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Original Research Article

Comparison of screening tests for gestational diabetes mellitus between "one step" and "two step" methods in an urban secondary care hospital – a prospective study

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ABSTRACT

Background: Gestational diabetes mellitus (GDM) is a common pregnancy complication linked to adverse maternal and fetal outcomes. Screening is crucial, but the optimal method remains debated. This prospective study aimed to compare the prevalence of GDM and associated pregnancy outcomes using the "one-step" (75 gm GTT, IADPSG criteria) versus the "two-step" (50 gm GCT followed by 100 gm OGTT, ACOG criteria) screening methods in an urban secondary care hospital setting in India.
Methods: A total of 466 pregnant women (24-32 weeks gestation) were assigned to one-step (n=233) or two-step (n=233) GDM screening. Participants were followed until delivery for maternal and neonatal outcomes. GDM was diagnosed by established criteria for each method, and groups were compared.
Results: Baseline characteristics were comparable. GDM prevalence was 9.4% (one-step) versus 5.2% (two-step), a non-statistically significant difference (p=0.075). No significant differences were found in maternal or neonatal outcomes (including treatments, complications, or birth outcomes) between screening groups, even among those diagnosed with GDM.
Conclusion: In this setting, neither screening method demonstrated superior GDM detection rates or improved pregnancy outcomes. Larger, multicenter randomized controlled trials with cost-effectiveness analysis are recommended to determine the optimal GDM screening strategy for the Indian population.

Keywords: Gestational diabetes mellitus, Screening tests, One-step method, Two-step method

INTRODUCTION

The escalating global prevalence of diabetes mellitus, fueled by demographic shifts towards aging populations, increasingly sedentary lifestyles, and rising obesity rates, presents a formidable public health challenge. This burden is disproportionately felt in developing nations such as India, where a growing cohort of women of childbearing age are consequently at heightened risk for developing glucose intolerance during pregnancy. gestational diabetes mellitus (GDM) is defined as any degree of glucose intolerance with onset or first recognition during pregnancy distinct from overt diabetes identified pre-gestation or early in pregnancy. While pregnancy naturally induces a state of insulin resistance, GDM arises when pancreatic beta-cell compensation is insufficient to overcome this.[1,2]

The implications of GDM are particularly profound in India, where prevalence rates have been reported as high as 18%, and women exhibit an alarming eleven-fold increased susceptibility compared to Caucasian counterparts. This condition carries substantial risks for both the mother and the fetus. Maternal complications include an elevated likelihood of pre-eclampsia, polyhydramnios, preterm labor, infections, operative

delivery, and the subsequent development of type 2 diabetes and cardiovascular disease later in life. Fetal and neonatal risks encompass macrosomia, fetal growth restriction, congenital anomalies, respiratory distress syndrome, hypoglycemia, and potential fetal demise. Therefore, timely screening, detection, and management of GDM are essential to mitigate these adverse outcomes.[3-5]

Despite this urgent need, considerable controversy persists regarding the optimal screening methodology, and a universally accepted "gold standard" remains elusive. Historically, approaches such as the O'Sullivan and Mahan criteria (100 g oral glucose tolerance test, OGTT) were foundational. More recently, debate has centered on two main strategies: the "one-step" approach, proposed by the International Association of Diabetes and Pregnancy Study Groups (IADPSG) and informed by the HAPO study, which utilizes a universal 75 g OGTT between 24-28 weeks; and the "two-step" approach, often following American College of Obstetricians and Gynaecologists (ACOG) recommendations, involving an initial 50 g glucose challenge test (GCT) followed by a diagnostic 100 g OGTT only if the screen is positive.[6,7]

While the IADPSG one-step criteria are endorsed by organizations like the American Diabetes Association (ADA), others, including ACOG and a National Institutes of Health (NIH) Consensus Conference, have expressed reservations. These concerns primarily revolve around the potential for a significant increase in GDM prevalence and associated healthcare costs, without definitive, comparative evidence of improved clinical outcomes over the two-step method.[8,9]

Given this ongoing debate, the documented variability in GDM prevalence, and a specific lack of data directly comparing the IADPSG one-step versus the ACOG two-step approaches within an Indian obstetric population, this prospective study was undertaken. The primary objective was to compare the prevalence of GDM diagnosed using these two distinct methods in pregnant women at an urban secondary care hospital in Mumbai, India, with a secondary aim of comparing key maternal and neonatal outcomes between the groups screened by these two different strategies.

