Prevalence of Gestational Diabetes Mellitus Using the Latest World Health Organization Diagnostic Criteria among Omani Women in Muscat, Oman

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ABSTRACT

Objectives: In 2013, the World Health Organization (WHO) recommended new criteria for diagnosing gestational diabetes mellitus (GDM). Our study aimed to compare the incidence of GDM and its complications among Omani pregnant women using the new diagnostic criteria compared to previous criteria published in 1999. *Methods*: This retrospective cohort study was conducted between January and December 2016 at the Bawshar Specialized Polyclinic in Muscat, Oman. A total of 613 Omani women were included in the study. Baseline maternal characteristics such as age, body mass index, parity, and socioeconomic status were recorded in addition to maternal and neonatal outcomes. *Results:* Based on the current diagnostic criteria, the incidence of GDM was 48.5% (n = 297); however, this dropped to 26.4% (n = 162) when applying the old criteria. Moreover, rates of maternal complications including polyhydramnios (5.6% vs. 4.6%), pregnancy-induced hypertension (3.2% vs. 1.5%), and preterm delivery (3.2% vs. 1.5%) were slightly higher among women with GDM diagnosed using the latest criteria. However, these differences were not statistically significant. Neonatal complications were also slightly more frequent among the first group, without any significant differences. *Conclusions:* The incidence of GDM among Omani women rose dramatically when utilizing the latest WHO diagnostic criteria, owing to a lower fasting blood glucose cut-off value. In addition, a comparison of the frequencies of maternal and neonatal complications supports the validity of the new criteria. These findings should be taken into consideration by decision-makers in Oman when planning antenatal and postnatal services.

G estational diabetes mellitus (GDM) is defined as "any degree of glucose intolerance with the onset of first recognition during pregnancy".[1] This is regardless of the mode of treatment, if it is insulin or only diet modifications and whether or not the condition persists after pregnancy. It does not exclude the possibility that unrecognized glucose intolerance may have antedated or begun concomitantly with the pregnancy. Worldwide, the overall incidence is estimated to be between 1–14% depending on the study population, the method used, and diagnosis timing.[2–5] In the UK, up to 5% of women giving birth each year have pre-existing diabetes mellitus or GDM.[6] In Thailand, the prevalence of GDM is approximately 7%, which is similar to that of the US.[7,8] In Jordan, the incidence of GDM is much higher at around 13.5%.[9]

GDM is associated with several maternal, fetal, and neonatal complications such as pre-eclampsia, operative delivery, fetal macrosomia, birth trauma, birth asphyxia, prematurity, and respiratory distress syndrome (RDS). Timely diagnosis and management will lead to the subsequent reduction in these morbidities.[1–3]

Based on the results of the Hyperglycemia and Adverse Pregnancy Outcome, the International Association of Diabetes and Pregnancy Study Group (IADPSG) adopted a one-step approach for

the diagnosis of GDM, with the use of a two-hour 75 g oral glucose tolerance test (OGTT) between 24 and 28 weeks of pregnancy.[10,11] Derangement of any of the following values is considered sufficient to label the woman as having GDM; 1) a fasting plasma glucose (FPG) ≥ 5.1 mmol/L (≥ 92 mg/dL), 2) a one-hour plasma glucose level ≥ 10 mmol/L (≥ 180 mg/dL), or 3) a two-hour plasma glucose ≥ 8.5 mmol/L (≥ 153 mg/dL). All three cut-off values were selected to reflect an increase in the risk of large for gestational age (LGA) fetus of 75%, a cord serum C-peptide > 90th percentile, and neonatal adiposity > 90th percentile. The application of these IADPSG new diagnostic criteria has been accepted by the American Diabetes Association since 2011.[12] It has also been implemented by the Endocrine Society, the World Health Organization (WHO), and the International Federation of Obstetrics and Gynecology since 2013.[13–15] However, the American College of Obstetricians and Gynecologist and the National Institute of Health have not endorsed the above recommendations and still recommend the traditional 'two-step approach' in which the initial screening with oral glucose challenge test is done at 24–28 weeks of gestation with 50 g of oral glucose followed by a diagnostic three-hour 100 g OGTT for women who exceed the normal glucose threshold.[8,16]

