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ORIGINAL ARTICLE

DIAGNOSTIC ACCURACY OF 50 G GLUCOSE CHALLENGE TEST FOR SCREENING OF THE GESTATIONAL DIABETES MELLITUS USING 75 G ORAL GLUCOSE TOLERANCE TEST AS REFERENCE STANDARD

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ABSTRACT

Background: Gestational diabetes mellitus (GDM) is a common causative factor of grave maternal and fetal consequences. Prompt and precise diagnosis of GDM can aid in lessening the likelihood of these unfavorable outcomes. **Objective:** To find the diagnostic accuracy of 50 g GCT (glucose challenge test) for detecting GDM, using 75 g OGTT (oral glucose tolerance test) as the reference standard and to find complications of GDM were also reported. **Methodology:** A diagnostic cross-sectional study was executed at the outdoor patient department of gynecology unit, Lahore General Hospital, Lahore. It comprised of 285 pregnant females aged ≥ 18 years who were screened for GDM. All participants undertook 50 g GCT, followed by 75 g OGTT. Result was considered true positive if GDM was reported on both tests. A 2x2 table was made to estimate the sensitivity and specificity, positive predictive value (PPV) and negative predictive value (NPV) and diagnostic accuracy of GCT using OGTT as gold standard. **Results:** Mean age of patients was 26.28±4.183 years. According to GCT, 39 (13.68%) cases were positive for GDM. On the other hand, 42 (14.74%) tested positive for GDM using 75 g OGTT. We found Sensitivity = 85.71%, Specificity = 98.77% of 50 g GCT and PPV = 92.31 % NPV = 97.56% and overall diagnostic accuracy was found as 96.84%. A total of 86(30.17%) participants reported gestational hypertension whereas Hydramnios was reported in 26 (9.12%) participants. 94(32.98%) patients underwent cesarean section due to cephalopelvic disproportion. Macrosomia, shoulder dystocia and neonatal hypoglycemia was reported in 36(12.63%), 14(4.91%) and 84(29.47%) cases, respectively. **Conclusion:** 50g GCT provided significantly high sensitivity and specficity for diagnosing GDM. As it is a cost-effective and provides reasonably accurate results, it can be used as an alternate to 75 g OGTT. This could aid in minimizing the maternal and fetal consequences by timely identification of the condition.

Keywords: Gestational diabetes mellitus, screening, oral glucose tolerance test, glucose challenge test, diagnostic accuracy, accuracy

INTRODUCTION

Gestational diabetes mellitus is a prevailing health challenge, having grave consequences on wellbeing of pregnant women and fetuses throughout the world. It is developed when the pancreas cannot cater the enhanced diabetogenic impacts of pregnancy [1]. Similar to diabetes mellitus (DM), the incidence of GDM is also increasing, causing an augmented possibility of adverse event in both mothers and fetuses. Reports by International Diabetes Federation documented that the worldwide prevalence of GDM was 14% in 2021, making it a substantial public health apprehension [2]. The timely identification of GDM is critically significant to evade these unfavorable conditions. World Health Organization and American Diabetes Association regarded 75g OGTT as a reference standard to diagnose GDM between 24-28 weeks of gestation [3]. As the requirements of this assay are difficult like fasting for at least 8 hours, intricate patient preparation, instantaneous consumption of a large quantity of sugar, and several pricks within two hours, resulting in challenges to maintain consistent protocols across various testing laboratories [4].

50 g GCT is an attractive alternate to other blood glucose testing methods for diagnosing GDM [5, 6]. It was introduced as a screening test by O'Sullivan et al. in 1973. It was reported that at the cut-off point of ≥130 mg/dL, a sensitivity of 79% and specificity of 87% was showed by GCT for

diagnosing GDM. GCT had a sensitivity of 79% and specificity of 87% for diagnosing GDM [7]. It has a number of pros, such as not requiring fasting and being possible to conduct at any time of the day [8]. It offers more accurate results than random blood sugar evaluation [9]. Previous studies documented it as an index test for GDM screening, however the results were inconsistent [3, 5, 6, 10, 11].

Even though the early identification of GDM is recommended by all international guidelines [12, 13], there is lack of consensus on the preferable screening methods. Owing to a greater incidence of GDM and its associated consequences in Pakistan [14], this comparative study was performed to determine the diagnostic accuracy of 50 g GCT for diagnosing GDM, using 75 g OGTT as a reference standard.

MATERIAL AND METHODS

Study design: It was a diagnostic cross-sectional study.

Settings: It was executed at the outdoor patient department of gynecology unit, Lahore General Hospital, Lahore.

