ORIGINAL ARTICLE

Diagnosing Gestational Diabetes Mellitus: 1 - step approach versus 2 - step approach

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ABSTRACT

Aim: To determine the frequency of positive cases in 1 - step approach versus 2-step approach for diagnosing gestational diabetes mellitus.
Methods: This descriptive, cross-sectional study was conducted in the Department of Obstetrics and Gynecology, Unit I, Services Hospital, Lahore over a period of 6 months from 15-01-2017 to 15-07-2017. 177 pregnant patients were included in this study. All patients under went both 1-step approach and 2-step approach with a gap of one week. Frequency of positive cases were recorded on both approaches. Data was analyzed in SPSS version 20.0. Quantitative data like age, body mass index (BMI) and gestational age were presented in the form of mean and standard deviation. Qualitative data like parity and positive cases by 1 and 2-step approach was presented in the form of frequency and percentage.
Results: Age of patient ranged from 21 to 40 years. Mean age (years) was 29.01 ±3.30, mean BMI 27.20 ±1.70 Kg/m^2 and mean gestational age was 28.04 ±1.85 weeks. Majority (83.6 %) of the patients were of ≤ 2 parity. Positive cases by 1 - step approach was seen in 11.3% patients versus 5.1 % by 2-step approach.
Conclusions: Careful consideration should be given to an internationally recommended method of universal screening for GDM which minimizes the burden and cost for individual women and the healthcare system, yet provides diagnostic efficacy. The one-step method accomplished this better than the two-step method.
Keywords: Gestational diabetes mellitus, 1 - step approach, 2 -step approach, Pregnancy

INTRODUCTION

Gestational diabetes mellitus (GDM) is defined as glucose intolerance of variable degree with onset or first recognition during pregnancy[1]. A study by Stuebe et al found this condition to be associated with persistent metabolic dysfunction in women at 3 years after delivery, separate from other clinical risk factors[2]. Infants of mothers with preexisting diabetes mellitus experience double the risk of serious injury at birth, triple the likelihood of cesarean delivery, and quadruple the incidence of newborn intensive care unit (NICU) admission[3]. GDM accounts for 90 % of cases of diabetes mellitus in pregnancy, while preexisting type 2 diabetes accounts for 8% of such cases[4]. GDM can be diagnosed by either 2 - step approach i.e. 50 - gram, 1 - hour oral glucose challenge test (OGCT) is done initially and if positive then followed by 100 -gram, 3 - hour oral glucose tolerance test (OGTT) or 1 - step approach i.e. 75 - gram, 2 - hour oral glucose tolerance test (OGTT). National Institutes of Health (NIH) Panel[5] and American College of Obstetrics and Gynecologists (ACOG)[6] have recommended 2 - step approach. This approach identifies approximately 5% to 6% (frequency of positive cases) of the population as having GDM. Alternatively, Endocrine Society[7]. World Health Organization (WHO)[8], Australasian Diabetes in Pregnancy Society (ADIPS)[9] and International Association of Diabetes and Pregnancy Study Groups (IADPSG)[10] issued new clinical - practice guideline advocating a 1 - step approach. This approach is anticipated to increase the frequency of the diagnosis of GDM by 2 - 3 times i.e., approximately 15% to 20% (frequency of positive cases).

Received on 17-08-2019
Accepted on 12-01-2020

The American Diabetes Association (ADA)[11] which had previously supported a 1 - step approach, issued a new recommendation stating that there is not enough evidence to favor switching to this strategy, so either approach is acceptable. The US Preventive Services Task Force (USPSTF)[12] recommendation also does not specify whether the 1 - step or 2 - step approach would be preferable. Till now it is not cleared that whether 1 - step approach for diagnosing the pregnant women for gestational diabetes mellitus is enough or 2 - step approach is better. There are no local guidelines available regarding gestational diabetes mellitus. International guidelines are followed for managing such patients, which don't clearly prefer one approach over other. Hence, some obstetricians are in favor of 1 - step approach in contrary to others favoring 2 - step approach. This study was conducted to find which approach is better in diagnosing the gestational diabetes mellitus as to help us to improve our knowledge and practice and implement more optimal approach for diagnosing GDM, so that adverse fetal and maternal outcomes associated with gestational diabetes mellitus can be prevented.

METHODS

This descriptive, cross sectional study of conducted in the Department of Obstetrics and Gynecology, Services Hospital, Lahore over a period of 6 months from 15-01-2017 to 15-07-2017. By using statistics for 2 - step approach for GDM as 6% and margin of error as 3.5%, the calculated sample size was 177. Non-probability consecutive sampling technique was used. Pregnant females of age 21 - 40 years with parity < 5 and gestational age > 24 completed weeks (according to 1st day of last

menstrual period) presenting for routine prenatal checkup were included in this study. Patients already diagnosed case of diabetes mellitus (on medical record), multiple pregnancy (on ultrasound), abnormal placenta like previa or accrete (on ultrasound), gestational hypertension (BP ≥ 140/90 mmHg), preeclampsia (BP ≥ 140/90 mmHg with proteinuria + 1 on dipstick method), eclampsia (convulsions with BP ≥ 140/90 mmHg), already diagnosed with ovarian / intrauterine / cervical malignancy (on medical record) were excluded from this study.