Previously, the 1999 WHO criteria of diagnosing GDM were based on fasting blood sugar (FBS)/FPG values of ≥ 7.0 mmol/L and the two-hour glucose levels of ≥ 7.8 mmol/L.[17] This marked reduction of the FBS cut-off value in the new WHO criteria has led to controversy and arguments as more women would be labeled as GDM and treated when they were considered normal with the old diagnostic criteria. The rationale behind supporting the 2013 WHO criteria is that this will improve the perinatal morbidities, as milder cases of GDM would be detected and timely managed with low-cost interventions of diet and exercise. In addition, the 2013 WHO criteria are based on pregnancy outcome, while the old criteria were most often based on the risk of developing type two diabetes mellitus (T2DM) after delivery.

In the Gulf Cooperation Council states, the prevalence of T2DM is among the highest in the world, ranging between 14–19%.[18,19] On applying the IADPSG criteria, the prevalence of GDM in Qatar, UAE, and Saudi Arabia was found to be 24.0%, 37.7%, and 51%, respectively.[20,21] These figures are predicted to increase further in this region due to the sedentary lifestyle and change in dietary habits resulting in a growing obesity epidemic. Subsequently, it is anticipated that there will be a considerable rise in T2DM and perhaps GDM.[22–24]

In Oman, the Ministry of Health was initially applying the two-step approach for diagnosing GDM. However, in March 2015, a new national protocol was adopted by the endocrine team in collaboration with the obstetrics and gynecology department of the Royal Hospital (RH) and the Sultan Qaboos University Hospital. The national protocol was based on the 2013 WHO criteria in which all pregnant women throughout the country are screened for GDM using the one-step approach of OGTT, diagnosing GDM based on FBS of ≥ 5.1 mmol/L and the two-hour post glucose level of ≥ 8.5 mmol/L.[25]

According to the Ministry of Health annual health statistics, the incidence of GDM has shown a steady rise in the last five years. The incidence of GDM among the registered pregnant population was 11.3% in 2015, 13.5% in 2016, and 15.13% in 2017. This indicates a significant increment in the incidence compared to the preceding years (4.8% in 2012, 5.7% in 2013, and 7.5% in 2014).[26] One of the main reasons for this dramatic rise is the implementation of the new national protocol.

The statistics related to GDM and its complications among Omani women are limited, especially those related to the new diagnostic criteria. No studies have been published yet comparing the incidence of GDM and its complications among Omani women based on the old and the newly implemented national protocol. Therefore, the main objectives of this study were to estimate the incidence of GDM based on the old and new diagnostic criteria among Omani pregnant women and compare the maternal and neonatal outcomes and complications.

METHODS

We conducted a retrospective cohort study at Bawshar Specialized Polyclinic (BSPC) in Muscat. This polyclinic serves women from Bawshar and receives clients from five primary health care centers. The antenatal care (ANC) clinic at BSPC

is well developed in terms of the availability of an ANC register, appointment system, trained doctors, trained nurses, dieticians, and a wide range of modern pharmacological anti-diabetic medications. The GDM clinic at BSPC is run by experienced and qualified obstetrician-gynecologist doctors in conjunction with the RH, which is the referring tertiary institution and where most of the followed-up pregnant women gave birth.