Duration: It was completed in six months

Sample size: The sample size of 286 was calculated using 95% confidence level, 10% absolute precision, 83.5% expected sensitivity of 50 g GCT [10], and 18.6% prevalence of GDM [15].

Sampling technique: Purposive sampling was utilized to gather the data.

Sample selection criteria:

Inclusion criteria:

- All women who are undergoing glucose screening between 24 and 28 weeks of gestation.

Exclusion criteria:

- Known diabetics
- Patients with chronic medical conditions
- Patients who refused to take part in the study

Data collection procedure:

Following approval from the institutional committee and getting consent from the patients, 285 pregnant women were recruited from the outpatient department of the gynecology unit at Lahore General Hospital, Lahore. After observing their demographic profile, all women were initially screened with 50 g GCT between 24-28 weeks of gestation. For patients undergoing 50 g GCT, they were considered positive for GDM if the blood sugar level (BSL) of >140 mg/dl was observed an hour after glucose ingestion [16]. OGTT was then performed between 3-7days after GCT. The OGTT was conducted following an overnight fast of minimum 8 hours, with subjects maintaining an unrestricted diet and unlimited physical activity for at least 3 days prior, to determine the presence of GDM. Diagnosis of GDM was made if any two of the following criteria were met a) Fasting BSL ≥ 5.3 mmol/L (95 mg/dL), b) BSL ≥ 10 mmol/L (180 mg/dL) at 1 hour after ingesting glucose solution, c) BSL ≥ 8.6 mmol/L (155 mg/dL) at 2 hours after ingesting glucose solution, or d) BSL ≥ 7.8 mmol/L (140 mg/dL) at 3 hours after ingesting glucose solution [17]. Diagnostic accuracy was assessed by identifying positive or negative cases.

True positive (TP): It was considered if GDM was positive on both GCT and OGTT.

False positive (FP): It was considered if GDM was positive on GCT and negative on OGTT.

False negative (FN): It was considered if GDM was negative on GCT and positive on OGTT.

True negative (TN): It was considered if GDM was negative on both GCT and OGTT. All these patients were followed up till delivery to observe the clinical outcomes in term of maternal (hypertension, hydramnios, and mode of delivery) and neonatal outcomes (macrosomia, hypoglycemia, and shoulder dystocia). Data analysis was performed using SPSS version 24. Frequency and percentage was estimated for qualitative variables like gravidity, parity, diagnosis of GDM on GCT and OGTT, and feto-maternal complications. Mean ± Standard Deviation was presented for quantitative variables including age, and gestational age. A 2x2 table was made to estimate the sensitivity and specificity, positive predictive value (PPV) and negative predictive value (NPV) and diagnostic accuracy of GCT using OGTT as gold standard.

RESULTS

The study consisted of 285 pregnant females. Baseline characteristics are presented in the Table 1. Mean age of patients was 26.28±4.18 years, with minimum and maximum ages of 18 and 40 years. Mean gestational was 25.27±1.205 weeks. A total of 253(88.77%) females had parity between 0 and 3, and 32(11.23%) of females had parity greater than 3. Gravidity between 1 and 3 was reported in 206(72.28%) and more than 3 in 79(27.72%) cases. Table 2 demonstrates the descriptive statistics for GCT and OGTT. According to GCT, 39 (13.68%) patients tested positive for GDM and 246(86.32%) patients tested negative. On the other hand, there were 42 (14.74%) patients who were diagnosed positive using 75 g OGTT. When diagnostic accuracy was compared, 36 cases reported positive on both testing techniques, while 240 cases reported negative. 3 cases tested positive on GCT and negative on OGTT, whereas 6 tested positive on OGTT and negative on GCT. The sensitivity, specificity, PPV, NPV and diagnostic accuracy was 85.71%, 98.77%, 92.31 %, 97.56%, and 96.84%, respectively, as shown in table 3. Feto-maternal complications are listed in table 4. 86(30.17%) participants reported gestational hypertension whereas Hydramnios was reported in 26 (9.12%) participants. 94(32.98%) patients underwent cesarean section due to cephalopelvic disproportion. Macrosomia, shoulder dystocia and neonatal hypoglycemia was reported in 36(12.63%), 14(4.91%) and 84(29.47%) cases, respectively.

