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Original Research Article

A comparative study on one-step versus two-step screening methods for gestational diabetes mellitus and their impact on maternal and fetal outcome

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ABSTRACT

Background: Gestational diabetes mellitus (GDM) is a common pregnancy complication associated with adverse maternal and fetal outcomes. The one-step IADPSG and two-step ACOG screening methods are widely used for diagnosis. The one-step approach detects more cases of GDM, potentially enabling earlier treatment, but concerns regarding overdiagnosis and increased healthcare costs remain. Aim and objectives were to compare the one-step and two-step screening methods for gestational diabetes mellitus (GDM) in terms of prevalence, maternal and fetal outcomes, and to determine which method correlates better with adverse fetomaternal outcomes.
Methods: This prospective comparative study was conducted at Midnapore Medical College and Hospital from January to December 2024 and included 1,720 pregnant women with gestational age ≤24 weeks. Participants were randomly assigned to either group A (one-step IADPSG screening, n=860) or group B (two-step ACOG screening, n=860) for GDM screening. Women diagnosed with GDM were managed according to standard protocols and followed until delivery. Maternal and fetal outcomes were assessed and compared between the two groups using statistical analysis.
Results: Among 860 pregnant women screened by each method, GDM was diagnosed in 92 (10.69%) women using the one-step method and 66 (7.67%) women using the two-step method. During follow-up, 88 and 62 women remained in groups A and B, respectively. Maternal complications such as preeclampsia and polyhydramnios were comparable between the groups (p=0.964). The caesarean section rate was significantly higher in the one-step group than in the two-step group (68.18% versus 41.93%; p=0.024). Mean APGAR scores were similar in both groups (8.41±0.92 versus 8.71±0.82; p=0.151). Fetal outcomes, including preterm birth, low birth weight, neonatal hypoglycemia, large-for-gestational-age, hyperbilirubinemia, and NICU admission, were comparable between the groups (p=0.938).
Conclusions: One-step method detected more GDM cases than the two-step method, but maternal and fetal outcomes were similar. The one-step approach is simpler, more economical, and has better patient compliance.

Keywords: Fetomaternal outcome, Gestational diabetes mellitus, One-step screening, Oral glucose tolerance test, Two-step screening

INTRODUCTION

Gestational diabetes mellitus (GDM) is defined as glucose intolerance of varying degrees that is first identified or develops during the present pregnancy.[1] The prevalence of GDM varies across different populations worldwide and is influenced by the screening methods and diagnostic criteria employed.[2] Globally, GDM affects approximately 7% of

all pregnancies. Prevalence of GDM in India varied from 3.8 to 21% in different parts of the country.[3,4]

Gestational diabetes mellitus (GDM) causes a wide range of maternal and fetal complications. Maternal complications commonly associated with GDM include gestational hypertension, recurrent vaginal infections, preeclampsia, preterm labor, abruptio placentae, intrauterine growth restriction, and intrauterine fetal demise.[5,6] Furthermore, women with GDM have a significantly higher likelihood of undergoing caesarean delivery, with studies reporting nearly a twofold increase in its incidence.[5] The fetus is also at increased risk of several adverse outcomes, including macrosomia, shoulder dystocia, stillbirth, neonatal hypoglycemia, hyperbilirubinemia, and respiratory distress syndrome.[7] These complications contribute substantially to perinatal morbidity and mortality, emphasizing the importance of early diagnosis and effective management of GDM.

