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RESEARCH ARTICLE
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COMPARISON OF 2 HOUR 75 GM ORAL GLUCOSE TOLERANCE TEST WITH A SINGLE TEST 75 GRAM GLUCOSE CHALLENGE TEST FOR UNIVERSAL SCREENING OF GESTATIONAL DIABETES MELLITUS.

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ABSTRACT

INTRODUCTION: Around 3-5% of pregnancies are affected by pre-existing diabetes or gestational diabetes. The 75g OGTT is the standard test used worldwide to screen for gestational diabetes (GDM). According to the Diabetes in Pregnancy Study Group India (DIPSI), the 75g GCT is a simple one-step procedure for diagnosing GDM.

Aim: Evaluation of the efficacy of 75 gm GCT (DIPSI) with that of 75 gm OGTT for screening of GDM.

Materials and methods: The study was conducted on 400 pregnant women who visited the antenatal clinic at the Department of Obstetrics and Gynaecology, Government Medical College, Amritsar, from February 2010 to August 2011, after approval from the ethics committee. The women were assessed based on their history and clinical profile, after giving informed consent. The data collected included age, number of pregnancies, weight, height, gestational age at diagnosis, uterine size, whether they lived in urban or rural areas, and family history. For the 75g GCT (DIPSI), the women were given a 75g glucose solution at random times, and their blood glucose was measured 2 hours later. After 72 hours, the 75g OGTT was done by first taking a fasting blood sample, then giving the woman 75g of glucose to drink, and measuring her blood glucose 2 hours later.

Result: 3.8% of women were GDM positive with 75 gm, GC(DIPSI), However, true incidence was 2 % (according to 75 gm OGTT). Sensitivity and specificity of 75 gm GCT:100 % and 98.47 % respectively. Positive and negative predictive values came out to be 57.14 % and 100% respectively. Gestational diabetes is more common in urban women and in those with positive family history of diabetes.

Conclusion: 75 gm GCT (DIPSI) done between 16 to 28 weeks of gestation with a cut-off value of >/= 140 mg/dl cannot act as both screening and diagnostic test for GDM since it has very low positive predictive value.

Keywords: Gestational diabetes mellitus, Oral glucose challenge test, Dipsi, Oral glucose tolerance test

INTRODUCTION:

Gestational Diabetes Mellitus (GDM) is a form of carbohydrate intolerance that causes hyperglycemia, first detected during pregnancy. It can occur with varying severity, regardless of prior diabetes status, and may require insulin. The diagnosis is made without consideration of whether

blood sugar levels normalize after delivery. This condition can impact both maternal and fetal health and requires careful management. Women may have unrecognized pre-existing type II diabetes , or preclinical type I or type II which became apparent due to increased metabolic demand of pregnancy and a few may have onset of disease coincidental with pregnancy.

Diabetes mellitus and less serious forms of glucose intolerance are widespread in almost every population in the world[1]. Accurate estimates of how often gestational diabetes occurs worldwide are hard to find. This is because countries use different standards for testing glucose tolerance, making it difficult to compare results globally.[2] By 2030, probably 361 million people will be affected by gestational diabetes mellitus[1].

The main risk factors for developing gestational diabetes are:[3] having had gestational diabetes or prediabetes before, a close family member with type 2 diabetes, being over 35, and certain ethnic backgrounds (like African-American, Afro-Caribbean, Native American, Hispanic, and Pacific Islander) and people originating from South Asia)being overweight, obese or severely obese increases the risk by a factor 2.1, 3.6 and 8.6, respectively[4], a previous history of macrosomia (>90th centile, or >4000 g (8 lbs 12.8 oz), previous bad obstetric history. In addition to this, statistics show a double risk of GDM in smokers.[5] Polycystic ovarian syndrome is also a risk factor although relevant evidence remains controversial.[6]