177 patients fulfilling the inclusion criteria were recruited from outdoor of Department of Obstetrics and Gynecology, Services Hospital Lahore. Patient was requested to sign an informed consent. They were assured regarding confidentiality and expertise used for the procedure. Demographics (name, age, parity, gestational age, address) were noted. All patients under went both 1 - step approach and 2 - step approach with a gap of one week.

One - step approach was defined as 75 - gram, 2 - hour oral glucose tolerance test (OGTT) i.e. after 8 hour of fasting, 24 weeks pregnant female was given 75 gram of oral glucose. Blood glucose level was measured in fasting state and then at 2 hours post prandial. Positive if fasting glucose ≥ 126 mg/dL (7 mmol/L) OR ≥ 140 mg/dL (7.8 mmol/L) at 2 hours post prandial.

Two - step approach was defined as 50 - gram, 1 - hour oral glucose challenge test (OGCT) done initially and if positive then followed by 100 - gram, 3 - hour oral glucose tolerance test (OGTT). (Both should be positive).

1. *50 gram, 1 - hour oral glucose challenge test (*OGCT*):* Non fasting pregnant female at 24 weeks was given 50 gram of oral glucose and blood glucose level after 1 hour is measured. Test was said to positive if blood glucose level after 1 hour of load is ≥ 140mg/dL (7.8mmol/L) 2.*100 gram, 3 - hour oral glucose tolerance test (*OGTT*):* After 8 hour of fasting, 24 weeks pregnant female was given 100 gram of oral glucose. Blood glucose level was measured in fasting state and then at 1 hour interval for 3 hours. (Positive if 2 or more levels were raised i.e. fasting glucose ≥ 105mg/dL (5.8mmol/L), at 1 hour ≥190mg/dL (10.6mmol/L), at 2 hours ≥165mg/dL (9.2mmol/L) and at 3 hours ≥145mgdL (8.0mmol/L)) (Any one or more of these). All procedures were performed by a single operator and using same glucometer to control bias. All data was collected. Frequency of positive cases were recorded on both approaches

Data was entered and analyzed in SPSS version 20.0. Quantitative data like age, BMI and gestational age were presented in the form of mean and standard deviation. Qualitative data like parity and positive cases by 1 and 2-step approach was presented in the form of frequency and percentage approaches. Confounding factors like age, gestational age, parity and Body Mass Index (BMI) were controlled through stratification. Post stratification chi-square test was applied by taking P ≤ 0.05 as significant.

RESULTS

Age range in this study was from 21 to 40 years with mean age of 29.01 ± 3.30 years, mean BMI was 27.20 ± 1.70 Kg/m^2 and mean gestational age was 28.04 ± 1.85 weeks. Majority (83.6 %) of the patients were of ≤ 2 parity. Positive cases by 1 - step approach was seen in 11.3 % patients versus 5.1 % in 2 - step approach. Stratification of data of both approaches with respect to age of patients (years) (Table 1 and 2), gestational age (weeks) (Table 3 and 4), parity (Table 5 and 6) and BMI (kg/m^2) (Table 7 and 8) showed statistically insignificant association of frequency of positive cases in relation to all above mentioned factors.

Table 1: Age stratification of 1 – step approach

Age (years)	1 – step approach		Total
	YES	NO	
21 – 30	13 (10.7 %)	108 (89.3 %)	121(68.4 %)
31 – 40	7 (12.5 %)	49 (87.5 %)	56 (31.6 %)
Total	20 (11.3 %)	157 (88.7 %)	177 (100%)

P value 0.731

Table 2: Age stratification of 2 – step approach

Age (years)	2 – step approach		Total
	YES	NO	
21 – 30	7 (5.8 %)	114 (94.2 %)	121 (68.4 %)
31 – 40	2 (3.6 %)	54 (96.4 %)	56 (31.6 %)
Total	9 (5.1 %)	168 (94.9 %)	177 (100%)

P value 0.533

Table 3 : Gestational age stratification of 1 – step approach\

Gestational Age weeks	1 – step approach		Total
	YES	NO	
25 – 28	11 (10.6 %)	93 (89.4 %)	121 (68.4 %)
> 28	9 (12.3 %)	64 (87.7 %)	56 (31.6 %)
Total	20 (11.3 %)	157 (88.7 %)	177 (100%)

P value 0.717

Table 4: Gestational age stratification of 2 – step approach

Gestational Age weeks	2 – step approach		Total
	YES	NO	
25 – 28	5 (4 .8 %)	99 (95.2 %)	104 (58.8 %)
> 28	4 (5.5 %)	69 (94.5 %)	73 (41.2 %)
Total	9 (5.1 %)	168 (94.9 %)	177 (100%)

P value 0.841

Table 5: Parity stratification of 1 – step approach

Parity	1 – step approach		Total
	YES	NO	
0 – 2	15 (10.1 %)	133 (89.9 %)	148 (83.6 %)
3 – 4	5 (17.2 %)	24 (82.8 %)	29 (16.4 %)
Total	20 (11.3 %)	157 (88.7 %)	177 (100%)

