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# Diagnostic Accuracy of Fasting Blood Sugar and Oral Glucose Challenge Test for Gestational Diabetes Mellitus

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## ABSTRACT

Despite multiple studies on gestational diabetes mellitus (GDM) screening, evidence on the concurrent validity and practical use of fasting blood glucose (FBS) and glucose challenge test (GCT) remains limited. **Objectives:** To compare the diagnostic accuracy of FBS, and oral GCT in detecting GDM, taking oral glucose tolerance test (OGTT) as the gold standard. **Methods:** This cross-sectional study was conducted at the Department of Obstetrics and Gynecology, Shahida Islam Teaching Hospital, Lodhran, Pakistan, from March to December 2023. A total of 160 pregnant women aged 20-40 years (gestation>20 weeks) were included. Diagnostic performance of FBS and GCT was assessed using sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy. IBM-SPSS Statistics, version 26.0, was used for data analysis. McNemar's test was applied to these how FBS, or GCT, agreed with GTT in diagnosing GDM, taking $p<0.05$ as significant. **Results:** The mean age and gestational age were 29.54 ± 5.35 years and 27.81 ± 2.48 weeks, respectively. The sensitivity of FBS in the diagnosis of GDM was 78.3%, and that of GCT was 84.2% (p=0.700).The specificity of FBS and GCT was 86.8% and 96.9%, respectively. The PPV of FBS was 81.8%, and that of GCT was 85.7%. The NPV of FBS and GCT were 84.0% and 91.8%, respectively (p=0.994). Accuracy of FBS was 83.1%, and GCT was 89.4%. **Conclusions:** It was concluded that the diagnostic accuracy of FBG and GCT in diagnosing GDM is high, with GCT demonstrating superior effectiveness. OGTT remains the definitive gold standard for confirming GDM.

## INTRODUCTION

Gestational diabetes mellitus (GDM) is a condition occurring in pregnancy associated with significant complications, and its prevalence is rising, particularly among Asian women [1]. The prevalence of GDM varies between 4.4% and 57.9% in Pakistan [2]. Research has shown a strong association of GDM with many adverse pregnancy outcomes like macrosomia, polyhydramnios, shoulder dystocia, preeclampsia, higher cesarean delivery rates, and long-term effects on both mothers and infants [3]. Females with GDM are estimated to have a raised risk of developing type 2 diabetes mellitus (T2DM) in the following years of life. Management strategies for GDM, including exercise, dietary changes, blood glucose monitoring, and insulin therapy, have evolved over the years and resulted in improved management of associated short-term and long-term complications [4]. No screening test is universally accepted despite the rising prevalence and impact of GDM globally. Not only do the diagnostic tests, but also the criteria for diagnosis, vary widely. According to ACOG and ADA, universal screening should be done with oral glucose tolerance test (OGTT) between 24-28th week of pregnancy. Fasting blood sugar (FBS) is often used for GDM screening due to its affordability, accessibility, simplicity, and reliability [5, 6]. The debate still goes on about the diagnostic accuracy (DA) of the glucose challenge test (GCT) and FBS levels [7-9]. Asians, particularly Pakistani women, have a high prevalence of diabetes and genetic susceptibility to metabolic syndromes with an elevated risk

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of developing GDM and its associated complications. This highlights the need for a cost-effective, universal screening and diagnostic approach. GCT seems less time-consuming, although no consensus guidelines or endorsements exist in this regard. FBS is easier to obtain, but it needs the patient to come fasting. The high accuracy of FBS could alleviate the strain on laboratories and conserve resources, as conducting a 2-hour, 75g OGTT can be challenging in large populations and resource-limited areas. This study was conducted to collect data from the local population to help identify more accurate, less time and cost-effective tests so that this research may help in formulating national protocols and guidelines for the diagnosis of GDM.

This study aims to compare the diagnostic accuracy of FBS and GCT in identifying GDM, using the OGTT as the gold standard, in pregnant women attending a tertiary care hospital. Despite numerous international and national studies on GDM screening, there remains limited evidence evaluating the concurrent validity and practical applicability of FBS and GCT in low-resource, peripheral tertiary care settings within Pakistan. This study seeks to provide context-specific data to inform more feasible and cost-effective screening strategies for early GDM detection in such environments.