Some studies have explored other possible risk factors for gestational diabetes, like shorter height, though these are less certain. Around 40-60% of women with GDM don't have obvious risk factors, which is why universal screening is recommended. GDM can lead to complications for the mother, such as high blood pressure, preeclampsia, and a higher chance of needing a C-section. There's also a moderate to high risk of developing diabetes after pregnancy, especially in women with high blood sugar, obesity, or an early GDM diagnosis before 24 weeks.[9]

Fetal complications include congenital malformations (caudal regression syndrome, situs inversus, spina bifida, anencephaly, cardiac anomalies, anal/rectal atresia, renal anomalies) macrosomia, hypoglycemia, hyperbilirubinemia, respiratory distress syndrome, polycythemia, hypertrophic cardiomyopathy, and hypocalcemia, with varying frequency.

Good periconceptional glycemic control may reduce the risk to 0.8-2%. Risk can be estimated by glycosylated haemoglobin measurement. Children born to mothers with gestational diabetes have a higher risk of developing glucose intolerance, diabetes, and obesity later in life. Unexplained fetal death in the third trimester could sometimes be due to a lack of oxygen (from poor placental function). This life threatening metabolic state could be prevented by maintaining maternal euglycemia throughout the pregnancy.[11]

SCREENING STRATEGY FOR DETECTING GDM:[12]

Universal screening for gestational diabetes (GDM) finds more cases than selective screening and helps improve health outcomes for mothers and babies.[13] In India, it is especially important to screen all pregnant women because Indian women have a much higher risk of developing glucose intolerance in pregnancy than Caucasian women.[14] Among South Asians, Indian women have the highest rate of GDM.[15] Recent data shows that 16.55% of pregnant women in India have GDM, making universal screening essential.[16]

BENEFITS OF SCREENING

Screening for GDM and its consequent diagnosis and management reduces the incidence of macrosomia[12] while possibly increasing the CS rate,[20,21] reduction of birth trauma and possibly neonatal metabolic disorders. Treatment of GDM reduces serious perinatal morbidity and improves the woman`s health related quality of life.

American Diabetes Association recommends two step procedure for screening and diagnosis of GDM, that too in high risk population. The ADA recommends a 3-hour test with 100g of glucose for diagnosing gestational diabetes (GDM). If two or more of the following values are met or exceeded,

GDM is diagnosed: fasting > 95 mg/dL, 1 hour > 180 mg/dL, 2 hours > 155 mg/dL, or 3 hours > 140 mg/dL. This test requires fasting.

DIPSI uses a simpler, one-step test for GDM, diagnosing it if the 2-hour glucose level is above 140 mg/dL. This test is more practical and affordable in India.
This study aimed to compare the standard 75g OGTT with the 75g glucose challenge test (DIPSI) for diagnosing GDM.

MATERIAL AND METHODS:

In this study, pregnant women between 16 to 28 weeks were screened using a single 75g glucose test. Each woman was tested again 72 hours later with a 75g oral glucose tolerance test. The study included 400 pregnant women from the antenatal clinic at the Obstetrics and Gynecology department of Government Medical College in Amritsar. It took place from February 2010 to August 2011, after approval from the ethics committee.
Study procedure: After initial evaluation by history and clinical profile, and getting informed consent from the participants, the following parameters were noted: urban or rural, family history of diabetes mellitus, age, parity, weight, height, BMI, gestational age at diagnosis, uterine height in relation to period of gestation. For single step 75 gm test, At the antenatal clinic, each pregnant woman had a basic check-up and then drank a 75g glucose solution, regardless of when she last ate. A blood sample was taken 2 hours later to measure blood glucose levels.
For the 2-hour, 75g oral glucose tolerance test, the woman fasted for 10 to 16 hours beforehand. This test was done in the morning, after 3 days of a diet with at least 150g of carbohydrates each day and normal physical activity. After obtaining a fasting specimen, a 75 gm glucose loading dose was consumed over 5 minutes. Patient remained seated throughout the test and drank as much water as desired. Blood was drawn at 2 hours after the glucose load and blood glucose levels estimated. The test was done using O' Toluidine method.

