTS:

A total of 439 pregnant women medical records met the predetermined set of criteria. Of these, 214 (48.7%) were GDM, and 225 (51.3%) were non-diabetics. Of the 214 GDM, diagnosis was made by a very high non-fasting 50 g GCT in 37 (17.3%) women, and with 100 g OGTT meeting two or more CC thresholds in 177 (82.7%) women. Maternal characteristics with GDM as compared to non-diabetic women are presented in detail in Table 1.

Table 1. Maternal Characteristics

Maternal Characteristics	Group		*P*-value
	GDM n = 214 (%)	**Non-diabetic n = 225 (%)**	
Age at delivery (years)	31.24 ± 5.0	27.47 ± 4.9	<0.001[a]
Occupation[*]			
Housewife	166 (77.6)	158 (70.2)	
Employee	33 (15.4)	31 (13.7)	0.036[b]
Student	10 (4.7)	25 (11.1)	
Gravidity	3.73 ± 2.3	2.71 ± 1.6	<0.001[c]
Parity	2.12 ± 1.9	1.39 ± 1.4	<0.001[c]
Previous preterm deliveries	0.13 ± 0.4	0.06 ± 0.3	0.059
Previous miscarriages	0.60 ± 1.0	0.32 ± 0.7	<0.001[c]
Living children	2.06 ± 1.8	1.33 ± 1.4	<0.001[c]
Previous history of GDM	63 (29.4)	6 (2.7)	<0.001[b]
Family history of DM[#]	144 (67.3)	107 (47.6)	<0.001[b]
Height (cm)	156.81 ± 5.9	157.41 ± 5.6	0.274
Pre-pregnancy weight (kg)	69.81 ± 15.0	61.36 ± 12.9	<0.001[c]
Pre-pregnancy BMI	28.38 ± 5.8	24.79 ± 5.3	<0.001[c]

Abbreviations: GDM, gestational diabetes mellitus; DM, diabetes mellitus; N/A, not applicable
[a]significant using independent *t*-test at <0.05
[b]significant using Chi-square test at <0.05
[c]significant using Welch's t-test at <0.05
[*]16 women had unknown occupation
[#]4 cases had an unknown family history of DM

GDM women were significantly older, and had significantly higher number of gravidity, parity, and had previous miscarriages as compared to non-diabetic women. They also had a significantly higher estimated pre-pregnancy weight and pre-pregnancy BMI compared to non-diabetics. Previous history of GDM and family history of DM were significantly more common in women with GDM. Table 2 describes GDM-specific characteristics. Of all the women with GDM, 193 were on diet-based control, and 21 (9.8%) women were treated with insulin. The mean gestational age at which insulin treatment was initiated was 31.58 ± 6.3 weeks.

Table 2. Characteristics of the GDM group

GDM Group	N = 214 (%)
Treatment for GDM	
Diet	193 (90.2)
Insulin	21 (9.8)
Positive early screening for GDM (initial test ≤ 20 gestational weeks)	
Yes	54 (25.2)
No	160 (74.8)
	Mean (SD)
Gestational age at which initial test was done (weeks)*	25.12 (8.1)
Gestational age at which diagnosis of GDM was obtained (weeks)#	27.78 (7.8)
If treated by insulin, gestational age at which insulin was started (weeks)&	31.58 (6.3)

*three cases had missing date of initial test
#one case had a missing date of diagnosis of GDM
&two cases had a missing date of the start of insulin therapy

A comparison of maternal outcomes between the GDM and non-diabetics women is shown in Table 3. There was no significant association between premature delivery and GDM (*P* = 0.386). Compared to non-diabetics, pregnant women with GDM had significantly higher rates of induction of labor, even after adjustment for maternal age, pre-pregnancy BMI, parity, and gestational age at the time of delivery (adjusted OR, 3.44: 95% CI, 2.03–5.81, adjusted *P* < 0.001).

Considering the modes of delivery, rates of emergency cesarean section were initially found to be significantly higher in the GDM group (OR, 1.74; 95% CI, 1.08–2.81; *P* = 0.022). However, after adjustment for maternal age, pre-pregnancy BMI, parity, gestational age and induction of labor, this association was found to be non-significant (adjusted OR, 1.30; 95% CI, 0.75–2.25; adjusted *P* = 0.356). Additionally, no significant association existed between the other types of delivery and GDM (*P* > 0.05).

Newborns of women with GDM had a significantly higher mean birth weight (3171 g ± 546) compared to the control group (3069 g ± 502; *P* = 0.041). However, there was no significant difference between the groups in terms of the frequency of macrosomia, low birth weight, or Apgar score less than 7 at 5 minutes (*P* > 0.05). Two intrauterine fetal deaths occurred in the study; one in the GDM group and the other in the control group.