METHODS

This was a prospective comparative observational study conducted at Seth V. C. Gandhi and M. A. Vora Municipal Hospital, Ghatkopar(E), Mumbai, Maharashtra, India which is a secondary care hospital in a country. The study was carried out between February 2023 and February 2024 in the antenatal clinic. Study was conducted after obtaining Institutional Ethical Committee approval. Written informed consent was secured from all participants.

Pregnant women with singleton pregnancies between 24-32 weeks of gestation, regardless of maternal age and parity, at low or average GDM risk, were included. Women with known pre-gestational diabetes or those outside the specified gestational age were excluded. A target sample of 466 participants was assigned to either the one-step (group A, n=233) or two-step (group B, n=233) GDM screening arm. Eligible participants were assigned in a predefined comparative manner to either the one-step (group A, n=233) or two-step (group B, n=233) screening group to ensure balanced cohort sizes and minimize selection bias. Baseline data, including medical, obstetric, family histories, and anthropometrics, were collected.

Diagnostic approaches

Group A

One-step approach: A 75 g oral glucose tolerance test (OGTT) was administered after overnight fasting, with plasma glucose measured at fasting, 1 hour, and 2 hours. Diagnostic thresholds were based on the IADPSG criteria.

Group B

Two-step approach: A 50 g glucose challenge test (non-fasting) was performed. Women with plasma glucose ≥ (threshold, e.g., 140 mg/dl) at 1 hour underwent a subsequent 100 g OGTT. GDM was diagnosed using the Carpenter–Coustan criteria.

Management of GDM

Women diagnosed with GDM were managed according to institutional protocols. Initial management included dietary counseling and lifestyle modification. If glycemic control was not achieved within (timeframe, e.g., 2 weeks), pharmacologic therapy was initiated. Patients were categorized as: diet-controlled GDM (maintained target glucose without pharmacotherapy), and uncontrolled/pharmacologically managed GDM (required insulin or oral hypoglycemic agents).

All glucose measurements were performed in the hospital's central laboratory using standardized enzymatic methods. All participants were followed until delivery. The primary outcome was GDM prevalence in each group. Secondary outcomes included birth weight, gestational age at delivery, preterm birth, LGA/SGA, RDS, shoulder dystocia, pregnancy-induced hypertension, polyhydramnios, and C-section rates.

Data collection

Clinical and demographic details were recorded prospectively using standardized case record forms (case proforma).

Data analysis was done using licensed statistical package for the social sciences (SPSS) software version 24.0 (IBM Chicago, Illinois), with Chi-square/Fisher's exact tests for

categorical data and Unpaired student's t-tests for continuous data; $p<0.05$ was considered significant.

RESULTS

Baseline characteristics

A total of 466 pregnant women meeting the inclusion criteria were enrolled, with 233 participants allocated to group A (one-step screening) and 233 to group B (two-step screening). The baseline demographic and clinical characteristics were comparable between the two groups (Table 1). The mean maternal age was 23.96±3.06 years in group A and 23.53±3.08 years in group B, with no statistically significant difference (p=0.132). The majority of participants in both cohorts were 25 years old or younger (77.7% in group A versus 80.7% in group B, p=0.592). Similarly, there were no significant differences in the distribution of gravidity (60.1% multigravida in group A versus 56.2% in group B, p=0.398).

Anthropometric measurements, including mean height (154.3 cm versus 154.2 cm), weight (57.3 kg versus 57.8 kg), and body mass index (BMI) (24.03±3.09 kg/m^2 versus 24.31±3.46 kg/m^2), were also similar at the time of screening (p>0.05 for all). Relevant past obstetric and medical histories, such as family history of diabetes or previous abortions, did not differ significantly between the groups. The mean gestational age at the time of screening was comparable, at 26.66±2.32 weeks for group A and 26.57±2.35 weeks for group B (p=0.132).

Gestational diabetes mellitus prevalence and management

The primary outcome, the prevalence of GDM, was higher in the one-step group (group A) at 9.4% (22 out of 233 participants) compared to 5.2% (12 out of 233 participants) in the two-step group (group B) (Table 2). However, this observed difference did not reach statistical significance (p=0.075). In the present study, the distribution of participants according to treatment received. In group A, 9 participants (3.9%) are managed with diet alone, compared to 5 participants (2.2%) in group B (p=0.287).

A total of 2 participants (0.42%) in group A and 4 participants (1.7%) in group B require diet plus insulin. Only 1 participant (0.4%) in group A receives a combination of diet, metformin, and insulin, whereas none in group B receive this treatment. Diet plus metformin is prescribed to 10 participants (4.3%) in group A and 8 participants (3.4%) in group B. The majority of participants do not require treatment, with 211 (90.5%) in group A and 216 (92.7%) in group B. Overall, both groups consist of 233 participants each.

