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Research Article

Comparison of the Screening Tests for Gestational D.M One Step and Two Step Methods among the Pregnant Women

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Introduction

Gestational Diabetes Mellitus (GDM) has defined by the World Health Organization (WHO) in 1999 as any degree of carbohydrate intolerance resulting in hyperglycemia of variable severity, with onset or first recognition during pregnancy, excluding overt diabetes in early pregnancy [1]. Its prevalence varies worldwide and also with the testing method and diagnostic criteria used [2]. Extensive research has demonstrated that GDM is associated with short- and long-term complications concerning both mother and child. Screening and treating GDM are an effective means to prevent short term complications and a significant opportunity for intervention in order to avoid long term ones [3]. Short term complications of GDM such as macrosomia, shoulder dystocia, birth trauma, increased rate of cesarean section, in uterine fetal death, neonatal hypoglycemia, congenital anomalies, and respiratory distress syndrome, and to the occurrence of maternal hypertensive disorders [4]. Long term complications include maternal increased risk of developing Type 2 Diabetes (T2DM) later in life and major potential metabolic pattern disorders in the offspring, which would lead to increased risks of abnormal glucose tolerance, obesity and metabolic syndrome [5].

The American College of Obstetricians and Gynecologists (ACOG) recommends a two-step approach for screening and diagnosis of GDM in moderate and high-risk population, first screening with the 50-g Glucose Challenge Test (GCT), those individuals meeting or exceeding the screening threshold (>140 mg/d) undergo a 100-g 3-h diagnostic oral glucose tolerance test [2]. On the other hand, World Health Organization (WHO) recommends a single-step 75-g 2-h OGTT to be performed in fasting state [6].

The International Association of Diabetes and Pregnancy study groups (IADPSG) in 2010 is an international consensus group with representatives from multiple obstetrical and diabetes organizations, has proposed guidelines relied on a study of Hyperglycemia and Adverse Pregnancy Outcomes (HAPO study) to reach a single consensus and suggested new criteria for the diagnosis of diabetes in pregnancy based on the association of maternal glycaemia with perinatal outcomes [7]. It recommends screening high-risk women at the first visit, to screen universally at 24- to 28-week gestation, with use of the 75-g oral glucose tolerance test for the diagnosis of gestational diabetes (one-step approach) [8,9].

Applying IADPSG criteria invariably increases the prevalence of GDM, since it includes milder cases of GDM [10,11]. This approach has not been endorsed by ACOG [5]. ACOG emphasizes that 18 percent of all pregnant women will be diagnosed with GDM using the IADPSG criteria due to a lower threshold. They believed that the one-step approach with new criteria would increase health care costs in the absence of solid evidence for improvements in maternal or neonatal outcomes [12].

ADA guidelines now leave the choice between the one-step IADPSG screening strategy and the two-step screening strategy [13]. Since the new strategy using 75 g OGTT as one-step screening is still controversial, present study was undertaken to compare the one-step screening procedure (IADPSG recommended) with two-step procedure (ACOG recommended) in addition to incidence, maternal and fetal outcome of patients with GDM.

Materials and Methods

A prospective randomized study was conducted on 600 pregnant women attending antenatal care clinic (ANC), at Shatby University hospital between March 2019 and December 2019, were counseled and written informed consent was taken.

Inclusion criteria included women between 18-38years, singleton pregnancy with low or average risk for GDM which was defined by any pregnancies that had no criteria for the high risk for GDM as mentioned later, and gestational age between 24 and 28 weeks of gestation, based on regular menstrual period and ultrasound examination in the first half of pregnancy.

Exclusion criteria were pregnant women with high risk for GDM, including known cases of pre-gestational diabetes or high risk for gestational diabetes mellitus such as previous child birth weight of more than 4,000 grams, previous diagnosis of GDM, obesity or BMI 30 kg/m2 or more, previous neonatal hypoglycemia, and first degree relatives with diagnosed DM or glucosuria.

According to computer-generated random number table; group A comprised of300 patients screened with one-step approach for GDM and group B included 300 women screened by two-step approach.

Group A One-step screening procedure (IADPSG recommended) was based on 75 gram two-hour oral glucose tolerance test (75 g OGTT) with at least one abnormal result: fasting plasma glucose ≥92 mg/dl, but <126 mg/dl or one-hour OGTT ≥180 mg/dl or two-hour OGTT ≥153 mg/dl. If any one of the above values was abnormal, then subjects were labeled as having GDM.

Group B The two-step approach was as follows: firstly, a 50 g

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oral Glucose Challenge Test (GCT) was performed regardless of the fasting status. If the plasma glucose level after 1 h was of ≤140 mg/dl, it was considered as negative and needed no further test. If the level was>140 mg/dl, then 100 g OGTT was performed. The plasma glucose was measured after 100 g load at fasting, 1-, 2-, and 3-hour interval. The cut-off values were as follows: fasting ≥105 mg/dl, 1 h ≥ 188 mg/d, 2 h ≥ 165 mg/dl, and 3 h ≥ 140 mg/dl. A diagnosis of GDM was made if at least two values exceeded above plasma glucose concentration.