Table 1: Baseline characteristics of patients (n=285)

Characteristics		n	%
Age of patients* (years)		26.28±4.18	
Gestational age* (weeks)		25.27±1.205	
Parity	0-3	253	88.77
	>3	32	11.23
Gravidity	1-3	206	72.28
	>3	79	27.72

*n = number of participants; % = percentage of participants; * = mean ± standard deviation was given*

Table 2: Descriptive statistics of GCT and OGTT among patients (n=285)

	n	%
GCT		
Positive	39	13.68
Negative	246	86.32
OGTT		

Positive	42	14.74
Negative	243	85.26

n = number of participants; % = percentage of participants; GCT = Glucose challenge test; OGTT = Oral glucose tolerance test

Table 3: Diagnostic accuracy of GCT in comparison with OGTT

		OGTT			Sensitivity	Specificity	PPV	NPV	Diagnostic accuracy
		+	-	Total					
GCT	+	36	3	39	85.71%	98.77%	92.31%	97.56%	96.84%
	-	6	240	246					
	Total	42	243	285					

+ | positive; - \ negative; PPV| Positive predictive value; NPV | Negative predictive value; % | percentage; GCT | glucose challenge test ; OGTT | oral glucose tolerance test.

Table 4: Frequency of feto-maternal complications (n=285)

Complication	n	%
Gestational hypertension	86	30.17
Hydramnios	26	9.12
Cesarean section due to CPD	94	32.98
Macrosomia	36	12.63
Shoulder dystocia	14	4.91
Neonatal hypoglycemia	84	29.47

n = number of participants; % = percentage of participants; CPD = cephalopelvic disproportion.

DISCUSSION

GDM is a form of glucose intolerance first detected in pregnancy, which can lead to grave maternal and fetal consequences if not treated appropriately [18]. Global occurrence of gestational hyperglycemia negatively impacted 16.2% of all live births in the year 2017, with GDM comprising of 86.4% cases [19]. Prompt identification is vital so that maternal and fetal complications can be avoided. Diagnosis fluctuates based on the methods utilized for evaluation and in various populations. Therefore, this study was intended to determine the diagnostic accuracy of 50 g GCT for detecting GDM, using 75 g OGTT as the recommended standard.

This study described that GCT had sensitivity, specificity, PPV, NPV and diagnostic accuracy of 85.71%, 98.77%, 92.31 %, 97.56%, and 96.84%, respectively. A study conducted in Finland documented that 50g oral GCT was superior in diagnosing GDM as compared to screening based on risk factors. 79% patients were diagnosed using GCT while only 21% on the basis of risk factors [20]. Donovan et al. revealed that the sensitivity and specificity of oral GCT for detecting GDM at a cut-off value of 140 mg/dL was 70-88% and 69-89%, respectively [21]. Carpenter and Coustan reported the sensitivity and specificity of GCT to be 99% and 77%, respectively [22].

A randomized controlled trial compared the one- and two-step techniques for diagnosing GDM. All patients underwent GCT and those with value<200 mg/dL underwent either 75 g OGTT or 100 g OGTT. The incidence of GDM was reported to be higher in the 75 g OGTT group (14.4%) compared to the 100 g OGTT group (4.5%) [23]. A Malaysian study reported that 35% patients had GCT ≥ 130 mg/dL, 32.6% went through OGTT and 34.5% of OGTT had GDM. Multivariable logistic regression

described that GCT ≥ 140 mg/dL was an independent forecaster for GDM ($p < 0.01$) [24]. Another report described that at a threshold of 108 mg/dL, sensitivity of GCT was 83.5% (95% CI: 77.0-88.9%) and specificity was 49.2% (95% CI: 46.5-52.0%) [10]. Mahdavian et al. found out that at the threshold level of 5.7 mmol/L, sensitivity, specificity, PPV, and NPV of GCT in diagnosing GDM was 84.1%, 62.3%, 12%, and 98.5%, respectively [5]. A systematic review by Leeuwen et al. documented that the sensitivity and specificity of GCT at the cutoff of 7.8 mmol/L were 74% (95% CI: 62-87%) and 85% (95% CI: 80-90%), respectively. Various perinatal outcomes were also explained such as macrosomia (OR 3.66 95% CI: 1.30-10.32), shoulder dystocia (OR 2.85, 95% CI: 1.25-6.51), and delivery via cesarean section (OR 1.76, 95% CI: 0.99-3.14) [25]. The current study also reported a high percentage of adverse perinatal outcomes.

CONCLUSION

50g GCT provided significantly high sensitivity and specficity for diagnosing GDM. As it is a cost-effective and provides reasonably accurate results, it can be used as an alternate to 75 g OGTT. This could aid in minimizing the maternal and fetal consequences by timely identification of the condition.

Author's Contributions

SB: Main author

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