Maternal and neonatal outcomes

Secondary outcome analysis revealed no statistically significant differences in maternal or neonatal outcomes between the two screening groups (Tables 2 and 3). The distribution of mode of delivery (including spontaneous vaginal, induced vaginal, elective cesarean, and emergency cesarean) was similar (p=0.232). Overall vaginal delivery rates were 68.7% in group A and 75.1% in group B. The mean gestational age at delivery (38.19±1.04 weeks versus 38.22±1.10 weeks; p=0.741) and mean birth weight (2.85±0.36 kg versus 2.84±0.38 kg; p=0.721) were comparable between group A and group B, respectively.

Rates of preterm delivery (2.1% versus 2.6%; p=0.744) and NICU admission (4.7% versus 3.4%; p=0.122) were also similar. Furthermore, there were no significant differences observed in the rates of recorded antepartum complications (such as PIH, anaemia, oligohydramnios, polyhydramnios; p=0.333), intrapartum complications (such as fetal distress, meconium-stained liquor, failure of induction; p=0.868), or postpartum complications (such as PPH, hypoglycemia, LBW; p=0.736) between the two groups.

Table 1: Baseline maternal characteristics of study groups.

Baseline characteristics	Group A (one-step) (n=233)	Group B (two-step) (n=233)	P value
Mean maternal age (years)	23.96±3.06	23.53±3.08	0.132
Age ≤25 years (%)	77.7 (181)	80.7 (188)	0.592*
Age 26-30 years (%)	17.2 (40)	15.9 (37)	
Age >30 years (%)	5.2 (12)	3.4 (8)	
Multigravida (%)	60.1 (140)	56.2 (131)	0.398*
Primigravida (%)	39.9 (93)	43.8 (102)	
Mean height (cm)	154.3±4.7	154.2±4.7	0.937
Mean weight (kg)	57.3±8.2	57.8±8.7	0.44
Mean bmi (kg/m²)	24.03±3.09	24.31±3.46	0.35
Mean gestational age at screening (weeks)	26.66±2.32	26.57±2.35	0.132

*Statistically significant.

Table 2: Comparison of primary outcome and maternal outcomes between study groups.

Primary outcomes	Group A (one-step) (n=233)	Group B (two-step) (n=233)	P value
GDM prevalence (%)	9.4 (22)	5.2 (12)	0.075
Maternal outcomes			
Spontaneous vaginal delivery (%)	42.9 (100)	47.2 (110)	0.232
Induced vaginal delivery (%)	25.6 (60)	27.9 (65)	
Elective cesarean section (%)	18.5 (43)	16.3 (38)	
Emergency cesarean section (%)	14.2 (33)	8.6 (20)	
Mean gestational age at delivery (weeks)	38.19±1.04	38.22±1.10	0.741
Antepartum complication: PIH (%)	6.0 (14)	5.2 (12)	0.333*
Antepartum complication: anaemia (%)	1.3 (3)	3.0 (7)	0.333
Antepartum complication: polyhydramnios (%)	0.9 (2)	2.6 (6)	
Intrapartum complication: fetal distress (%)	2.1 (5)	3.0 (7)	0.868
Intrapartum complication: msl (%)	1.7 (4)	3.0 (7)	
Intrapartum complication: failure of induction (%)	2.6 (6)	2.1 (5)	
Postpartum complication: PPH (%)	2.1 (5)	2.1 (5)	0.736*

*Statistically significant.

Table 3: Comparison of neonatal outcomes between study groups.

Neonatal outcomes	Group A (one-step) (n=233)	Group B (two-step) (n=233)	P value
Mean birth weight (kg)	2.85±0.36	2.84±0.38	0.721
Preterm delivery rate (<37 weeks) (%)	2.1 (5)	2.6 (6)	0.744
NICU admission rate (%)	4.7 (11)	3.4 (8)	0.122
Postpartum complication: low birth weight (LBW) (%)	0.4 (1)	0.4 (1)	0.736*
Postpartum complication: respiratory distress syndrome (RDS) (%)	0.4 (1)	0.0 (0)	
Postpartum complication: hypoglycemia (%)	0.0 (0)	0.4 (1)	

*Statistically significant.

DISCUSSION

GDM, characterized by glucose intolerance emerging during pregnancy, represents the most common metabolic complication of gestation and is associated with significant adverse outcomes for both the mother and child. Risks include maternal complications like pre-eclampsia, polyhydramnios, preterm labor, and increased rates of cesarean delivery, as well as fetal issues such as macrosomia, growth restriction, respiratory distress, and potential demise.