Table 3. Maternal and Neonatal Outcomes

Items	Group		Unadjusted OR (95% CI)	*P*-value
	GDM n = 214 (%)	Non-diabetic n = 225 (%)		
Maternal Outcomes				
Preterm pregnancy	19 (8.9)	15 (6.7)	1.36 (0.67–2.75)	0.386
Term pregnancy	195 (91.1)	210 (93.3)		
Induction of labor	77 (36.0)	31(13.8)	3.54 (2.21–5.68)	<0.001[a]
Vaginal delivery	136(63.6)	157(69.8)	0.76 (0.51–1.12)	0.166
Instrumental delivery	11(5.1)	16(7.1)	0.71 (0.32–1.56)	0.390
Elective cesarean section	15(7.0)	17(7.6)	0.92 (0.45–1.90)	0.826
Emergency cesarean section	52(24.3)	35(15.6)	1.74 (1.08–2.81)	0.022[a]
Neonatal Outcomes				
Birth weight(grams)	3171.22 ± 545.8	3068.78 ± 502.5	n/a[b]	0.041[c]
Macrosomia(birth weight ≥ 4000 g)	11 (5.1)	5 (2.2)	2.37 (0.81–6.94)	0.105
Low birth weight (< 2500 g)	20 (9.3)	24 (10.7)	0.85 (0.46–1.60)	0.634
Apgar score of less than 7 at 5 minutes	7 (3.3)	4 (1.7)	1.83 (0.54–6.17)	0.321

[a]significant using Chi-square test at <0.05
[b]Risk estimate statistics cannot be computed; they are only computed for a 2 x 2 table.
[c]significant using independent *t*-test at <0.05

DISCUSSION:

Similar to several international [14-16] and local studies,[6-8] this study shows that pregnant women in the GDM group were significantly older, had higher gravidity and parity, and more previous miscarriages. As found in similar studies [7,15,16], women with GDM were significantly associated with higher pre-pregnancy weight and BMI. Women with GDM were also significantly more likely to have a history of previous pregnancy with GDM, and family history of DM, as also found by other studie [8,15,16].

Prematurity is a well-known neonatal complication in women with uncontrolled GDM [16,17]. In this study, however, was found no statistically significant difference in premature births between the GDM group and the non-diabetic group. This result agreed with other local studies [7,8]. Both groups of women in this study had similar reasons for their premature deliveries.

Some local and international studies have concluded that GDM is associated with higher frequencies of primary cesarean section and total cesarean section deliveries [8,14,15], while other studies have reported no significant relationship [7,18,19]. However, a limited number of studies have looked at the association of GDM and the urgency of cesarean section. In this study, emergency cesarean section rates were initially significantly higher in the GDM group than in non-diabetics. However, after adjusting for maternal age, pre-pregnancy BMI, parity, and induction of labor, there was no significant association, which is inconsistent with the findings of two regional studies [6, 16]. A probable explanation for this disparity is the lack of adjustment for these factors in the previous studies. Moreover, both groups had similar indications for emergency cesarean sections. Elective cesarean section rates were not significantly different between the GDM group and non-diabetics, which is inconsistent with previous reports [6, 16]. In contrary to these two reports, this study excluded those patients who had a history of two or more previous cesarean sections, since it was a clear indication to opt for elective cesarean section. Moreover, both groups had similar indications for elective cesarean section. For instrumental delivery, no significant difference was found between the GDM group and control, agreeing with similar studies [7,8,15].

It is common practice for pregnant women with GDM to undergo induction of labor so as to reduce the baby's birth weight and related adverse outcomes, such as shoulder dystocia. In this study, labor was induced significantly more frequently in the GDM group, in accordance with previously published work [7,8]. This finding was expected, since many induced labors are elective, and a routine part of the management of GDM. One study comparing the rates of induction of labor in untreated GDM with a control group showed no significant differences [20].

Newborn babies of women with GDM had a significantly higher mean birth weight compared to those born of women in the control group; this has also been found in similar studies [1-4]. As found in a similar local study [3], Carpenter-Coustan (CC) criteria was used for the diagnosis of GDM, the mean birth weights of newborns of GDM women in our study were found to be similar, which may correspond to similar glycemic control. Nevertheless, it is vital to note that the GDM group had significantly higher parity, pre-pregnancy weight and BMI, and higher gestational age at the time of delivery; and all of these factors contribute to higher birth weight. On the other hand, compared to non-diabetics, women in the GDM group were significantly older, and had significantly higher rates of induction of labor – these factors ultimately led to significantly lower gestational age at the time of delivery (38.65 ± 1.5 weeks versus 39.07 ± 1.7 weeks; $P = 0.006$), and correspond to lower birth weights. Additionally, several other factors not accounted for in this study may have affected birth weights, e.g., genetics, economic status, and maternal weight gain during pregnancy. Therefore, the difference in birth weight between the groups cannot be solely attributed to GDM.