The target population of this study was Omani pregnant women who attended BSPC between January and December 2016. The minimum calculated sample size for the primary objective (to determine the incidence of GDM) was 419 women based on the expected GDM incidence of 11.3% and a 95% confidence interval (CI) with 3% error. However, the sample size was raised to 613 to increase the validity of the study. For the secondary objective (to determine the maternal and neonatal outcomes and complications), a total of 250 patients diagnosed with GDM with complete data related to pregnancy outcomes were included. Clients whose blood sugar levels were suggestive of overt diabetes and those whose GDM status was not known were excluded from the study. Clients who did not deliver at the RH were also excluded owing to missing follow-up information and delivery details.

The participants were selected through systematic random sampling by including every fifth patient. A well-designed data collection sheet was developed by the researchers to collect the required information. Baseline characteristics of the participants were obtained, including age, body mass index (BMI), parity, history of GDM, family history of diabetes, FBS, GTT levels, and the gestational age at which GTT was recorded. The cut-off points for BMI were based on the WHO Expert Committee on Physical Status.[27] The diagnosis of GDM was made by OGTT using 75 g glucose. Clients were labeled as GDM if any one value was above the cut-off values of GTT based on the new national protocol (FBS > 5.0 mmol/L, 2-hour post glucose level ≥ 8.5 mmol/L). Information was gathered on the mode of management, maternal and fetal antenatal complications, mode of labor and delivery, intrapartum complications for normal deliveries, indications of cesarean sections, and neonatal outcomes and complications.

All the relevant information pertaining to the study were gathered by reviewing the patient's medical record files and delivery registers in BSPC and the RH. EpiData software was used for data entry, and the statistical analysis was carried out using SPSS (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.). Descriptive statistics were used to describe the data. For categorical variables, frequencies and percentages were reported. The mean and standard deviation were computed for continuous variables. The incidence will be presented as percentages with a 95% CI. Since the main difference between the old and new diagnostic criteria is falling in the FBS readings, the maternal and neonatal complications were compared between those who were labeled as GDM based on the old and new FBS readings, excluding those who had deranged second GTT value. The Pearson's χ^2 test (or Fisher's exact tests for low cell frequencies) was used to test significance when appropriate, and a p-value ≤ 0.050 was considered significant.

Ethical approval for the study was granted in 2015 by the Center of Studies and Research, Ministry of Health, Oman.

RESULTS

A total of 613 pregnant women were included in the study. The incidence of GDM based on the new diagnostic criteria was found to be 48.5% (n = 297) compared to 26.4% (n = 162) based on the old cut-off values. This indicates that 45.5% (n = 135) of the patients with GDM would have been considered normal by the old diagnostic criteria.

A total of 250 pregnant women with GDM were included in studying the secondary objective. The age ranged between 18 and 45 years, with a mean age of 30.6±5.3 years. More than one-third of the study population (n = 83; 35.9%) were overweight, and another one-third (n = 83; 35.9%) suffered from different stages of obesity. More than half of the participants (n = 154; 61.6%) were para one to four, and almost one-third (n = 77; 30.8%) were primigravida. Only 7.6% (n = 19) of the participants were multipara. Forty-five (28.1%) of the participants had a history of GDM, and 23.5% (n = 24) had a positive family history of diabetes mellitus. The majority of those diagnosed with GDM (n = 187; 74.8%) were managed with diet and exercise. The rest were treated with either metformin alone (n = 49; 19.6%), metformin and insulin (n = 3; 1.2%), or insulin alone (n = 2; 0.8%) in

Table 1: Characteristics of Omani women with gestational diabetes mellitus (GDM) (N = 250).