The optimal strategy for screening gestational diabetes mellitus (GDM) remains a subject of ongoing debate. The existence of multiple diagnostic criteria for gestational diabetes mellitus (GDM) across different countries has created challenges in the delivery of healthcare as well as in the conduct, comparison, and interpretation of research studies.[8,9] To address these inconsistencies and promote a standardized approach to diagnosis, the hyperglycemia and adverse pregnancy outcomes (HAPO) study was undertaken. Findings from the HAPO study provided important evidence linking maternal glucose levels with adverse pregnancy outcomes and served as the basis for developing uniform diagnostic standards.[10] Subsequently, in 2010, the International Association of Diabetes and Pregnancy Study Groups (IADPSG) introduced revised diagnostic criteria for GDM, which were formulated using data derived from the HAPO study.[11] In the one-step screening approach, pregnant women undergo a 75-g oral glucose tolerance test (OGTT). Gestational diabetes mellitus (GDM) is diagnosed when 2-hour plasma glucose value of 75 gm OGTT is $\geq$140 mg/dl. The diabetes in pregnancy study group of India (DIPSI) recommends a modified version of the World Health Organization (WHO) criteria for the diagnosis of gestational diabetes mellitus (GDM). According to the DIPSI guidelines, GDM is diagnosed using a 2-hour 75-gm oral glucose tolerance test (OGTT), performed irrespective of the woman's fasting status. Presence of a single abnormal value is sufficient to establish the diagnosis of GDM. But disadvantage of 1 step method for screening of GDM is over diagnosis.

At present, the American College of Obstetricians and Gynecologists (ACOG) recommend universal screening of pregnant women using assessment of medical history, evaluation of clinical risk factors, or a 50-gm oral glucose challenge test (GCT). Women who screen positive on the 50-gm, 1-hour glucose challenge test (GCT) are subsequently advised to undergo a diagnostic 100-gm, 3-hour oral glucose tolerance test (OGTT). For screening positive, any two of fasting plasma glucose ($\geq$95 mg/dl), 1 hour ($\geq$180 mg/dl), 2 hour ($\geq$150 mg/dl) and 3-hour plasma glucose value ($\geq$140 mg/dl) of 100 gm OGTT should be positive. This sequential screening and diagnostic approach, commonly referred to as the two-step method, continues to be the most widely adopted strategy for the detection and diagnosis of GDM.[12,13]

Studies also have demonstrated that applying the diagnostic criteria recommended by the International Association of Diabetes and Pregnancy Study Groups (IADPSG) substantially increases the detection of GDM. The prevalence of GDM identified through the one-step approach has been reported to be approximately two to three times higher than that observed with the conventional two-step screening strategy.[8,11]

The present study was conducted to compare the one-step screening approach recommended by the International Association of Diabetes and Pregnancy Study Groups (IADPSG) with the two-step screening method recommended by the American College of Obstetricians and Gynecologists (ACOG). Additionally, the study aimed to determine the incidence of gestational diabetes mellitus (GDM) and evaluate its associated maternal and fetal outcomes.

Aim of this study

To evaluate and identify the screening method for gestational diabetes mellitus (GDM) that demonstrates a better correlation with fetomaternal outcome.

Objectives of this study

To determine and compare the prevalence of gestational diabetes mellitus diagnosed by the one-step and two-step screening methods. To compare maternal outcomes among women diagnosed with GDM using the two screening approaches, with respect to the incidence of preeclampsia, polyhydramnios, preterm delivery, cesarean section, and shoulder dystocia. To assess and compare perinatal outcomes in GDM patients identified by the one-step and two-step screening methods, including the occurrence of large-for-gestational-age infants, neonatal hypoglycemia, hyperbilirubinemia, and admission to the sick newborn care unit (SNCU).

METHODS

This prospective, comparative, single-center study was conducted in the Outpatient Department (OPD) and In-Patient Department (IPD) of the Department of Obstetrics and Gynaecology, Midnapore Medical College and Hospital, over a period of one year from 1st January 2024 to 31st December 2024. A total of 1,720 pregnant women were enrolled in the study. Pregnant women with gestational age up to 24 weeks who attended the antenatal OPD or were admitted to the department of obstetrics and

gynecology and provided informed written consent were included in the study.

The exclusion criteria were: first antenatal visit after 24 weeks of gestation. Previously diagnosed type 1 or type 2 diabetes mellitus. History of gestational diabetes mellitus in a previous pregnancy. Previous delivery of a large-for-gestational-age infant or history of stillbirth. History of fetal congenital anomalies. Presence of significant medical disorders such as severe anemia, cardiac disease, or other major systemic illnesses.