Glycemic Criteria for Diagnosis of different categories of glucose intolerance by 75 g, 2 hr OGTT[18]

Criteria	FPG mg/dl	2-hr PG mg/dl
Normal Glucose Tolerance (NGT)	<100	<140
Impaired Fasting Glucose (IFG)	100-125	-
Impaired Glucose Tolerance (IGT)	-	140-199
Diabetes Mellitus (DM)	> 126 and/or	> 200

* Glycemic cut-off for the diagnosis of IGT outside pregnancy is the same for the diagnosis of GDM during pregnancy

Inclusion Criteria:
1. Age above 18 years
2. Singleton pregnancy
3. Gestational age above 16 weeks.
4. Previously non-diabetic women.

Exclusion criteria
1. Previously diabetic women
2. Multiple pregnancy
3. Co-existing medical disorders including gestational hypertension, liver disease, thyroid disorder, heart disease.

Statistical methods: Data was recorded in a Microsoft excel spread sheet and analysed using Statistical Package for the IBM SPSS Statistics for Windows, Version 23.0 Armonk, NY: IBM Corp., Chicago. Continuous data was presented as mean with standard deviation. Categorical data was expressed as percentages. Numerical variables were normally distributed and analysed using independent t-test, for correlation, Pearson`s correlation test was applied. Categorical variables were analysed using chi square test. P- value less than 0.05 was taken as statistically significant.

OBSERVATIONS

In this study, 14 out of 400 pregnant women had 2-hour blood glucose levels over 140 mg/dL after the 75g glucose challenge test. Of these, only 8 were confirmed to have gestational diabetes (GDM) using the 75g oral glucose tolerance test, giving a GDM rate of 2% among participants. Women who tested positive in the glucose challenge were slightly older and had a higher BMI than those who tested negative.

Among the glucose challenge positive women:

71.4% were from urban areas. 42.85% were first-time pregnant (primigravida), while 57.14% had previous pregnancies (multigravida).

28.57% were between 16-20 weeks pregnant, and 57.14% were between 24-28 weeks. 42.85% had a family history of diabetes

TABLE 1 MATERNAL DEMOGRAPHIC CHARACTERISTICS

PARAMETERS	GCT POSITIVE	GCT NEGATIVE	p-value
AGE(YEARS)	24.57 ± 2.07	24.25 ± 3.33	0.721
WEIGHT(KG)	60.42 ± 9.98	53.30 ± 9.54	0.006
HEIGHT(CM)	153.86 ± 6.96	152.68 ± 6.31	0.561
B.M.I (kg/m^2)	25.58 ± 4.72	22.85 ± 3.69	0.007