## METHODS

It was a cross-sectional validation study conducted in the Department of Obstetrics and Gynecology, Shahida Islam Teaching Hospital, Lodhran, from 1st March 2023 to 30th December 2023. A sample size of 160 cases was calculated, taking the frequency of GDM as 11.8%, with a 95% confidence level, and a 5% margin of error using the Open EPI online sample size calculator [10].The sample was selected by non-probability, consecutive sampling. Women, 20-40 years of age, presenting after the 20th week of gestation, who came to the outpatient department for their antenatal check-ups, were included. All patients with a history of chronic hypertension, multiple gestation, obesity, history of diabetes, chronic liver disease, and chronic kidney disease were excluded.After obtaining approval from the ethical committee of the institution (letter number: SIMC/ET.C/10013/23), women fulfilling eligibility criteria were enrolled from the outpatient department following informed and written consent. Data about age, gestational age (as per LMP), body mass index (BMI), residence, monthly income, and family history of DM were collected.Blood samples were sent to the institutional laboratory to measure FBG on two consecutive days. On day 1, the patients also underwent a 50g non-fasting GCT. One week later, during their next visit, the patients received a 75 g OGTT. The results of the gold standard were then compared with those from the FBG and GCT. FBG ≥ 92 mg/dL was considered positive for GDM. The 50g GCT, performed without fasting, was considered positive if ≥200 mg/dl. The OGTT confirmed GDM if glucose levels exceeded fasting ≥92 mg/dL, 1-hour ≥180 mg/dL, or 2-hour ≥153 mg/dL. Data analysis was done by IBM-SPSS Statistics 26.0. Mean and standard deviation were calculated for quantitative variables. Frequencies and percentages were determined for qualitative variables. The diagnostic evaluation analysis calculated sensitivity, specificity, PPV, NPV, and DA. McNemar's test was applied to these to determine how FBS, or GCT, agreed with GTT in diagnosing GDM, taking $p<0.05$ as significant.

## RESULTS

In a total of 160 women, the mean age was 29.54 ± 5.35 years, while 87 (54.38%) were between 20-30 years. The mean gestational age was 27.81 ± 2.48 weeks, while the mean BMI was 30.43 ± 2.66 kg/m2. Distribution of patients according to parity, place of living, family history of DM, and monthly family income is shown in Table 1.

**Table 1:** Characteristics of Women with Gestational Diabetes Mellitus(n=160)

| Variables | | Frequency (%) |
|---|---|---|
| Age in Years | 20-30 | 87 (54.4%) |
| | 31-40 | 73 (45.6%) |
| BMI (Kg/M$^2$) | ≤ 27 | 29 (18.1%) |
| | >27 | 131 (81.9%) |
| Parity | 1-2 | 73 (45.6%) |
| | 3-5 | 87 (54.4%) |
| Place of Living | Rural | 65 (40.6%) |
| | Urban | 95 (59.4%) |
| Family History of Diabetes | Yes | 56 (35.0%) |
| | No | 104 (65.0%) |
| Monthly Income (PKR) | <25000 | 33 (20.6%) |
| | 25000-50000 | 76 (47.5%) |
| | >50000 | 51 (31.9%) |

In 66 blood FPG positive women, 54 had GDM, and 12 had no GDM on GTT. Among 94 FPG negative patients, 15 had GDM on GTT, whereas 79 had no GDM on GTT (p=0.700). Overall sensitivity, specificity, PPV, NPV, and DA of FPG in detecting GDM, taking GTT as gold standard, were 78.3%, 86.8%, 81.8%, 84.0% and 83.1%, respectively. In 63 GCT-positive women, 54 had GDM, and 9 had no GDM on GTT. Among 97 GCT negative women, 8 had GDM on GTT, whereas 89 had no GDM on GTT (p=0.994). Overall sensitivity, specificity, PPV, NPV, and DA of GCT for detecting GDM were 84.2%, 96.9%, 85.7%, 91.8%, and 89.4%, respectively and shown in Table 2.

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**Table 2:** Diagnostic Validity of Fasting Blood Sugar and Oral Glucose Challenge Test Concerning Oral Glucose Tolerance Test in Diagnosing Gestational Diabetes Mellitus

| Variables | Positive GTT | Negative GTT | p-value | Sensitivity | Specificity | PPV | NPV | DA |
|---|---|---|---|---|---|---|---|---|
| Positive FBS | 54 (TP) | 12 (FP) | 0.700 | 78.3% | 86.8% | 81.8% | 84.0% | 83.1% |
| Negative FBS | 15 (FN) | 79 (TN) | | | | | | |
| Positive GCT | 54 (TP) | 09 (FP) | 0.994 | 87.1% | 90.8% | 85.7% | 91.8% | 89.4% |
| Negative GCT | 08 (FN) | 89 (TN) | | | | | | |

Among women aged 20–30 years, FBS demonstrated a sensitivity of 80.4%, specificity of 85.9%, and diagnostic accuracy of 83.4%. In women with BMI >27 kg/m$^2$, sensitivity and specificity were 77.6% and 87.5%, respectively. Diagnostic accuracy ranged from 82.5% to 83.5% across BMI strata. Similar trends were observed by parity, with accuracy for FBS being 84.1% in women with 1–2 children and 83.7% in those with 3–5 children. The details about the stratified diagnostic utility evaluation of FBS in diagnosing gestational diabetes mellitus concerning the oral glucose tolerance test are shown in Table 3.