After obtaining informed written consent, a detailed history was recorded and a thorough clinical examination was performed. Participants were then randomly allocated into two equal groups.

Group A (n=860): Screening for gestational diabetes mellitus was performed using the one-step International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria, consisting of a 75-gm oral glucose tolerance test (OGTT).

Group B (n=860): criterias of two-step screening method of American College of Obstetricians and Gynaecologists (ACOG), which included an initial 50-g glucose challenge test (GCT) followed, if positive, by a diagnostic 100-gm OGTT.

The prevalence of gestational diabetes mellitus was determined separately in each group. Women diagnosed with GDM by either screening method were followed up regularly throughout pregnancy. Management included blood glucose monitoring and appropriate treatment in the form of medical nutrition therapy (MNT), oral metformin, and/or insulin therapy as required. Adequate glycemic control was achieved in all study participants diagnosed with GDM. Maternal and fetal outcomes were compared between the two groups. Pregnant women were monitored until delivery and for 48 hours postpartum for the occurrence of adverse maternal outcomes. Neonates born to these mothers were evaluated for adverse perinatal outcomes and followed until hospital discharge. Data was collected using a comprehensive tool and pre-designed proformas. The collected data was analyzed using descriptive statistics and presented in a structured format.

RESULTS

Out of 860 patients screened using one step method, 92 (10.69%) were positive for GDM. Out of 860 patients screened using two step method, 66 (7.67%) were positive for GDM (Table 1). Four patients from each group were lost to follow up, so finally 88 patients were present in group A and 62 patients in group B.

Table 1: Patients diagnosed with GDM.

	Group A (%)	Group B (%)
Prevalence	92/860 (10.69)	66/860 (7.67)

Out of 88 patients screened using one step method, 8 patients (9.09%) were having preeclamsia, 2 patients (2.27%) were having polyhydramnios and 78 patients (88.63%) were without complications. Out of 62 patients screened using two step method, 6 patients (9.67%) were having preeclampsia, 2 patients (3.22%) patient were having polyhydramnios and 54 patients (87%) were without complications (Table 2). P value was 0.964 which is not significant.

Table 2: Maternal complications.

Maternal complications	Group A (n=88) (%)	Group B (n=62) (%)
Pre-eclampsia	8 (9.09)	6 (9.67)
Polyhydraminos	2 (2.27)	2 (3.22)
None	78 (88.63)	54 (87)

Table 3: Mode of delivery.

	Group A (n=88) (%)	Group B (n=62) (%)
Mode of delivery	Caesarean 60 (68.18)	Caesarean 26 (41.93)
	Vaginal 28 (31.81)	Vaginal 36 (58.06)

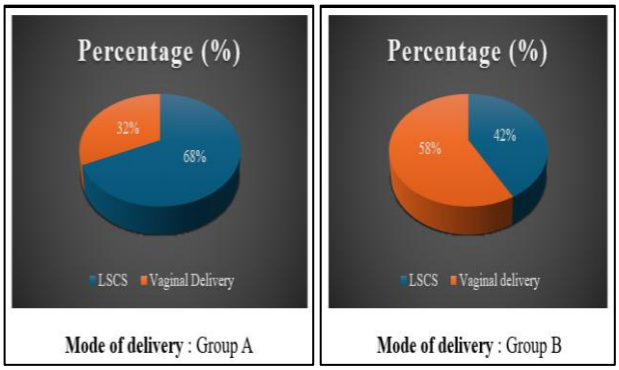

Figure 1: Mode of delivery of GDM mothers of group A and group B.