TABLE 2 PREVALENCE OF GDM IN URBAN OR RURAL POPULATION

POPULATION	GCT +VE (n=14)	%AGE	GCT –VE (n=386)	%AGE
RURAL	4	28.57	270	69.94
URBAN	10	71.4	116	30.05

X^2: 10.71; p value= 0.001

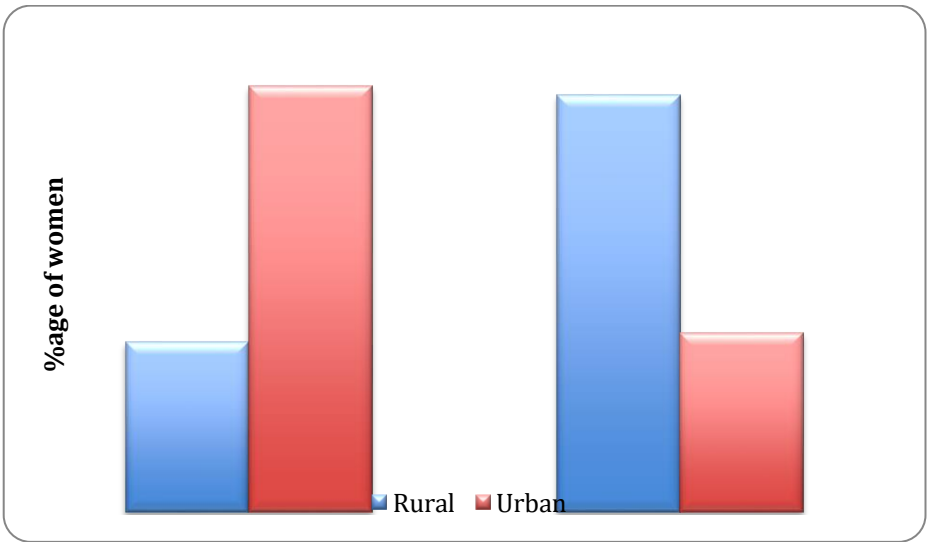


TABLE 3 DISTRIBUTION OF GLUCOSE CHALLENGE TEST POSITIVE PATIENTS BY GRAVIDITY

GRAVIDITY	NUMBER OF PATIENTS (n=14)	PERCENTAGE
G1	6	42.85
G2	6	42.85
G≥3	2	14.28

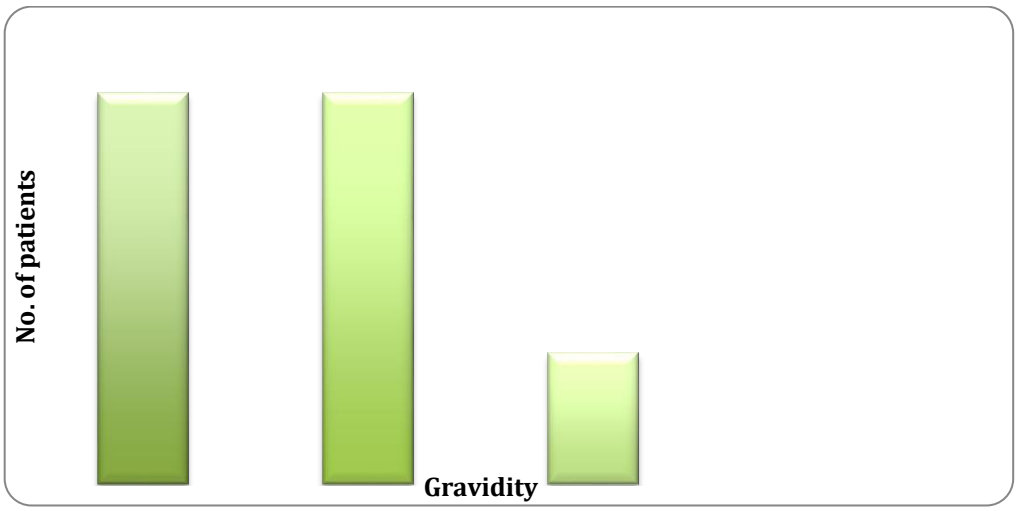
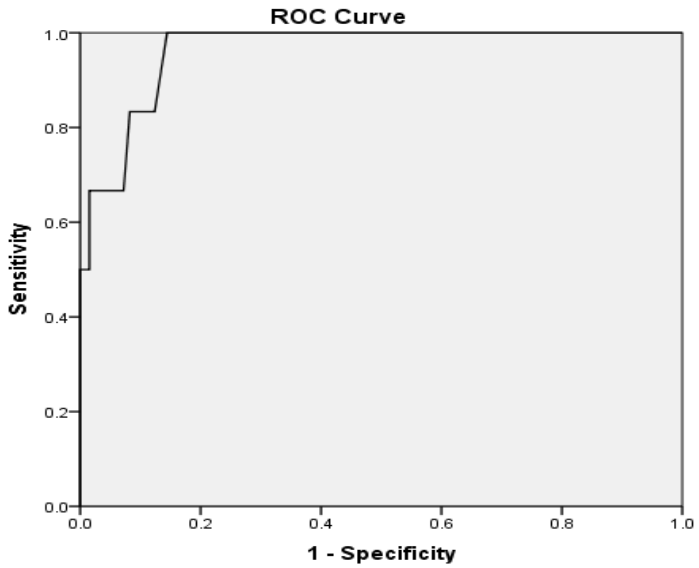


