Screening and diagnosis of gestational diabetes mellitus by IADPSG criteria

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ABSTRACT

Background: GDM is a complex clinical entity and its screening, diagnosis, and management warrants attention. With this issue in mind, we aimed to study the prevalence of gestational diabetes mellitus in the antenatal group of patients attending tertiary hospital in New Delhi and its association with maternal outcome.

Methods: 300 pregnant patients were enrolled in the first trimester and RBS (random blood sugar) was done. Those who had RBS ≥200mg/dl were labelled as overt diabetes and excluded from the study. The patients who were screened negative in phase 1 of screening were subjected to the next phase of screening at 24-28 weeks of gestation with 2-hour 75g OGTT using IADPSG criteria. Those who were diagnosed as GDM were followed in the antepartum, intrapartum and postpartum period.

Results: The prevalence of overt diabetes and GDM in the study population is 1.33% and 13.33%. The prevalence of gestational hypertension, pre-eclampsia, chronic hypertension, polyhydramnios was 15%, 5%, 5%, 7.5% respectively. Normal and instrumental vaginal delivery was in 50%, 5% patients respectively and 45% had the caesarean section.

Conclusions: The single step OGTT with lower threshold value cut-offs and single abnormal value for the diagnosis of GDM as advocated by IADPSG seem to be effective as it helps to screen and diagnose GDM at the same time as a single step procedure and thus more cost-effective.

Keywords: Gestational diabetes mellitus, IADPSG criteria, Maternal outcome, Screening

INTRODUCTION

Diabetes mellitus is defined as disturbance in carbohydrate metabolism characterized by hyperglycemia with peripheral insulin resistance or insulin deficiency.1 Diabetes in pregnancy can be of (a) Pre-gestational diabetes/overt diabetes mellitus (b) Gestational diabetes mellitus (GDM).2 GDM is carbohydrate intolerance of variable severity with its onset or first recognition during pregnancy.3 Risk factors for GDM include advanced maternal age, increased parity, obesity, associated polycystic ovarian syndrome, previous GDM or macrosomic infant and a family history of diabetes. It is a complex clinical entity, with conflicting guidelines and diagnostic protocols. Despite more than 40 years of research, there is no consensus regarding the optimal approach for screening of gestational diabetes.4 The global prevalence of diabetes in 2000 was 2.8% which is likely to increase to 4.4% in 2030.5 In India, the prevalence of GDM ranges from 0.25-5.5%.6-10 There is no uniform international standard to diagnose GDM. Lawrence et al assessed the changes in the prevalence of pre-existing diabetes and GDM from 1999-2005, pre-existing diabetes was identified in 2,784 (1.3%) of all pregnancies, GDM was identified in 15,121 (7.6%) pregnancies.11 Wahi P et al from Jammu in India recently...
showed the prevalence of GDM as 6.94%.12 In a study conducted in a tertiary care hospital in Haryana Rohtak, the prevalence of GDM was found to be 7.1% and a single abnormal value was observed in 10.87% of women.13 A study by K Sreekantan et al at a medical college in Kollam, Kerala found the prevalence of GDM to be 17%.14 There are evidences now that treating even mild form of GDM is beneficial to the mother and the baby.15

Miscarriages and pre-term labour are common in patients with pre-existing diabetes. Antepartum and peripartum complications include pre-eclampsia, polyhydramnios, and operative delivery due to macrosomic baby. The perinatal complications include macrosomia, birth trauma, shoulder dystocia, neonatal hypoglycemia, neonatal respiratory complications, hypocalcemia, polycythaemia, stillbirths and increased perinatal mortality. The different diagnostic methods for detecting and diagnosing GDM being employed around the globe today have led several groups to call for the universal adoption and implementation of a single screening and diagnostic strategy. The International collaborative group, recommended a new terminology and a new diagnostic cut off based primarily on the Hyperglycemia and Pregnancy Outcomes study (HAPO).16 Under the new IADPSG (International Association of Diabetes and Pregnancy Study Groups), there is a two-phase strategy of screening all pregnant women for diabetes mellitus at first antenatal visit in first trimester and with one step 75g OGTT at 24-28 weeks of pregnancy.

This proposed new strategy would include changing from a 2-step to a 1-step screening process, along with a lower glucose threshold for the diagnosis of GDM. Universal screening for GDM detects more cases and improves maternal and offspring prognosis compared to selective screening.17 Present study was thus aimed to determine the prevalence of gestational diabetes mellitus in the antenatal group of patients registered in our hospital and to study the association of gestational diabetes mellitus with maternal outcome.

METHODS

Present study was an observational study conducted from November 2013 to March 2015 in antenatal outpatient department and labour room of Lady Hardinge Medical College, New Delhi. Sample size was calculated using the formula N= 4PQ/L2 where P is 10, Q is 100-P and L is 4 i.e. allowable error. It calculated as 225 and so we rounded the figure as 300. So, a total of 300 pregnant women registered at the antenatal clinic with single live fetus in first trimester were enrolled randomly in the study after taking informed consent.

Exclusion criteria

- Patients with history of renal, liver, thyroid disorder and on medications such as steroids or thiazides.