**Table 3:** Stratified Diagnostic Utility Evaluation of Fasting Blood Sugar in Diagnosing Gestational Diabetes Mellitus Concerning Oral Glucose Tolerance Test

| Variables | | Sensitivity | Specificity | PPV | NPV | DA |
|---|---|---|---|---|---|---|
| | | (%) | | | | |
| Age in Years | 20-30 | 80.4% | 85.9% | 78.0% | 86.1% | 83.4% |
| | 31-40 | 76.2% | 88.4% | 85.7% | 83.4% | 83.2% |
| BMI (kg/m$^2$) | ≤27 | 82.8% | 84.4% | 76.4% | 88.6% | 82.5% |
| | >27 | 77.6% | 87.5% | 83.6% | 83.7% | 83.5% |
| Parity | 1-2 | 79.1% | 88.1% | 80.2% | 85.4% | 84.1% |
| | 3-5 | 78.0% | 86.8% | 82.0% | 84.3% | 83.7% |
| Place of Living | Rural | 76.5% | 85.4% | 79.9% | 83.4% | 82.2% |
| | Urban | 79.4% | 87.6% | 83.4% | 84.7% | 84.9% |
| Family History of Diabetes | Yes | 77.5% | 86.5% | 81.6% | 84.3% | 83.5% |
| | No | 78.5% | 87.2% | 82.3% | 85.7% | 83.4% |
| Monthly Income (PR) | <25000 | 75.4% | 84.6% | 77.7% | 81.7% | 81.5% |
| | 25000-50000 | 79.9% | 86.7% | 81.2% | 85.2% | 83.6% |
| | >50000 | 81.0% | 88.9% | 85.0% | 86.6% | 84.5% |

In women aged 20–30 and 31–40 years, GCT yielded diagnostic accuracies of 89.2% and 89.8%, respectively. For BMI >27 kg/m$^2$, sensitivity was 86.5% and specificity 97.5%, with 89.6% DA. Urban women had slightly better diagnostic performance (accuracy 89.5%) compared with rural women (88.5%). GCT also showed robust accuracy in women with (89.5%) and without (89.5%) a family history of diabetes. The details about the stratified diagnostic utility evaluation of FBS in diagnosing gestational diabetes mellitus for the oral glucose tolerance test are shown in Table 4.

**Table 4:** Stratified Diagnostic Utility Evaluation of Glucose Challenge Test in Diagnosing Gestational Diabetes Mellitus Concerning Oral Glucose Tolerance Test

| Characteristics | | Sensitivity | Specificity | PPV | NPV | DA |
|---|---|---|---|---|---|---|
| | | (%) | | | | |
| Age in Years | 20-30 | 85.5% | 95.1% | 83.0% | 92.7% | 89.2% |
| | 31-40 | 89.9% | 98.3% | 88.1% | 91.2% | 89.8% |
| BMI (kg/m$^2$) | ≤ 27 | 88.2% | 94.4% | 84.7% | 93.9% | 87.2% |
| | >27 | 86.5% | 97.5% | 87.5% | 91.5% | 89.6% |
| Parity | 1-2 | 86.7% | 97.2% | 85.1% | 92.6% | 89.5% |
| | 3-5 | 88.6% | 96.9% | 87.2% | 92.4% | 89.5% |
| Place of Living | Rural | 84.4% | 95.4% | 84.7% | 91.2% | 88.5% |
| | Urban | 88.5% | 97.4% | 87.2% | 92.7% | 89.5% |
| Family History of Diabetes | Yes | 85.5% | 96.5% | 86.9% | 91.2% | 89.5% |
| | No | 88.1% | 97.2% | 87.4% | 92.1% | 89.5% |
| Monthly Income (PR) | <25000 | 82.0% | 94.6% | 82.3% | 90.8% | 87.5% |
| | 25000-50000 | 88.9% | 96.7% | 85.4% | 91.0% | 89.7% |
| | >50000 | 90.4% | 98.2% | 89.5% | 93.4% | 90.6% |