Furthermore, GDM predisposes mothers to future metabolic diseases like type 2 diabetes and cardiovascular conditions.[10] Given these risks, effective screening is paramount, although the optimal method remains debated. This prospective study, conducted at Seth V. C. Gandhi and M. A. Vora Municipal General Hospital, aimed to compare the prevalence of GDM and associated pregnancy outcomes when using the "one-step" (75 gm GTT, IADPSG criteria) versus the "two-step" (50 gm GCT followed by diagnostic 100 gm GTT, ACOG criteria) screening methods in an urban secondary care setting.

The study successfully enrolled 466 pregnant women between 24- and 32-weeks' gestation into two groups (group A: one-step, n=233; group B: two-step, n=233). An essential finding was the comparability of the two groups at baseline, minimizing the risk of selection bias influencing the results. There were no statistically significant differences in mean maternal age, distribution of age groups, gravidity, anthropometric measurements (height, weight, BMI), relevant past medical or obstetric history, or mean gestational age at the time of screening. This baseline similarity is consistent with other comparative studies by Tehrani et al, Sahin et al, and Khalifeh et al, lending robustness to the comparison.[11-13]

Regarding the primary outcome, the prevalence of GDM was found to be 9.4% in the one-step group versus 5.2% in the two-step group. Although numerically higher in the one-step group, this difference did not achieve statistical significance (p=0.075) in this study cohort. This particular finding aligns with the randomized trial by Khalifeh et al, which also reported a non-significant difference in GDM incidence between the one-step (8.1%) and two-step (5.6%) approaches.[13] However, our result contrasts with several other studies, including those by Can et al, Sahin

et al, and Luewan et al, which all demonstrated a significantly higher prevalence of GDM diagnosis using the one-step method compared to the two-step approach.[12,14,16] These discrepancies across studies underscore the ongoing debate and potential population-specific variations influencing GDM prevalence based on screening methodology. One step approach identifies a greater no of women as having GDM due to its Lower diagnostic thresholds and requirement for only a single abnormal value one step approach may facilitate earlier recognition and treatment, it may also increase risk of over-diagnosis and associated healthcare burden. Additional attrition between these steps further lowers the number of cases detected in the two-step group. Our findings align with previous reports showing greater diagnostic yield with the one-step criteria, although evidence regarding effects on maternal and neonatal outcomes remains inconsistent. We also interpret these differences in light of our cohort's risk profile and the practical challenges of each testing pathway. Furthermore, we report treatment patterns, including the proportions managed with diet alone or pharmacotherapy, and the share of cases that remained uncontrolled in late pregnancy, to emphasize the clinical and resource implications of the chosen diagnostic strategy.[13,14,16,17]

Crucially, the comparison of maternal and neonatal outcomes revealed no statistically significant differences between the groups screened by the One-step versus the two-step method. This included key indicators such as mode of delivery (vaginal versus cesarean rates), gestational age at delivery, mean birth weight, rates of preterm birth, NICU admission, and the incidence of specific antepartum, intrapartum, and postpartum complications. These findings are consistent with the large community trial by Tehrani et al and the RCT by Khalifeh et al, both of which reported comparable risks for major adverse pregnancy outcomes irrespective of the screening strategy used.[11,13]

However, our results differ from the meta-analysis by Saccone et al, which suggested potential benefits (lower LGA, NICU admission, neonatal hypoglycemia) associated with the One-step approach, and from the study by Davis et al, which found higher neonatal morbidity with IADPSG screening but similar rates for other outcomes like cesarean birth.[16,17] The variability in reported outcomes across different studies highlights the complexity of evaluating screening strategies and emphasizes the need for further large-scale research, particularly within diverse populations like India, to definitively determine the most effective approach for identifying and managing GDM to optimize maternal and child health.

CONCLUSION

The findings of our study suggest that the prevalence of GDM did not significantly differ between the one-step and Two-step approaches for screening. Furthermore, our study indicates that maternal and neonatal outcomes in women diagnosed and managed for GDM using the one-step approach were comparable to those in the two-step approach.

To comprehensively address the efficacy and cost-effectiveness of the one-step IADPSG GDM screening approach, a large-scale, multicenter RCT conducted across diverse geographical locations in India, with pregnancy outcomes as the primary endpoint and including a cost-effectiveness analysis, is warranted. Such a study could provide valuable insights into whether the One-step approach is advantageous for both mothers and their infants while being economically viable.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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