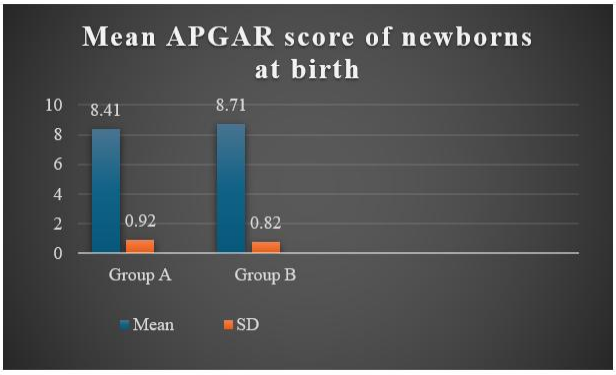

Figure 2: Mean APGAR score of newborns at birth.

Out of 88 patients screened using one step method, 60 patients (68.18%) delivered by LSCS and 28 patients

(31.81%) delivered vaginally. Out of 62 patients screened using two step method, 26 patients (41.93 %) delivered by LSCS and 36 patients (58.06%) delivered vaginally (Table 3, Figure 1). P value was 0.024 which was significant.

The mean APGAR score in group A was 8.41±0.92 and it was 8.71±0.82 in group B (Table 4, Figure 2). The p value was 0.151 which was not significant.

In group A, 11.35% newborn was preterm, 9.09% newborn was low birth weight, 6.81% newborn developed neonatal hypoglycemia, 6.81% newborn was large for gestational age, 11.35% newborn required NICU admission, 4.54% newborn developed hyperbilirubinemia and 77.25% newborns had no complication. In group B, 9.67% newborn was preterm, 6.45% newborn was low birth weight, 6.45% newborn developed neonatal hypoglycemia, 6.45% newborn was large for gestational age, 12.90% newborn required NICU admission, 6.45% newborn developed hyperbilirubinemia and 74.19% newborns had no complication (Table 5). After comparing newborn complications in group and B, p value was 0.938 which was not significant.

Table 4: Distribution of mean APGAR score at birth.

		Number	Mean	SD	Minimum	Maximum	P value
APGAR Score	Group A	88	8.41	0.92	6	10	0.151
	Group B	62	8.71	0.82	6	10	

Table 5: Newborn complications.

Newborn complications	Group A (n=88) (%)	Group B (n=62) (%)
Preterm	10 (11.35)	6 (9.67)
Low birth weight	8 (9.09)	4 (6.45)
Neonatal hypoglycemia	6 (6.81)	4 (6.45)
Large for gestational age	6 (6.81)	4 (6.45)
NICU admission	10 (11.35)	8 (12.90)
Hyperbilirubinemia	4 (4.54)	4 (6.45)
None	68 (77.27)	46 (74.19)

DISCUSSION

There have been many criteria for screening of GDM, however, an ongoing global debate continues about when and how to screen and diagnose GDM.

Our study was a prospective comparative clinical study to calculate and compare the prevalence of GDM by one step and two step method, and to compare which method better correlates with the fetomaternal outcome. Total 1720 patients were selected based on the inclusion and exclusion criteria. Out of 1720 patients, 860 (group A) were screened using one step method and 860 (group B) were screened using two step method. Out of 1720 patients, total 158 (9.18%) patients (92 in group A and 66 in group B) were screened positive for GDM by both method, which correlates with the other studies. Anjana et al, in their study reported a prevalence of 4.6 to 14% in urban region and 1.7 to 13.2% in rural area.[14]

Out of 860 patients in group A (one step method), 92 (10.69%) patients were positive for GDM while in group B, out of 860 patients, 66 (7.67%) patients were positive for GDM.

Various prospective and retrospective observational studies, comparing IADPSG diagnosed untreated GDM women with women with a group of women having normal glucose tolerance, found an increased risk of polyhydramnios, preeclampsia, pre term delivery, primary caesarean section, neonatal hypoglycemia, large for gestational age.[12,13,15] Women with untreated GDM by IADPSG criteria had larger birth weight infants than women with treated GDM by Carpentar Coustan criteria.