Macrosomia is a well-known adverse outcome of GDM; in fact, one systematic review [21] revealed that it was the most common adverse effect of GDM. In our study, women in the GDM group had higher rates of macrosomia compared to non-diabetics (11 [5.1%] versus 5 [2.2%]), but the difference was not significant ($P = 0.105$). This is largely because the study was underpowered for this outcome; larger international and local studies [7,8,16,22] have reported similar percentages of GDM pregnancies to be significant, and although a small local study reported no significant association, this study was probably also underpowered [8]. However, many studies have reported that effective management leads to a decrease in the frequency of macrosomia [19,20,22,23], to a level even comparable to normoglycemic pregnancies in some studies [19,23]. Therefore, a larger sample size is needed to further establish the association between GDM and macrosomia in our population.

Low birth weight is a known pregnancy outcome for women with type 2 diabetes, attributed to placental insufficiency. For women with GDM, one study found an inverse relationship between GDM and low birth weight [16], while another found no significant difference [8]. However, this study found no significant association between GDM and low birth weight.

One study showed that the babies of women with GDM had significantly higher rates of having an Apgar score less than 7 at 5 minutes [3], but two other studies found no significant difference in this outcome [1,2]. In this study, the rate of having an Apgar score less than 7 at 5 minutes was 3.3% (n = 7) in the babies of women with GDM, and 1.7% (n = 4) in the babies of non-diabetic women. However, this difference was not statistically significant (OR 1.83; 0.54–6.7; *P* = 0.321). Perhaps no significant difference was found because this study was underpowered to assess this outcome.

To our knowledge, our study is the first in Saudi Arabia to compare the maternal and neonatal outcomes of women with GDM who were otherwise healthy, with healthy non-diabetic pregnant women. Patients with significant medical or psychological morbidities, as well as other potential and known confounding factors were excluded in this study. Our study had the advantage to study the rates of cesarean sections based on their urgency, adjusting for confounding factors, such as induction of labor, and excluding those who had previous 2 cesarean sections, a well-recognized indication to go for cesarean. As a result we reported no association between the rates of emergency and elective cesarean sections with GDM. Limitations of the study include its retrospective nature and small sample size, which meant that it was underpowered to make meaningful comparisons for some parameters, e.g., macrosomia and Apgar score less than 7 at 5 minutes. Moreover, 63 (29.4%) women with GDM had a history of GDM, and 54 (25.2%) women with GDM had undergone early GDM screening (initial test $\leq$ 20 gestational weeks). These women had a higher probability of having unrecognized type 2 DM, yet they were labeled and treated as having GDM during their pregnancy, and then followed up with a 75 g OGTT for persistence glucose intolerance 6–12 weeks after delivery. Another limitation is that the first recording of maternal weight, taken at the pregnant women's first prenatal appointment, differed between each case. For this reason, pre-pregnancy weight was calculated using a weight-gain-for-gestational-age z score chart developed by Hutcheon et al. [13], devised using data from women who delivered a singleton birth at Magee Women's Hospital in Pittsburgh, PA, USA, so it may have affected our subjects' true pre-pregnancy weight measurements. Nevertheless, in both groups, most women presented in the first and second trimesters, and GDM patients were shown to have higher maternal weights compared to those in the non-diabetic group in the first, second and third trimester, and around delivery.

CONCLUSION:

This study found out that women with GDM at KAMC-J had no significant difference in terms of adverse maternal and neonatal outcomes as compared to non-diabetic. However, although the study findings represents the effective diabetes control and management as observed among GDM women, still it's undeniable that cases of adverse maternal and neonatal outcomes are still presented in this study population and carries risks for the mother and neonate; and has been documented in local and international studies. It is therefore shown that the exact utility of diabetic control and management to eradicate completely the occurrence of associated maternal and neonatal outcomes is still undetermined. This study therefore recommended that multi-center study in a national perspective of this country is indeed necessary. To further evaluate the effectiveness of GDM management and to determine effective measures to prevent completely the maternal and neonatal adverse outcomes associated with GDM.

Compliance with Ethical Standards

This study was approved by the Institutional Review Board (IRB) of King Abdullah International Medical Research Center (KAIMRC), National Guard Health Affairs, Jeddah, Saudi Arabia with Memorandum Reference No. IRBC/640/60 dated July 31, 2016. Because of the retrospective study design patient consent to participate in the study was not applicable.

Conflict of Interest Statement

All authors declare that they have no conflict of interest.

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