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ORIGINAL ARTICLE

Comparison of One-Step Versus Two-Step Screening for Diagnosis of GDM in Indian Population: A Randomized Controlled Trial

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Abstract

Objective To compare the incidence, maternal and fetal outcomes of gestational diabetes mellitus using one step versus two steps as a screening procedure.

Methodology A prospective randomized trial involving screening of 1000 pregnant women for gestational diabetes mellitus was conducted. Women were divided in two groups (500 each). Group A comprised of patients screened with two-step approach (ACOG recommendation), and group B comprised of women screened by one-step method (IADPSG criteria). Women diagnosed with 'gestational diabetes' were followed in an antenatal clinic, and incidence of GDM and maternal and fetal outcome between two groups were analyzed using SPSS.

Results The incidence of GDM was almost double using one-step versus two-step approach which was 19.2 and 11.8%, respectively. Maternal outcomes were comparable

in both the groups except the risk of preterm delivery which was 2.5 times more in group A than group B (odds ratio = 2.43 95% CI 1.01–5.79). Further, fetal outcomes were also comparable except neonatal hypoglycemia which was seen in 29.31% in group A versus 7.4% in group B. In the group B, 15 patients (15.8%) with GDM (based on FBS ≥ 92 mg/dl at first ANC visit) showed clinical symptoms and blood sugars in hypoglycemic range on MNT requiring resumption of normal diet.

Conclusion The incidence of GDM using IADPSG criteria was almost double versus ACOG criteria. Maternal and fetal outcomes were comparable except in 15.8% women diagnosed as GDM (using FBS ≥ 92 mg/dl at first ANC visit as per IADPSG) and suffered from hypoglycemia. A large trial is being proposed before these criteria are adopted.

Keywords Gestational diabetes mellitus · IADPSG · HAPO study · ACOG

Introduction

Gestational diabetes mellitus is defined as any degree of carbohydrate intolerance with onset or first recognition during pregnancy [1]. Its prevalence varies worldwide and also with the testing method and diagnostic criteria used [2].

The American College of Obstetricians and Gynecologists (ACOG) recommends a two-step approach for screening and diagnosis of GDM in high-risk population, i.e., first screening with the 50-g glucose challenge test. Those individuals meeting or exceeding the screening threshold undergo a 100-g 3-h diagnostic oral glucose tolerance test [2]. On the other hand, World Health Organization (WHO) recommends a single-step 75-g 2-h OGTT to be performed in fasting state [3].

The International Association of Diabetes and Pregnancy study groups (IADPSG) formed in 1998 reviewed the published results of Hyperglycemia and Adverse Pregnancy Outcome (HAPO study) to reach a single consensus and suggested new criteria for the diagnosis of diabetes in pregnancy based on the association of maternal glycaemia with perinatal outcomes. It recommends screening high-risk women at the first visit, to screen universally at 24- to 28-week gestation, with use of the 75-g oral glucose tolerance test for the diagnosis of gestational diabetes (one-step approach) [4, 5]. The Diabetes in Pregnancy Study Group of India (DIPSI) recommends modified version of WHO criterion to diagnose GDM. DIPSI recommends 2-h 75-g OGTT irrespective of fasting status [6].

Prevalence of GDM in India varied from 3.8 to 21% in different parts of the country [6–8]. Present study was undertaken to compare the one-step screening procedure (IADPSG recommended) with two-step procedure (ACOG recommended) in addition to incidence, maternal and fetal outcome of patients with GDM.

Methodology

It was a prospective randomized trial including 1000 pregnant women. Women attending antenatal clinic between 6 and 24 weeks, who consented for participation in the study, were included. Pregnant women with overt diabetes were excluded from the study.

Women were divided into two groups (500 each) according to computer-generated random number table; group A comprised of patients screened with two-step approach for GDM and group B included women screened by one-step approach.

Group A

Following the two-step approach, at first visit, a 50-g oral glucose challenge test (GCT) was done irrespective of the fasting status and plasma glucose was measured by the enzymatic method. Plasma glucose value after 1 h, if ≤130 mg/dl, was considered as normal, and further, screening was repeated at 24–28 weeks. If plasma glucose value was ≥130 mg/dl, then it is abnormal and women underwent 100-g OGTT. The plasma glucose was measured after 100-g load at fasting, 1-, 2- and 3-h interval. The cutoff values were fasting ≥95 mg/dl, 1 h ≥180 mg/dl, 2 h ≥155 mg/dl and 3 h ≥140 mg/dl, respectively. A diagnosis of gestational diabetes was made if at least two values meet or exceed the above plasma glucose concentration.