In cases of normal results, routine standard antenatal care was instituted, while women diagnosed as 'gestational diabetes' were followed in an antenatal clinic, the patients were taken care as a standard guideline for diabetic patients during pregnancy. At each antenatal visit, records of weight, blood pressure and obstetric examination were taken. BMI was measured at first ANC visit. Blood sugar profile which includes fasting blood sugar and post-meal blood sugar (2 h after meal) was monitored weekly in third trimester. Ultrasound for congenital malformation was done between 18 and 20 weeks. Blood glucose was usually controlled with diabetic diet and exercise. Insulin was used only when fasting glucose was more than 105 mg/dl, the target was to maintain fasting glucose <95 mg/dl or 2-hour postprandial glucose <120 mg/dl. Ultrasound monitoring for fetal well-being in the form of biophysical profile was done after 34 weeks on weekly basis. Women controlled on insulin were allowed to go in spontaneous labor till 38 weeks if there was no fetal or maternal indication of termination of pregnancy. Elective termination of pregnancy was done at 38 weeks if they did not go in labor. Further, women controlled on MNT alone were allowed to go in spontaneous labor up to 40 weeks, if antenatal period was uncomplicated.

The main outcome was the prevalence of GDM, and the secondary outcomes included birth weight, gestational age at delivery, rates of preterm birth (delivery before completed 37weeks), large-for gestational age (birth weight of greater than 90th percentile for each gestational week), cesarean section, pregnancy-induced hypertension and neonatal complications.

Results

A total of 600 pregnant women were included in the study, 300 pregnant women were screened by one-step procedure group (A) and300 were screened by two-step procedure group (B). As regard baseline characteristics for all 600 women in both groups, which included maternal age, pre-pregnancy weight, maternal weight, BMI, gestational age at screening, and parity, fasting blood glucose were not statistically significantly difference including normal and GDM as shown in (Table 1). But as regard prevalence of GDM was higher in group A (one-step procedure) than in group B (two-step procedure) with statistically significantly difference (Table 2).

In Table 3, the prevalence of GDM was significantly higher in the one-step subgroup than that in the two-step subgroup: (19.3%) versus (11%), respectively which was significantly difference P (0.001). In one step procedure (74.2%) *versus.* (66.7%) in two step procedure responded to medical nutritional therapy MNT only, while (25.8%) in one step *versus.* (33.3%) in two step responded to MNT and insulin and achieved normoglycemic status. In one step procedure (subgroup A) blood glucose response was controlled in all patient

Table 1: Comparison of baseline characteristics between one-step and two-step groups.

Characteristics	Group A One step (n=300)	Group B Two step (n=300)	*P* value
Maternal age	28.0±4.9	28.5±3.52	0.171
Pre-pregnancy Weight	74.9±7.6	74..8±7.5	0.854
Maternal BMI	26.87±5.32	26.75±5.41	0.054
Maternity Weight at screening	82.4±8.7	82.5±8.5	0.993
Gestational age at screening (weeks)	26.8±1.5	26.8±1.5	0.856
Fasting blood glucose	81±7	81±5	0.812
Primi-gravida	198(66%)	176(58.7%)	0.061
Multi-gravida	102(34%)	124(41.3%)	
Prevalence of GDM	58 (19.3%)	33 (11%)	0.001

Table 2: Comparison of baseline characteristic of pregnancies with GDM between the groups diagnosed by the one-step and two-step technique.

Characteristic	Subgroup A one step (n=58)	Subgroup B Two steps (n=33)	*P* value
Maternal age	28.71±5	28.56±5.3	0.903
Pre-pregnancy Weight	72.2±8	72.3±8.3	0.974
Maternal BMI	26.94±2.26	27.26±2.99	0.058
Maternity weight at screening	81.9±7.6	81.8±7.5	0.854
Gestational age at screening wks	25.7±1	25.8±1	0.111
Fasting blood glucose	84±7	84±7	0.879
Prim-gravida Multigravida	34(58.6%) 24(41.4%)	19(57.58%) 14(42.42%)	

Table 3: Gestational diabetic status and variables.

Variables	One step (n=58)	Two step (n=33)	*P* value
Prevalence of GDM	58 (19.3%)	33 (11%)	0.001
Medical nutrition therapy (MNT)	43 (74.2%)	22 (66.7%)	
MNT with insulin	15 (25.8%)	11 (33.3%)	
Blood sugar response Controlled on MNT	30 (51.7%)	21(63.6%)	
Controlled on MNT and insulin therapy	15 (25.8%)	11 (33.3%)	
Hypoglycemic values on MNT(required resumption of normal diet)	13(22.4%)	1(3%)	

treated by MNT and insulin, while those treated by MNT, (22.4%) (Table 4) women required resumption of normal diet as the blood sugar profile values were falling in hypoglycemic range and were symptomatic for hypoglycemia but in group B only one case on MNT needed resumption of normal diet (Table 5).