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## DISCUSSION

Having a convenient method for screening and early diagnosis of GDM is crucial. A significant drawback of the gold standard for detecting GDM (OGTT at 24 weeks) is that it is typically assessed late in the second trimester, which can increase the risk of developing various health problems [11]. This study showed that FBG had a sensitivity of 78.3%, specificity of 86.8%, PPV of 81.8%, NPV of 84.0%, and DA of 83.1%. Oral GCT exhibited sensitivity of 84.2%, specificity of 96.9%, PPV of 85.7%, NPV of 91.8%, and DA of 89.4%. The findings of this study align closely with another study, which reported FBG sensitivity as 97.0%, specificity 78.2%, PPV 17.8%, and NPV 99.81% for screening GDM [7]. Another local study found FBG sensitivity to be 96.77%, specificity at 98.4%, PPV 98.6%, NPV 96.3%, and DA at 97.5%, also taking OGTT as the gold standard, and these findings, along with the present research, exhibit the efficiency of FBG in screening for GDM [8]. A meta-analysis indicated pooled sensitivity and specificity for GCT at 79.0% and 74.0%, respectively, while FBG had pooled sensitivity and specificity of 81.0% and 70.0%, further reinforcing the utility of FBG in GDM screening as was exhibited in the present study [9]. Some experts advocate for screening for previously undiagnosed diabetes during pregnancy, especially in populations at higher risk [12]. The primary advantage of FBG testing is its ability to diagnose overt diabetes, especially when FPG levels exceed 125 mg/dl. While the IADPSG in 2010 recommended GDM to be diagnosed with FBS between 92-125 mg/dl at any point during pregnancy, this recommendation has faced criticism due to insufficient supporting evidence [13].A study done by Souha AA concluded that GCT > 140 mg/dl is an effective threshold due to high NPV, and also the specificity to rule out GDM.This study also stated that lowering the threshold to 135 mg/dl increases the sensitivity, but the specificity decreases [14]. Salini *et al.*, showed that the 75g GCT demonstrated significantly greater DA compared to other methods.The authors also advocated that this GCT could replace all existing screening approaches and may serve as an alternative to the two-step 100g OGTT [15]. In this study, FBG≥92 mg/dL was considered positive for GDM, and this threshold has been a popular endorsement by other researchers like Chukwunyere *et al.*, who revealed that a FBG threshold of 92 mg/dl to exhibit excellent diagnostic performance, achieving a sensitivity of 90.0% and a specificity of 97.1%, along with an area under the curve as 0.920 [16].In comparison, the random plasma glucose (RPG) threshold of 140 mg/dl demonstrated a much lower sensitivity of 13.8%, although it maintained a specificity of 97.1%, resulting in an AUC of 0.845.These findings support the consideration of FBG as a viable standalone alternative for GDM screening, and the present study reinforces these findings [17]. Beunen *et al.*, showed FBG<78 mg/dl was identified as the optimal cut-off for minimizing missed cases of GDM, resulting in 44 missed cases (19.0%) with a NPV of 97.3%. This approach also helped to avoid 52.2% of OGTTS. Women with this FBG level exhibited a more favourable metabolic profile and, among those with normal glucose tolerance, showed reduced fetal growth [18]. Hasan et al., concluded that, FBG cut-off value of 81 mg/dl can serve as an effective initial screening test for GDM, helping to minimize the need for OGTTS [19].Overall sensitivity, specificity, PPV, NPV, and DA of FPG in detecting GDM, taking GTT as gold standard, were 78.3%, 86.8%, 81.8%, 84.0% and 83.1%, respectively, showing the effectiveness of FPG screening for GDM. A study from India comparing GCT versus OGTT indicated that the GCT may overlook a significant number of pregnancies while screening for GDM, and recommended using the OGTT as the more established as well as effective diagnostic approach for GDM [20].A study from South Africa concluded that universal screening and diagnosis of GDM are commonly recommended to enhance treatment and improve pregnancy outcomes; this approach could often be unfeasible in many resource-constrained settings [21].

## CONCLUSIONS

It was concluded that both FBG and GCT are highly accurate in identifying GDM, with GCT demonstrating superior effectiveness. However, OGTT remains the definitive gold standard for confirming the diagnosis of GDM. Utilizing GCT as a primary screening tool may aid in early detection, allowing timely referral for OGTT and thereby helping to prevent complications associated with undiagnosed GDM.

## Authors Contribution

Conceptualization: JS
Methodology: KA, AA[1], AA[2], FU, SH
Formal analysis: FU
Writing review and editing: JS
All authors have read and agreed to the published version of the manuscript

## Conflicts of Interest

All the authors declare no conflict of interest.

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