Group B

Patients were screened by one-step procedure (IADPSG recommended). At first visit below 24 weeks, subjects were screened for fasting blood sugar or random blood sugar (by enzymatic method) or HbA1c. If fasting blood sugar was ≥92 mg/dl and <126 mg/dl, then subjects were categorized as GDM and no further testing was done. If fasting blood sugar was <92 mg/dl or HbA1C <6.5% or random blood sugar <200 mg/dl, then patients were screened at 24–28 weeks with 75-g 2-h OGTT. Subjects were given 75 g of anhydrous glucose orally and plasma glucose level was measured at fasting, 1- and 2-h interval. The cutoff values were FBS ≥ 92 mg/dl, 1 h ≥180 mg/dl and 2 h ≥153 mg/dl. If any one of the above values was abnormal, then subjects were labeled as having GDM.

Women diagnosed with 'gestational diabetes' were followed in an antenatal clinic. In first, second and third trimesters, antenatal checkup was done every 21, 10 and 7 days, respectively. At each antenatal visit, records of

weight, blood pressure and obstetric examination were taken. BMI was measured at first ANC visit. Blood sugar profile which includes fasting blood sugar and post-meal blood sugar (2 h after meal) was monitored two weekly in first and second trimesters and weekly in third trimester.

Ultrasound for congenital malformation was done between 18 and 20 weeks. Women were advised medical nutrition therapy (MNT), insulin/metformin as needed to keep FBS $\leq$ 95 mg/dl and 2 h postprandial $\leq$120 mg/dl. Ultrasound monitoring for fetal well-being in the form of biophysical profile was done after 34 weeks on weekly basis. Women controlled on insulin were allowed to go in spontaneous labor till 38 weeks if there was no fetal or maternal indication of termination of pregnancy. Elective termination of pregnancy was done at 38 weeks if they did not go in labor. Further, women controlled on MNT alone were allowed to go in spontaneous labor up to 40 weeks, if antenatal period was uncomplicated.

The maternal outcomes studied were mode of delivery, preterm labor, preeclampsia, eclampsia, cesarean section, postpartum hemorrhage and perineal injuries. Fetal outcomes studied were birth weight, birth injuries, Apgar score, neonatal hypoglycemia, hyperbilirubinemia, congenital malformations and need for intensive neonatal care.

Statistical Analysis

The statistical analysis was carried out using Statistical Package for Social Sciences (SPSS Inc., Chicago, IL). All quantitative variables were estimated using measures of central location and measures of dispersion. Normality of data was checked by measures of skewness and Kolmogorov–Smirnov tests of normality. For normally distributed data, means were compared using Student's t test for two groups. For skewed data, Mann–Whitney test was applied for two groups. Qualitative or categorical variables were described as frequencies and proportions. Proportions were compared using Chi-square or Fisher's exact test whichever was applicable. All statistical tests were two-sided and performed at a significance level of $\alpha = .05$.

Results

In group A, women were screened by two-step procedure, and in group B, women were screened by one-step approach as shown in Fig. 1. Various demographic variables were comparable in both groups (Table 1).

The mean age of subjects was 25.67 $\pm$ 4.03 years in group A, while 25.39 $\pm$ 3.92 years in group B. Mean BMI in group A was 27.26 $\pm$ 2.99 and 26.94 $\pm$ 2.26 kg/m^2 in group B which was comparable.

The incidence of GDM was 11.81% in group A and 19.23% in group B which was statistically significant ($p = 0.001$).

In group A, among 58 women diagnosed as GDM, 48 (82.8%) were controlled on MNT only, while remaining 10 (17.2%) required both MNT and insulin for achieving normoglycemic status. In group B, of the 95 women with GDM, 83(87.4%) were given MNT only, while 12(12.6%) required MNT and insulin. Further in group B, out of 83 women who were prescribed MNT, 15 women required resumption of normal diet as the blood sugar profile values were falling in hypoglycemic range and were symptomatic for hypoglycemia (Table 2).

The mean period of gestation at time of delivery was 37.28 $\pm$ 1.38 weeks in group A versus 37.04 $\pm$ 3.45 weeks in group B. In group A, 24.1% of women had preterm delivery, while in group B, 11.6% women had preterm delivery ($p = 0.046$) (RR 2.08; 95% CI 1.01–4.27), showing statistically significant difference. Women requiring induction of labor were comparable in both the groups (37.9 vs 35.78%). Cesarean deliveries were also comparable (27.5 vs 22.10%). Most common indication of CS was fetal distress in both the groups. Postpartum hemorrhage was seen in 15.51% in group A versus 12.63% in group B and was not statistically significant (Table 3).