TABLE 4 COMPARISON OF RESULTS OF OGCT AND OGTT

	OGTT POSITIVE (n=8)	OGTT NEGATIVE (n=392)	TOTAL
OGCT POSITIVE	8	6	14
OGCT NEGATIVE	0	386	386
TOTAL	8	392	400

Sensitivity of 75 gm single test = 100%
Specificity of 75 gm single test = 98.47%
Positive predictive value of 75 gm single test = 57.14%
Negative predictive value of 75 gm single test = 100%



r-value: 0.538
p-value: 0.001

TABLE 05 GESTATIONAL AGE AT DIAGNOSIS

GESTATION (WEEKS)	GCT+VE(n=14)	%AGE	GCT-VE (n=386)	%AGE
16-20	4	28.57	134	34.71
20-24	2	14.28	102	26.42
24-28	8	57.14	150	38.86

X^2: 2.057; p value= 0.570

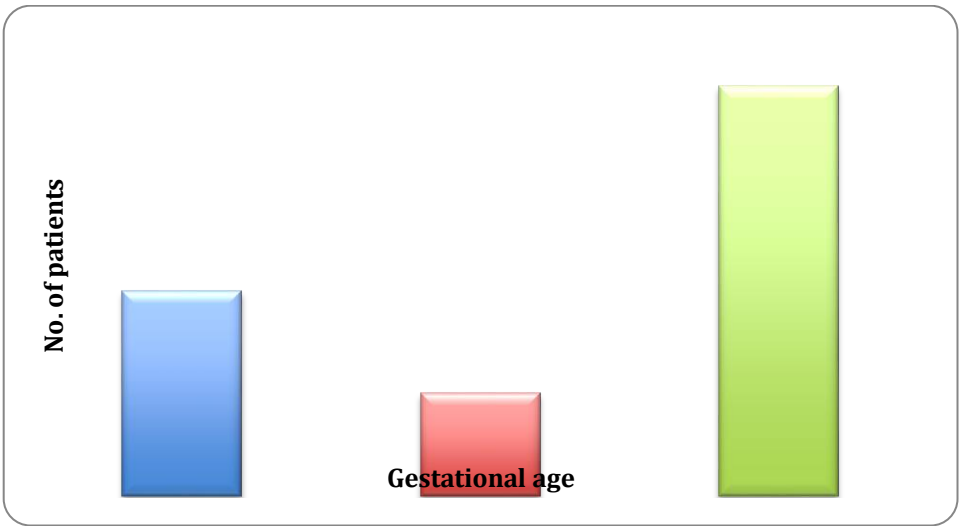
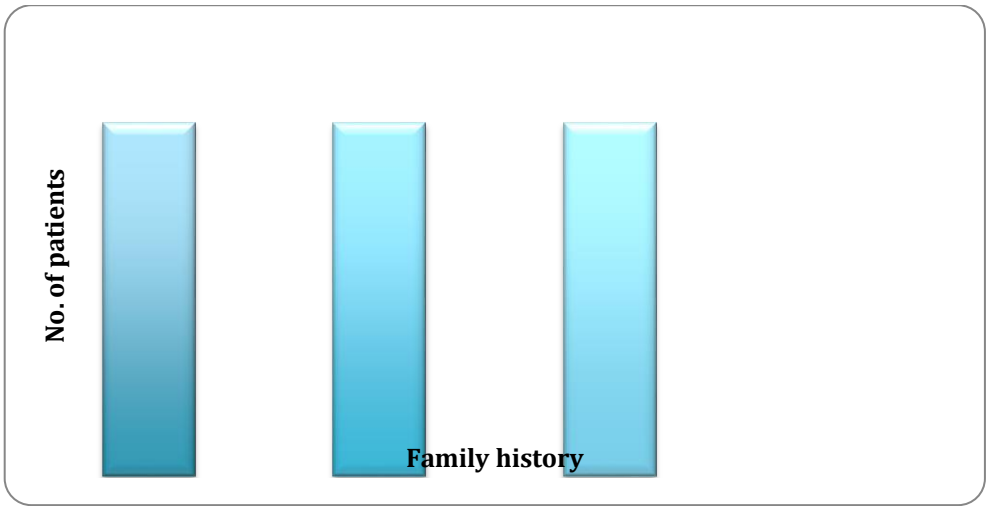