In phase 1 of screening random blood sugars of all pregnant women were measured. Samples were analyzed on fully automated clinical chemistry analyzer AU480 (Olympus, Beckman coulter, USA), using commercially available kit provided by Randox, UK using GOD-Pod method. Random blood sugars > 200 mg/dl were labelled as overt diabetes and treated accordingly. Those who were tested negative i.e. random blood sugars < 200 mg/dl were included in phase 2 of screening and at 24-28 weeks of gestation, 2-hour 75 gm OGTT was done for them. IADPSG criteria was followed in which fasting blood sugars ≥92mg/dl, 1 hour ≥180 mg/dl and 2 hours ≥153mg/dl were considered abnormal. Overt diabetes was defined as fasting plasma glucose levels >126mg/dl, GDM as one or more values exceeding IADPSG thresholds and normal as all 3 glucose values less than threshold.

Those who were tested positive as per the IADPSG criteria were managed with dietary modification, lifestyle modification, exercise regimen, insulin/hypoglycemic agents as per the hospital protocol taking target therapy value as fasting blood glucose levels less than 95mg/dl and two-hour postprandial blood glucose levels less than 120 mg/dl. The women having GDM were kept under intense surveillance by SMBG (self-monitoring of blood glucose) and were screened for complications like pre-eclampsia and polyhydramnios.

Ultra-sonography, for fetal biometry and amniotic fluid indices was carried to monitor fetal growth, three weekly USG was done to detect macrosomia during the antenatal checkups. Antepartum fetal surveillance was done by daily fetal movement count, non-stress test, and biophysical profile score.

The time and mode of delivery was individualized. Some of the patients went in spontaneous labour and were directly admitted to the labour room and some of them were admitted in wards and were induced and some of them were electively taken up for cesarean due to good size baby.

The patients were followed up in the labour room for the intrapartum events till the delivery of the baby. The patient’s blood sugar monitoring was strictly done in the first, second and the third stage of labor to maintain good glycemic control (2 hourly dextrose charting and 4 hourly random blood glucose) while avoiding hypoglycemia.

The birth weight of babies was estimated using the weighing machine and baby was examined by pediatrician to rule out any birth injury. So, the outcome of present study was to detect the prevalence of Gestational Diabetes Mellitus in pregnant women following universal screening and one step OGTT and to study the association of GDM with adverse maternal complications of pre-eclampsia and polyhydramnios and its association with caesarean delivery for CPD, shoulder dystocia and birth trauma.
**RESULTS**

In present study, 300 patients were recruited for Phase 1 of screening. 4 patients were excluded from the study after being diagnosed as overt diabetes. The prevalence of overt diabetes in present study population was 1.33%. The remaining 296 were screened with 2-hour 75 g OGTT at 24-28 weeks as per IADPSG criteria in Phase 2 of screening. 40 patients out of 296 were tested positive for GDM which constituted the study group. The prevalence of gestational diabetes mellitus following one step OGTT was 13.33%.

The demographic and clinical parameters of the study group is shown in Table 1.

### Table 1: Demographic characteristics and clinical parameters of study group (GDM positive patients).

| Parameter                        | Study group |
|----------------------------------|-------------|
| Mean age±SD (years)              | 28.75±4.73  |
| Mean gravidity±SD                | 2.5±0.574   |
| Mean height±SD (cm)              | 156±4.64    |
| Mean weight±SD (kg)              | 70.90±9.58  |
| Mean BMI±SD (kg/m²)              | 29.15±4.96  |
| Mean SBP±SD (mm hg)              | 126.28±12.29|
| Mean DBP±SD (mm hg)              | 79.85±1.01  |

Table 2 shows distribution of study group on the basis of past history in study group. The mean RBS value in study population was 96.64±25.74 whereas in study group it was 109.32 mg/dl. The mean fasting, 1st hr, 2nd hr in the study population were 76.5±16.26, 125.57±33.16, 111.64±28.99 respectively.

### Table 2: Distribution of study group on the basis of past history.

| History               | Frequency | %  |
|-----------------------|-----------|----|
| Family history of DM  | 6         | 15 |
| Previous abortion     | 9         | 22.5|
| Preterm deliveries    | 1         | 2.5|
| Macrosomia            | 2         | 5  |
| Still birth           | 3         | 7.5|
| Shoulder dystocia     | 1         | 2.5|

Out of abnormal thresholds of fasting, 1st hour and 2nd hour values, the mean fasting value was 98.64 mg/dl, the mean 1st hour value was 197.117 mg/dl and the mean 2nd hour value was 167.12 mg/dl as seen in Table 3.

### Table 3: Mean blood sugar values in total study population and group.

| Parameter | Total study population (n=300) | Study group (n=40) |
|-----------|--------------------------------|-------------------|
| Fasting   | 96.64±25.74                    | 109.32±28.02      |
| 1 hour    | 125.57±33.16                   | 197.117±20.11     |
| 2 hours   | 111.64±28.99                   | 167.12±19.38      |

In the total of 40 patients, 20 had only one value deranged, 16 had two values deranged and 4 had all three values deranged. Among the women who had only one value deranged, only fasting value was deranged in 11, only 1st hour value was deranged in 4 and only 2nd hour value was deranged in 5 (Table 4).