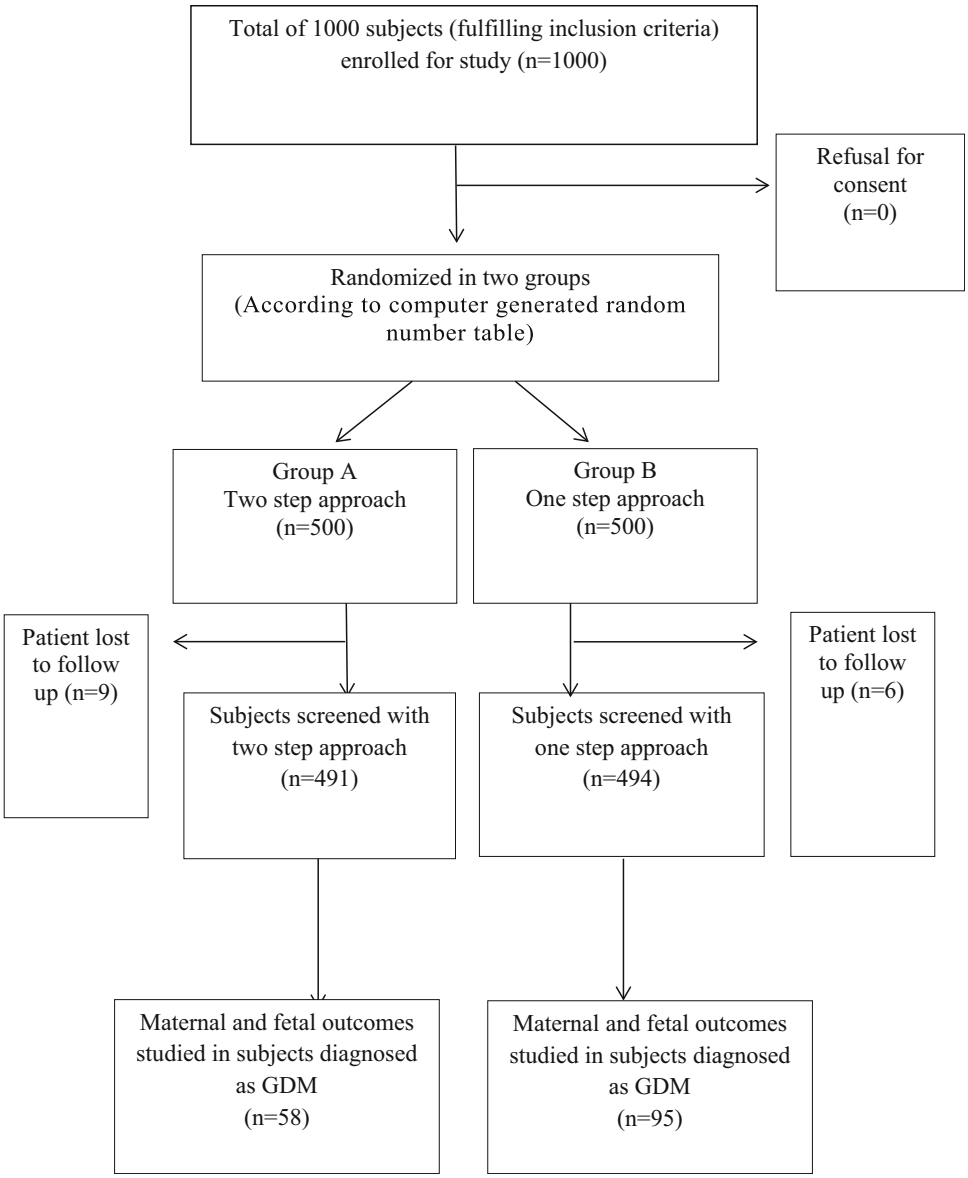
Mean birth weight was 3.05 $\pm$ 0.54 kg in group A and 2.95 $\pm$ 0.43 kg in group B, similar in both the groups. In group A, 6.9% of neonates were LGA versus 8.4% in group B. There was only one case of stillbirth in the group A due to cord prolapse because of noncompliance on patient's part as she did not come for regular follow-up and presented with cord prolapse in labor. Apgar score at 1 and at 5 min of delivery was not statistically different between two groups.