TABLE 06 FAMILY HISTORY OF DIABETES MELLITUS IN GCT POSITIVE PATIENTS

	NUMBER OF PATIENTS(n=14)	PERCENTAGE
DIABETIC MOTHER	2	14.28
DIABETIC FATHER	2	14.48
DIABETIC SIBLING	2	14.28
NONE	8	57.14



DISCUSSION

Indian women have a high rate of diabetes, and their risk of developing gestational diabetes (GDM) is 11.3 times higher than that of White women.[14] This makes it essential to screen all pregnant women in India for glucose intolerance. When only selected women are screened instead of all, GDM is

missed in about one-third of cases. With around 20 million women of reproductive age in India, many women with glucose intolerance could go undiagnosed without universal screening.

For universal screening, Seshiah V and colleagues suggest a simple test where a pregnant woman drinks 75g of glucose, and if her blood glucose level is over 140 mg/dL after 2 hours, she is diagnosed with gestational diabetes (GDM). This one-step test, recommended by WHO, is both a screening and diagnostic method that is easy to do and affordable.[16]

According to a study done by Anjalakshi et al[29] on South Indian population, there was 100 per cent sensitivity and 100 per cent specificity of 75 g, two hour non-fasting GCT (DIPSI) test when compared with the WHO-recommended 75 g OGTT for the diagnosis of GDM. They made the conclusion that there was no significant difference between the two tests in diagnosing women with GDM[29].

On the other hand, according to a study done by Mohan et al[30], there is very low sensitivity of 'non-fasting 75 gm GCT as compared to the fasting OGTT'. These authors further inferred that DIPSI test when compared to the WHO criteria had sensitivity of 27.7 per cent and specificity of 97.7 per cent. This should be considered important as it was done on a population similar to the DIPSI study[29].

According to another study done in the Maharashtra[31], GDM was reported in only 6.52 per cent cases and they suggested that this low prevalence could be the result of 'less sensitivity of DIPSI criteria'.

Another study, although conducted in fewer subjects[32] stated that 22.36 per cent of cases of GDM were missed by the DIPSI criteria. A study done on Sri Lankan women has also concluded that '75 gm GCT with two-hour cut-off value ≥140 mg/dl is not sensitive enough to diagnose GDM recognized by 75 gm OGTT'[33]. This study analyzed only 274 women, but prevalence rate of GDM in this study was 22 per cent and therefore, their results should be considered important.

According to a study done by Tripathi et al[34], sensitivity of 75 gm, GCT was 65.1 percent and specificity was 96.3 percent, on comparison with 75 gm OGTT. The large number of false positives along with fewer false negatives is a major constraint of DIPSI test. They have concluded that almost one fourth of patients with GDM, would be missed and many women would be falsely labelled as GDM.

In our study, the rate of gestational diabetes (GDM) was 2%. This is lower than the 3.6% rate found in a study by Sawant PA. In another study from Kashmir by Zargar AH., the rate of GDM was 3.8%.[22]

The rate of gestational diabetes (GDM) in this study is lower than average. Several factors may explain this low rate. In rural India, women often marry and conceive at a younger age, and older age is a known risk factor for GDM. So, early marriage and pregnancy could be one reason for the lower GDM rate here. Additionally, rural Indian women tend to have a low-fat diet and high physical activity, which helps prevent obesity, a major risk factor for GDM.