Characteristics	n (%)
Age group, years	
18–20	3 (1.2)
21–30	134 (53.6)
31–40	104 (41.6)
> 40	9 (3.6)
Parity	
Primigravidae	77 (30.8)
1–4	154 (61.6)
5–8	19 (7.6)
> 8	0 (0.0)
BMI, kg/m²*	
≤ 24.9	65 (28.1)
25–29.9	83 (35.9)
30–39.9	76 (32.9)
≥ 40	7 (3.0)
Previous history of GDM*	
Yes	45 (28.1)
No	115 (71.9)
Family history of DM*	
Yes	24 (23.5)
No	78 (76.5)
Gestational age at OGTT in weeks*	
< 22	108 (50.9)
≥ 22	104 (49.1)
Mode of management	
Normal diet	9 (3.6)
DDE	187 (74.8)
DDE and metformin	49 (19.6)
DDE, metformin, and insulin	3 (1.2)
DDE and insulin	2 (0.8)

BMI: body mass index; DM: diabetes mellitus; OGTT: oral glucose tolerance test; DDE: diabetic diet and exercise.
*Missing data were not included in the statistical analysis.

Table 2: Antenatal and postnatal outcomes among Omani women with gestational diabetes mellitus (N = 250).

Outcome category	n (%)
Maternal and fetal antenatal complications	
LGA	12 (4.8)
SGA	26 (10.4)
Polyhydramnios	15 (6.0)
PIH	10 (4.0)
Preterm delivery	8 (3.2)
Mode of delivery	
Spontaneous onset	173 (69.2)
Induced	61 (24.4)
Spontaneous vaginal delivery	190 (76.0)
Instrumental	8 (3.2)
Cesarean section	52 (20.8)
Neonatal complications	
Macrosomia*	6 (2.4)
SCBU admission	14 (5.6)
Hypoglycemia	2 (0.8)
Hypocalcemia	1 (0.4)
Jaundice	10 (4.0)
RDS	4 (1.6)
Apgar score < 7 at five minutes	2 (0.8)

LGA: large for gestational age; SGA: small for gestational age; PIH: pregnancy-induced hypertension; SCBU: special care baby unit; RDS: respiratory distress syndrome.
*Birth weight of ≥ 4.0 kg.

addition to diet and exercise. In half of the participants (n = 108; 50.9%), the OGTT was performed before 22 weeks gestation due to factors that predisposed them to GDM. The other half (n = 104; 49.1%) had their OGTT either repeated or performed for the first time after 22 weeks gestation. The characteristics of this subgroup are given in Table 1.

The most common antenatal complication among the 250 pregnancies was small for gestational age (SGA) fetus (n = 26; 10.4%). Only 6.0% (n = 15) were complicated by polyhydramnios and 4.8% (n = 12) had LGA fetus. Ten women (4.0%) developed pregnancy-induced hypertension (PIH) and eight women (3.2%) delivered prematurely. The majority of the pregnancies ended up with spontaneous onset of labor (n = 173; 69.2%), while 24.4% (n = 61) had their labor induced, either because of GDM or for some other obstetric indications. Among the two groups, 76.0% (n = 190) had spontaneous vaginal delivery, and 3.2% (n = 8) had instrumental delivery [Table 2].

The cesarean section rate among this GDM population was 20.8% (n = 52). The most common indications for cesarean section were abnormal cardiotocography (n = 14; 26.9%), previous multiple scars (n = 11; 21.2%), abnormal fetal lie/presentation (n = 8; 15.4%), and maternal request for cesarean section (n = 7; 13.5%). Four women (7.7%) had cesarean section due to unresponsiveness to induction of labor. Among women who had a vaginal delivery, four (2.1%) had postpartum hemorrhage and two (1.1%) had

Table 3: Comparison of maternal and neonatal outcomes based on fasting plasma glucose levels among Omani women with gestational diabetes mellitus (N = 250).