### Table 4: Frequency of single abnormal blood sugar value in study group.

|       | Fasting | 1 hour | 2 hours |
|-------|---------|--------|---------|
| N=20  | 11mg/dl | 4mg/dl | 5mg/dl  |

These 40 women diagnosed with GDM were followed up till delivery for the antenatal, intrapartum and post-partum events. Out of 40, 30 patients had normal BP records, i.e. BP <140/90 mm Hg. 8 patients had Pregnancy Induced Hypertension (PIH) in which 2 patients had pre-eclampsia i.e. BP >140/90 mm Hg associated with proteinuria and 6 patients had BP>140/90 mm Hg without proteinuria and 2 patients had chronic hypertension. There were no cases with eclampsia. Hence, the prevalence of gestational hypertension in study group was 15%, of pre-eclampsia was 5% and of chronic hypertension was 5%. 3 patients out of 40 patients had polyhydramnios contributing to 7.5% of the study group. 20 out of 40 (50%) of patients had normal vaginal delivery, 2 out of 40 (5%) of patients had instrumental delivery (1 forceps and 1 vacuum) and 18 out of 40 (45%) patients had caesarean section. Only 1 (2.5%) baby had birth injury and birth asphyxia was observed in 2 out of 40 patients (5%).

**DISCUSSION**

The prevalence of gestational diabetes mellitus is on the rising trend and is known as one of the most common complications during pregnancy due to increase in the number of women of obesity among the women of child bearing age.18 Early detection and management of gestational diabetes mellitus improves the outcomes for both the mother and the fetus that includes treatment of even mild GDM.15 HAPO study, hyperglycemia and adverse pregnancy outcome study reported that glucose levels lower than that was required for the diagnosis of gestational diabetes mellitus were significantly associated with adverse pregnancy outcomes.16 IADPSG criteria was similarly based on HAPO study, and thus recommended new diagnostic criteria for the diagnosis of GDM.19,20 IADPSG criteria has found a fairly wide acceptance since
the time of its introduction. As per the IADPSG criteria, GDM was diagnosed using fasting blood sugar levels in the first trimester and oral glucose tolerance test in 2nd/3rd trimester.

Screening in the first trimester helps in detecting overt diabetes and also universal screening at 24-28 weeks is more sensitive than selective screening recommended by American Diabetic Association. So, we planned this study to determine the prevalence of gestational diabetes mellitus and to study its association with maternal outcomes i.e. hypertension, polyhydramnios and caesarean delivery.

Table 5: Studies on prevalence of GDM.

| Studies                  | Prevalence of GDM |
|--------------------------|-------------------|
| Bhavadharini et al       | 18.5              |
| O’Sullivan et al         | 12.4              |
| Gopalakrishnan V et al   | 41.9              |
| Hung et al               | 12.4              |
| Arora et al              | 34.9              |
| Nayak et al              | 27                |
| Dahanayaka et al         | 8.9               |

The prevalence of overt diabetes and GDM in present study population was 1.33% and 13.33% respectively. The prevalence of gestational diabetes mellitus has been studied worldwide using IADPSG criteria as shown in table 522-28. In majority of studies the prevalence of GDM was comparable to present study. Higher prevalence rate reported in a study by Arora et al, was due to larger sample size and they used capillary blood sample rather than venous sample as in present study. In a study done by Bhavadhari et al, screening for GDM started in first trimester and then between 24-28 weeks of gestation as in present study, thus detecting prevalence of overt diabetes as 1.2%. Fasting hyperglycaemia was seen in 55 % of our patients in present study. Gopalakrishnan et al reported that 70.5% patients had fasting hyperglycemia and in a study by Moradi et al, 48% of GDM diagnosed using IADPSG criteria had elevated fasting blood sugar levels alone.

In a study by M Shang et al, an IADPSG criteria was used to detect the prevalence of gestational diabetes mellitus and predicting adverse outcomes. The prevalence of GDM in this study was 19.9%. The prevalence of preeclampsia in GDM patients was 7.2% and caesarean section was done for 54.9% patients. In this study the prevalence of GDM was calculated using both IADPSG and ADA criteria and also prevalence of adverse pregnancy outcomes was compared between patients with gestational diabetes mellitus and those with normal glucose tolerance. Present study on the other hand, did not include the controls with normal blood sugar values. If it would have been included results would have been clearer and statistically significant. Further studies are necessary to replicate the benefits of correctly diagnosing and managing GDM in larger populations.

CONCLUSION

The single step OGTT with lower threshold value cut offs and single abnormal value for diagnosis of GDM as advocated by IADPSG seems to be effective because of its association with adverse pregnancy outcomes. It is anticipated that lowering the diagnostic criteria for GDM will lead to early diagnosis and effective management of patients with hyperglycemia starting from first trimester of pregnancy as well. Due to relatively small number of patients in present study, further studies with large sample size are required to ascertain the increased prevalence of GDM using IADPSG criteria.

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