In this study, 28.57% of women who tested positive for the glucose challenge were between 16-20 weeks pregnant, while 57.14% were between 24-28 weeks. The current recommendation is to do screening tests between 24-28 weeks of pregnancy. The ADA guidelines also suggest screening between 24-28 weeks.[12]

The 6th International Workshop on Gestational Diabetes in Pasadena (2008) introduced new guidelines based on the HAPO Trial. According to these guidelines, all pregnant women should be tested with a 75 g oral glucose tolerance test between weeks 24 and 28, without the need for separate screening first.[23]

The DIPSI guideline recommend screening on the 1st antenatal visit with 75 g OGCT irrespective of whether the patient fasting or not.[24]

In the present study, 42.85% of the glucose challenge test positive patients were less than 25 years of age. 57.14% were between 25 to 30 ye ars of age. Thus all the patients were less than 30 years of age. This is due to the fact that 93.5% of the total study population was less than 30 years of age. Coustan et al. also reported a similar finding of 56% of GDM cases under 30 years of age[12.] According to a study done in Maharashtra by Sawant PA. on 500 pregnant women, out of the 18 gestational diabetic patients, the maximum of 7 patients (39%) belonged to the age group of 26-30 years and 6 patients

(33%) were between 21 to 25 years i.e. 72% of all the gestational diabetic patients were between the ages of 21 to 30 years[25].

According to the present study, Gestational diabetes (GDM) was more common in urban areas than in rural areas. In this study, 71.4% of women who tested positive for the glucose challenge were from urban areas.[58] According to Balaji V et al., GDM is more common in urban areas than in rural ones. Seshiah V et al. reported that 17.8% of women in urban areas had GDM, compared to 13.8% in semi-urban areas and 9.9% in rural areas. The ADA also found that GDM is more common in urban areas.[13]

The incidence of gestational diabetes mellitus is 2.88% in primigravidae. It is 4.2% in multigravidae. The study done by Sawant PA. in Maharashtra shows an incidence of 3.8% GDM individuals in primigravida and 3.4% in multigravida. Thus it did not find any influence of parity on the incidence of GDM.[25]

In this study, 42.85% of women with gestational diabetes (GDM) had a family history of diabetes. This is similar to findings by Sawant P.A., where 50% of GDM cases had diabetic first-degree relatives.[26] Coustan DR also found a strong link between GDM and a family history of diabetes in close relatives.[27] Ouyang F showed that pre-pregnancy obesity, family history of type 2 diabetes, low birth weight, older age, higher triglyceride levels, and having a diabetic parent all increase GDM risk. The mother's or father's diabetes history contributed equally to the risk of GDM in their child.[28]

Zargar AH found that gestational diabetes (GDM) was more common in women living in urban areas, who had multiple pregnancies, or who had a history of abortion or GDM in previous pregnancies. Women who had given birth to a large baby, or had a family history of diabetes, were also more likely to develop GDM. Additionally, women with obesity, high blood pressure, signs of high blood sugar, protein in the urine, or excess amniotic fluid had a higher risk of GDM.[22]

CONCLUSION

Based on the study's data, it was concluded that the 75 g OGCT (DIPSI) test cannot be used as both a screening and diagnostic test for gestational diabetes (GDM). The 75 g OGTT remains the standard diagnostic test for GDM.

While the DIPSI test is simple, affordable, and suitable for India, it should only be used for screening. This test when used for diagnostic purpose would lead to erroneous diagnosis of GDM. This would add to the clinical, psychological and monetary burden on women.

Use of 75 gm OGCT(DIPSI) for confirmatory diagnosis of gestational diabetes mellitus needs further investigation before large scale implementation in our country.

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