Complication	FPG levels, n (%)		p- value
	5.1–5.49 mmol/L (n = 126)	≥ 5.5 mmol/L (n = 65)	
LGA	5 (4.0)	3 (4.6)	1.000
SGA	14 (11.1)	5 (7.7)	0.610
Polyhydramnios	7 (5.6)	3 (4.6)	1.000
PIH	4 (3.2)	1 (1.5)	0.660
Preterm delivery	4 (3.2)	1 (1.5)	0.660
Macrosomia*	4 (3.2)	1 (1.5)	1.000
Neonatal hypoglycemia	1 (0.8)	1 (1.5)	1.000
Neonatal hypocalcemia	0 (0.0)	0 (0.0)	1.000
Neonatal jaundice	3 (2.4)	4 (6.2)	0.446
RDS	3 (2.4)	0 (0.0)	0.310
SCBU admission	5 (4.0)	5 (7.7)	0.316

FPG: fasting plasma glucose; LGA: large for gestational age; SGA: small for gestational age; PIH: pregnancy-induced hypertension; RDS: respiratory distress syndrome; SCBU: special care baby unit.
*Birth weight of ≥ 4.0 kg.

their delivery complicated by third or fourth degree perineal tears.

In terms of neonatal outcome and complications, the mean birth weight was 3.0±0.4 kg, and macrosomia incidence was 2.4% (n = 6). The Apgar score at five minutes for the vast majority (n = 248; 99.2%) was ≥ 7. Only 14 neonates (5.6%) were admitted to the special care baby unit (SCBU). The commonest indications for these admissions were RDS (n = 3; 21.4%), sepsis (n = 3; 21.4%), and hypoglycemia (n = 2; 14.2%). There was one neonatal case (7.1%) for each of the other indications of SCBU admission, including prematurity, tachypnea, congenital heart disease, low Apgar score, birth asphyxia, and others.

In terms of neonatal metabolic complications, 4.0% (n = 10) had jaundice requiring phototherapy, 1.6% (n = 4) developed RDS, 0.8% (n = 2) had hypoglycemia, and 0.4% (n = 1) had hypocalcemia [Table 2].

On comparing the complications among those who were labeled as GDM based on the new diagnostic criteria and those based on the old FBS cut-off values, the incidence of macrosomia was 3.2% vs. 1.5%, polyhydramnios was 5.6% vs. 4.6%, PIH was 3.2% vs. 1.5%, and preterm delivery was 3.2% vs. 1.5%, respectively, with statistically insignificant difference among the two groups in all of these complications. The neonatal complications among the two groups, including hypoglycemia, hypocalcemia, jaundice, RDS, and SCBU admission, showed a slightly higher incidence among those diagnosed based on the new FBS cut-off values. However, these differences were not statistically significant [Table 3].

DISCUSSION

This is the first study in Oman and the Gulf region that estimates the incidence of GDM using both old and new WHO diagnostic criteria and compares their outcomes and complications. This study found that the incidence of GDM is 48.5% with the application of the new cut-off points compared to 26.4% if the old cuff-off points were applied. The incidence dramatically increased after applying the new cut-off values where approximately half of the patients with GDM would have been considered normal by the old diagnostic criteria. However, maternal and neonatal complications have not shown a statistically significant difference between the two groups. This high incidence of GDM is alarming and raises many queries that need to be looked at with more extensive multicenter studies. This figure should be considered a good indicator of the increased future burden on Oman's health services.

Globally, few studies have compared the incidence of GDM among the two groups with varying results. In Spain, a similar study reported a significant increment in the incidence of GDM from 10.6% when using the old diagnostic criteria to 35.5% with the use of the new diagnostic criteria.[28] Although the incidence was lower, but the increment was similarly large. In the Middle East region, many studies have assessed the incidence of GDM with the application of the new diagnostic cut-off values, but without comparison to the previous cut-off values. The incidence of GDM in the present study is comparable to the reported incidence in Saudi Arabia,[21] which is 51%, but it is lower than the rates reported from Jordan[9] (13.5%) and Qatar[20] (24.0%). The wide variation in these estimates may be attributed to the study design differences and in selecting the study subjects and ethnic and

sociocultural factors. Differences among ethnic groups have been reported in Western as well as Asian communities. However, it remained unclear whether the variation was related to biological or cultural factors.