Discussion

Gestational Diabetes Mellitus (GDM) has defined by the World Health Organization (WHO) in 1999 as any degree of carbohydrate intolerance resulting in hyperglycemia of variable severity, with onset or first recognition during pregnancy, excluding overt diabetes in early pregnancy [1]. Its prevalence varies worldwide and also with the testing method and diagnostic criteria used [2]. The American College of Obstetricians and Gynecologists (ACOG) recommends a two-step approach for screening and diagnosis of GDM, while the International Association of Diabetes and Pregnancy Study Groups

Table 4: Comparison of maternal outcomes.

Outcomes	Subgroup A, n=58	Subgroup B, n=33	*P* value
Gestational weeks at delivery	38.5±1.7	38.7±1.7	0.029
Preterm labour<37	3 (5.2%)	2 (6.1%)	0.162
Full term pregnancy	55 (94.8%)	31 (93.9%)	
Normal vaginal delivery	14(24.2%)	9 (27.2%)	
Elective cesarean section	30(51.7%)	15(45.5%)	0.795
Emergent cesarean section	14(24.1%)	9 (27.3%)	
Pre-eclampsia	4 (6.9%)	3 (9.1%)	0.409
Postpartum hemorrhage	3(5.2%)	1 (3.1%)	0.16

Table 5: Neonatal outcome.

	Subgroup A	Subgroup B	*P* value
Birth weight (in kgs)	3.41±0.44	3.42±0.45	0.231
Neonatal glucose	62±34	64±28	0.18
Still birth or neonatal death	0	1	
Large for gestational age	5 (8.6%)	3 (9.1%)	0.111
Shoulder dystocia	2 (3.4%)	1 (3%)	0.171
RDS	5 (8.6%)	5 (15%)	0.71
Birth injury	2(3.4%)	0(0%)	0.144
Hyperbilirubinemia	19 (32%)	5 (15%)	0.006

(IADPSG) recommends new strategy which is based on the one-step approach. In present study we found that, the prevalence of GDM in subgroup A (IADPSG, one step procedure) was 19.3 % *versus.* 11% in subgroup B (ACOG, two step procedure), since IADPSG criteria are designed to identify milder cases of GDM. Increased sensitivity of IADPSG is likely related to a lower threshold for a positive test; only one elevated glucose value is needed, and the cut-off is slightly lower. The magnitude of the increase varies in different reports [14,15], while the prevalence of GDM by the two-step approach approximately 5–10% as seen in most reports [6]. Moreover, the prevalence has been increasing over time, possibly associated with an increase in mean maternal age as well as maternal weight [16]. However, racial factor may also be implicated since the prevalence of GDM varies worldwide and among racial and ethnic groups [14-17]. Similar results were seen in other retrospective studies [14,17] as study by Ortio et al., where GDM prevalence went from 8 to 23% [18].The reported incidence of GDM in Indian population is 3.8–21% [6]. Bergella et al, trial showed a non-statistically significant difference in the prevalence of GDM (19), but it was probably due to the small sample size.

As regard, pregnancy outcomes there were no significant difference between two groups in all variables, which agreed with the study of Tongson et al. [19,20], where baseline characteristics and pregnancy outcomes were comparable in both groups as presented. Chang et al. [21] study also agreed with present study in pregnancy outcomes where the prevalence of obstetric complications most frequently linked to GDM appeared to remain stable. As regard neonatal outcomes there were no significant differences in all variables except neonatal hyperbilirubinemia was higher in subgroup A 32% *versus.* 15% in subgroup B. In Tongson et al, founded that hypoglycemia was higher in one step (29.31%) *versus.* (7.4%) in two step while Hyperbilirubinemia was (8.62%) `in one step *versus.* (20%) in two step [20].

There is no conclusive evidence that there is improvement in obstetric outcomes when treating milder cases of GDM [22,23] because the decrease in obstetric complications depends on many variables other than the screening strategy alone. These variables include screening and treatment acceptability by patients [24], glycemic targets, adherence to treatment, and the independent influence of maternal BMI. The strength of obstetrics and endocrinological care coordination may have impact.

Conclusion

The one-step approach has advantages for women and their health care providers as it would allow a diagnosis to be achieved within one visit instead of two. However, the increased prevalence raises several concerns for women with additionally diagnosed GDM. No evidence whether the additional women detected by the one step approach will benefit from treatment, and if so, to what extent. Additionally, the care of these women will certainly increase much health care costs. Moreover, the women labeled for GDM may have unintended consequences, such as an increase in rates of cesarean section and more intensive newborn assessments, increased patient costs, and possible psychosocial burdens, this new approach may not be appropriate for screening in a busy antenatal care clinic or other healthcare centers in developing countries, without strong evidence of obvious clinical benefit in term of pregnancy outcomes as shown in this study.

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