P value 0.269

Table 6 : Parity stratification of 2 – step approach

Parity	2 – step approach		Total
	YES	NO	
0 – 2	8 (5.4 %)	140 (94.6 %)	148 (83.6 %)
3 – 4	1 (3.4 %)	28 (96.6 %)	29 (16.4 %)
Total	9 (5.1 %)	168 (94.9 %)	177 (100%)

P value 0.661

Table 7 : BMI stratification of 1 – step approach

BMI(kg/m^2)	1 – step approach		Total
	YES	NO	
≤ 25	1 (3 %)	32 (97 %)	33 (18.6 %)
> 25	19 (13.2 %)	125 (86.8 %)	144 (81.4 %)
Total	20 (11.3 %)	157 (88.7 %)	177 (100%)

P value 0.096

Table 8: BMI stratification of 2 – step approach

BMI(kg/m^2)	2 – step approach		Total
	YES	NO	
≤ 25	1 (3 %)	32 (97 %)	33 (18.6 %)
> 25	8 (5.6 %)	136 (94.4 %)	144 (81.4 %)
Total	9 (5.1 %)	168 (94.9 %)	177 (100%)

P value 0.551

DISCUSSION

In this study positive cases by 1 - step approach was seen in 11.3 % patients and positive cases by 2 - step approach was seen in 5.1 % patients. Several studies evaluating the cost of GDM screening have also demonstrated that 2 - step method using 50 - g glucose screen (GS) is the least costly[13,14,15]. Lavin[14] found that the two-step protocol was associated with lower direct costs and less time than a one-step protocol, employing a model based on a Medline search of the prevalence of positive glucose screening tests and catalogue estimates of the costs involved in the screening process. Poncet et al. [15] established the costs involved in the diagnosis and treatment of GDM among 120 women using the French public health system and extrapolated the outcome measures from a 25-year Medline search. These values were combined in a decision and cost-effective analysis model comparing three screening strategies: selective screening with a 50 - g GS + 100 - g, 3 - hour OGTT (American Diabetes Association); universal screening with a 50 - g GS + 3 - hour, 100 - g OGTT; and universal screening with a 75 - g OGTT [World Health Organization (WHO) criteria]. Nicholson et al[13] reported that the 2 - hour, 75 - g OGTT one-step method was more costly and less effective than the two-step method in a statistical modelling study based on a literature review and including the derived costs for diagnosis, treatment and perinatal outcomes. Evidence that high-risk women do better with universal screening using a one-step method is limited; however, it has been suggested that a one-step OGTT may be more effective for high-risk populations[13,14,16].

Universal or selective administration of GDM testing remains a contentious issue. By definition, a screening test should be well defined, easy to administer, reproducible and inexpensive; it is not meant to be diagnostic, but rather to identify a subgroup of individuals at risk who require further testing for diagnosis. In addition, the sensitivity and specificity of GS vary with the ethnicity of the population, as reported by Esakoff and colleagues[17,18] a goal to maintain false positives below 10% would require a GS cut-off of 7.8 mmol/l for Caucasians and 7.5mmol/l for African-Americans; however, the threshold would need to be higher for Asians. Poncet et al. [15] found that selective screening had a more favorable cost-effectiveness ratio. This may be explained by the use of the more sensitive 2 - hour diagnostic criteria of WHO compared with the CDA criteria used in our study. In their nonrandomized retrospective study, Di Cianni et al[19] compared the estimated costs of screening and management strategies from two different periods and reported that universal screening was most cost-effective, whereas selective screening allowed a cost saving of only 5% per GDM diagnosis. Their study affirmed that, although GDM diagnosis and intensive management invoke costs to the healthcare system, they result in significant monetary savings related to reduce perinatal morbidity, which has also been reported for the treatment of mild GDM[19,20].

Most cost studies for GDM testing are based on projected not actual costs, and employ mathematical modelling to extrapolate the findings[13,14]. As recommended for economic evaluations in obstetrics, this study assessed in-depth the actual costs involved[21]. Lavin's study[22] included numerous direct and indirect costs; however, the data were based on modeling with an estimation that 12–17% of women would return for a second test; a value lower than our actual rates. This would lead to lower estimates of cost per case diagnosed. The direct cost of a 2 - hour, 75 - g OGTT of CAN$36.89 can be compared with the £17.58 (CAN$31.59) determined in the National Institute for Health and Clinical Excellence (NICE) Antenatal Care Diabetes in Pregnancy Costing Report. In addition, the women's time and transportation costs (indirect costs) represented a large proportion of the total costs, highlighting the need to incorporate the cost burden for women when evaluating the costs for GDM diagnostic methods. Such in-depth cost comparison of GDM testing methods provides important insights into the impact of choosing one method over another, whilst demonstrating that total actual individual direct and indirect costs are greatest for the one-step, universal, 2 - hour OGTT.

CONCLUSION

Careful consideration should be given to an internationally recommended method of universal screening for GDM which minimizes the burden and cost for individual women and the healthcare system, yet provides diagnostic efficacy. The one-step method accomplished this better than the two-step method.

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