This study reveals that almost half of the study population had an early screening for GDM because of different factors that predispose them to GDM, such as a history of GDM, positive family history, and obesity. This needs to be questioned here as the validity of applying the same GTT values to the first trimester (before 12 weeks of gestation), when these values have been originally suggested for the second trimester (24–28 weeks). No data so far have looked into the normal blood glucose values in the first trimester.

A previous study from Oman reported the incidence of PIH in women with GDM to be 24.4%.[29] This is far more than the incidence found in the current study (4.0%). The incidence of PIH in our cohort is also lower than that found in a study conducted at a local tertiary care institution (7.8%),[30] as well as in other studies conducted in Saudi Arabia (18.2%) and Thailand (11.2%).[31,32] This could be due to many factors such as small sample size and the fact that it was conducted in only one specialized polyclinic.

In this study, the rate of cesarean section among women with GDM was 20.8%. A study in Saudi Arabia reported a similar incidence at a rate of 21.6%.[33] Several other studies have reported the incidence of cesarean section among patients with GDM, with figures ranging from 26% to 33%.[29,30,32] Interestingly, a recent study from Saudi Arabia has reported a high cesarean section rate (double ours) in which they applied the new diagnostic criteria.[21] This is very striking as it raises the question of whether the use of these new cut-off values will increase cesarean section rates, hence increasing the burden on the health care services.

The incidence of preterm delivery in our study (3.2%) is very low compared to other studies where the incidence reached as high as 13.6%.[29–31] In addition, the rate of induction of labor in our cohort (24.4%) is, to some extent, lower than that observed in Saudi Arabia (31.8%).[31] On the other hand, the incidence of polyhydramnios in our cohort (6.0%) is almost double that found in Saudi Arabia, which was 3.2%.[31] The incidence of fetal macrosomia in this study is considerably low compared to what is reported nationally and internationally, ranging from 12.7% to 20.0%.[29,31,32] Surprisingly, there was no single case of shoulder dystocia among our population who had a normal delivery, whereas other studies reported a small rate between 0.7% and 1.4%.[29,32] In terms of neonatal RDS, this cohort's findings are almost similar to that reported by a previous local study.[30] Jaundice showed a higher incidence in our cohort (4.0%) than the above-mentioned study (2.4%). Low Agar score at five minutes was found in only 0.8% of infants born to mothers with GDM. However, this figure is much higher in Saudi Arabia (3.2%).[31] The neonatal outcomes in another study from Saudi Arabia showed the prevalence of GDM related complications higher than that observed in our study.[21] The lower rates of GDM complications in our study could be attributed mainly to implementing a well-structured antenatal program for universal screening of GDM that resulted in timely diagnosis and management of GDM. Close follow-ups of patients with GDM and good glycemic control were achieved in most of the cohort with simple diet and exercise measures.

Limited studies have compared the outcomes between those diagnosed with GDM based on the old cut-off values and those diagnosed by the new cut-off values. On comparing the complications between these groups, there was no statistically significant difference in all studied outcomes. A comparable study from Spain revealed similar rates for most complications, including gestational hypertension, preterm delivery, fetal macrosomia, and SGA and LGA among the two groups.[28] This stresses the validity of the new cut-off values and emphasizes the importance of its implementation and application.

There are several limitations to the current study. Being retrospective in nature has resulted in a limited number of patients with complete data. In addition, since this study was conducted in only one polyclinic in Muscat, the results may not be generalized to other regions or the entire country. Further comprehensive research (multicenter and multiregional) will be required to compare the current finding to those of the general population and would be extremely informative for better planning of antenatal and postnatal services.

CONCLUSION

GDM is common among Omani women. The new cut-off values have dramatically increased the

incidence of GDM. The maternal, fetal, and neonatal complications among patients diagnosed based on the old and new protocols were comparable, emphasizing the need for implementing and enforcing the new diagnostic values. This issue needs to be taken into consideration when planning antenatal and postnatal services.

Disclosure

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