Our study was different from the above-mentioned studies as all the patients diagnosed with GDM by either method, were treated by medical nutrition therapy, metformin or insulin. Blood sugar control was achieved in all the patients in both groups.

The incidence of all the complications like preterm labour, neonatal hypoglycemia, hyperbilirubinemia, neonatal ICU admission, preeclampsia were similar in both groups. Mean birth weight, APGAR score was also similar in both the groups. It might be because of the early diagnosis and treatment, as post treatment blood sugar control was achieved in all the patients and our study included patients less than 24 weeks of pregnancy.

Studies comparing the effects of treated GDM on outcomes for women diagnosed by IADPSG criteria versus prior/usual criteria, 75-gm Carpenter Coustan, NDDG, or a modified two-step WHO demonstrated similar pregnancy and neonatal outcomes as those diagnosed by CC and NDDG criteria, but greater risk of macrosomia and LGA compared with WHO criteria.[16-18]

Khalifeh et al, in their study of 249 GDM patients comparing one step vs two step method reported that preeclampsia, preterm birth (PTB), induction of labour and mode of delivery were not significantly different , similar to our study.[19] On the contrary Akgol et al, in their study

reported that pre-term birth and caesarean delivery rates were significantly lower in pregnant women who were screened with the one-step screening method compared to the two-step screening method.[20] In Akgol et al study, post term birth rates and APGAR scores were significantly lower in one step group, than those of the two-step screening method, while term birth and mean birth weight were significantly higher.[20] Saccone et al, in their metanalysis of 3 randomized control trials including 2333 patients found that women screened with the one step approach had a significantly lower risk of preterm birth, caesarean delivery, macrosomia, neonatal hypoglycemia, and admission to neonatal intensive care unit , compared to those randomized to screening with the two step approach.[21] However, Saccone et al, found that the mean birth weight was significantly lower in the one-step screening method.[21]

The rate of cesarean section was 68.18% in group A and it was 41.93% in group B. The difference was statistically significant. While Khalifeh et al reported no significant difference in mode of delivery between one step vs two step, Akgol et al reported a lower incidence of CS in one step method.[19,20] The rate of caesarean section overall was high in our study as compared to other studies, as ours is a prime tertiary care and referral center in West Bengal, due to which we see, comparatively more complicated pregnancies. Moses et al in their study reported a CS rate of 19.8% in GDM patients as compared to 15.6% in normal glucose tolerant patients, the difference was not significant.[22] Reddy et al reported a rate of 62% caesarean section using two step method, while Savitri et al, reported a exceptionally high rate of 96% caesarean section using one step method.[23,24] One reason for high rate of caesarean section in our study might be because of the mind set biased due to known diagnosis of GDM.

Despite our best efforts, this study has several limitations. The study groups were not matched for baseline characteristics such as age, BMI, and gestational age at enrollment, which may have affected the accuracy of true prevalence estimates. The sample size for outcome analysis was relatively small, with only 75 patients followed for fetomaternal outcomes. In addition, only women with gestational age ≤24 weeks were included, leading to exclusion of a considerable number of late-presenting cases. Follow-up period was limited and did not allow assessment of long-term maternal outcomes such as cardiovascular disease or the development of type 2 diabetes mellitus.

CONCLUSION

The prevalence of GDM was higher with the one-step screening method compared to the two-step method. However, maternal outcomes (preeclampsia, polyhydramnios) and fetal outcomes (preterm birth, LGA, neonatal hypoglycemia, NICU admission, and hyperbilirubinemia) were comparable between the two groups, and the difference was not statistically significant. Mean APGAR scores were also similar. Although the caesarean section rate was higher in the one-step group, this was likely influenced by the tertiary care setting with a higher proportion of complicated pregnancies. Overall, early diagnosis and effective management resulted in well-controlled glycemia and reduced complications in both groups. The study did not demonstrate a clear superiority of either screening method, and the optimal approach remains uncertain. However, the one-step method is more practical, cost-effective, and associated with better patient compliance.

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