Respiratory distress was present in 27.6% of neonates in group A compared to 23.2% of neonates in group B. Admission to neonatal intensive care unit was required in 16.34% neonates in group A, while in group B, 7.36% required admission showing no significant difference. Hypoglycemia was noted more in group A (29.32%) compared to group B (7.4%), and this difference was statistically significant ($p = 0.003$). The relative risk of neonatal hypoglycemia in two-step approach group was more compared to single-step approach group (RR 3.98; 95% CI 1.75–9.008). One neonate in group A (1.05%) had congenital malformation in form of ventricular septal defect (VSD) diagnosed after birth (Table 4).

Discussion

In this study, we compared traditional ACOG-recommended two-step approach with newer IADPSG-recommended one-step approach.

Fig. 1 Methodology



Incidence of GDM

The incidence of GDM using two-step approach (group A) was 11.8 versus 19.23% with IADPSG criteria (group B). Our study showed an almost double and statistically significant higher incidence of GDM when the IADPSG criteria were used. The reported incidence of GDM in Indian population as per DIPSI is 3.8–21% [6]. Using newer IADPSG criteria will increase the number of patients with GDM.

Maternal Outcome

Group A

Maternal outcome in women having GDM, with respect to mode of delivery, was compared. In group A, 63.8% had vaginal delivery, 8.6% required instrumental delivery, and 27.5% required CS. A study using the two-step approach by Chang et al. [9] reported vaginal delivery in 58.5%, instrumental delivery in 18.8% and cesarean section in 22.7%, which was similar to our study.

On comparing the incidence of preterm delivery, overall preterm delivery rate was 24.1%. Out of 14 preterm deliveries, seven of the preterm deliveries were due to PTPROM, six of them were spontaneous preterm birth, and two were due to severe preeclampsia. The incidence of spontaneous preterm birth in our study was 10.34 versus 9.5% reported by Chang et al. [9]. Postpartum hemorrhage was seen in 15.5% in group A versus 26.7% in study by Chang et al. [9]. Further, Chang et al. [9] reported higher incidence of perineal injury in 11.4 versus 5.14% in group A. This higher incidence of perineal injury can be due to

Table 1 Demographic characteristics

Demographic variable	Group A	Group B	*p* value
Age (years)	25.67 ± 4.03	25.39 ± 3.92	0.340
Socioeconomic status			
Upper	18 (3.6%)	15 (3.0%)	0.891
Upper middle	106 (21.2%)	98 (19.8%)	
Lower middle	222 (44.4%)	227 (45.4%)	
Upper lower	126 (25.2%)	135 (27.0%)	
Lower	28 (5.6%)	25 (5.0%)	
Background			
Urban	364 (72.8%)	376 (75.2%)	0.387
Rural	136 (27.2%)	124 (25.1%)	
BMI (kg/m^2)	27.26 ± 2.99	26.94 ± 2.26	0.058
Gravidity			
Primigravida	317 (63.4%)	288 (57.6%)	0.061
Multigravida	183 (33.6%)	212 (42.4%)	
Occupation			
Housewife	397 (79.4%)	381 (76.2%)	0.223
Working	103 (20.6%)	119 (24.1%)	

Table 2 Gestational diabetic status and variables

	Group A $N = 58$	Group B $N = 95$	*p* value
Incidence of GDM	11.81%	19.23%	0.001
Treatment therapy			
Medical nutrition therapy (MNT) only	48 (82.8%)	83 (87.4%)	
MNT with insulin	10 (17.2%)	12 (12.6%)	
Blood sugar response			
Controlled on MNT	48 (82.8%)	68 (71.6%)	
Controlled on MNT and insulin therapy	10 (17.2%)	12 (12.6%)	
Hypoglycemic values on MNT (required resumption of normal diet)	0 (0.0%)	15 (15.8%)	

higher percentage of instrumental delivery in study by Chang et al. [9].

Group B

The mode of delivery was by vaginal route in 77.8% in group B and 69.5% in study by Benhalima et al. [10] which was similar. Incidence of preterm delivery was 11.6% in group B versus a higher rate of preterm delivery of 29.2% by Benhalima et al. [10]. The incidence of preeclampsia was 5.71% in group B versus a low incidence of 0.6% as reported by Benhalima et al. [10]. Maternal outcome in terms of PPH was observed in 12.63% of patients.

Table 3 Comparison of maternal outcomes

	Group A $N = 58$	Group B $N = 95$	*p* value
Mean POG at delivery	37.28 ± 1.38	37.04 ± 3.45	
Mode of delivery			
(1) Vaginal deliveries	42 (72.4%)	74 (78.0%)	0.682
(2) Normal vaginal delivery	37 (63.8%)	67 (70.6%)	
(3) Instrumental delivery	5 (8.6%)	7 (7.4%)	
(4) Cesarean deliveries	16 (27.5%)	21 (22.0%)	
(5) Emergency cesarean section (CS)	11 (18.9%)	13 (13.7%)	
(6) Elective cesarean section (CS)	5 (8.6%)	8 (8.4%)	
Preterm birth (POG < 37 weeks)	14 (24.1%)	11 (11.6%)	0.046
Preeclampsia	0 (0.0%)	2 (5.71%)	
Maternal complications			
(1) Postpartum hemorrhage (PPH)	09 (15.51%)	12 (12.63%)	0.807
(2) Perineal injury	03 (5.17%)	02 (2.10%)	
(3) Perineal injury and PPH both	02 (3.44%)	05 (5.26%)	

Table 4 Neonatal outcome

Variable	Two-step group $n = 58$	Single-step group $n = 95$	*p* value
Birth weight (in kgs)	3.05 ± .542	2.95 ± .430	0.095
APGAR score at '1 min' (≤7)	8 (13.8%)	7 (7.4%)	0.195
APGAR score at '5 min' (≤7)	0 (0.0%)	2 (2.1%)	0.266
LGA (large for gestational age)	4 (6.9%)	8 (8.4%)	0.187
Stillbirth	0 (0%)	1 (1.1%)	
Neonatal complications			
Respiratory distress	16 (27.6%)	22 (23.2%)	0.567
Birth injury	2 (3.4%)	0 (0.0%)	0.144
RDS	4 (6.89%)	4 (4.21%)	0.710
Hypoglycemia	17 (29.31%)	7 (7.4%)	0.003
Hyperbilirubinemia	5 (8.62%)	19 (20%)	0.006
Hypoglycemia + hyperbilirubinemia	17 (29.31%)	17 (17.89%)	0.090
NICU care	6 (10.34%)	7 (7.36%)	0.067
Shoulder dystocia	1 (1.72%)	2 (2.10%)	0.807

Groups A and B

With respect to maternal outcome, groups A and B differed only in incidence of preterm delivery which was 24.11% higher in group A versus 11.6% in group B and was

statistically significant. The risk of preterm delivery was two and half times more in group A than group B (OR 2.43; 95% CI 1.01–5.79).

Fetal Outcome

Group A

The first parameter of comparison was large for gestational age which was 6.9% in group A as compared to 5.1% by Chang et al. [9], which was similar. Apgar score of less than 7 at 5 min was found in none of the neonates in group A versus 2.6% reported by Chang et al. [9]. 27.6% of the neonates had respiratory distress, out of which 6.89% were due to respiratory distress syndrome. Neonatal hypoglycemia was observed in 29.31% in our study versus 1.6% as reported by Chang et al. [9]. In group A, 10.34% neonates required NICU care as compared to 5.9% of neonates as reported by Chang et al. [9]. This higher incidence can be attributed to more number of preterm deliveries in our study. Shoulder dystocia was seen in 1.72% in group A versus 3.3% in study by Chang et al. [9]. No case of congenital malformation was reported in this group.

Group B

The incidence of LGA was 8.4% versus a higher rate of 10.8% reported by Benhalima et al. [10]. Apgar score of less than 7 at 5 min was seen in 2.1% in this group versus 2.6% by Benhalima et al. [10] which was similar. NICU admission was lower in the present study, i.e., 7.36 versus 12% in study by Benhalima et al. [10].

Groups A and B

On comparing the fetal outcome, both the groups showed similar findings as regards mean birth weight, LGA, Apgar score at 5 min and NICU admission. Both groups differed with respect to development of neonatal hypoglycemia in group A. 29.3% of neonates had hypoglycemia, while only 7.4% of neonates in group B suffered from hypoglycemia. This fetal outcome between the two groups reached statistical significance.

An important finding of study was that using IADSPG criteria, 15.8% women with diagnosis of GDM based on FBS $\geq$ 92 mg/dl were started on MNT-reported hypoglycemia. On investigation, the blood sugar profile was in the hypoglycemic range. These women resumed on normal diet and on follow-up showed a normal blood sugar profile. However, the number of women was small for drawing a conclusion. A randomized study on a larger population may solve this issue.

Conclusion

The incidence of GDM using IADPSG criteria was almost double versus ACOG criteria. Maternal and fetal outcomes were comparable except in 15.8% women diagnosed as GDM and suffered from hypoglycemia. A larger trial is being proposed before these criteria are adopted.

Compliance with Ethical Standards

Conflict of interest There is no conflict of interest.

Ethical Standard All the procedures followed in study were in accordance with the ethical standards of institution, ethical committee of institution had critically evaluated the study and its methodology and given the approval before the study has been started.

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