Frontiers in Health InformaticsISSN-Online: 2676-7104 www.healthinformaticsjournal.com
2024; Vol 13: Issue 3 Open Access

Incidence of Gestational Diabetes Determined by 75g Oral Glucose Tolerance Test and Its Impact on Maternal and Fetal Outcomes at a Tertiary Care Center in Jharkhand

Running Title: Incidence of GDM and its fetomaternal Outcome

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Cite this paper as: Divyanka Kumari, Atima Bharti (2024) Incidence of Gestational Diabetes Determined by 75g Oral Glucose Tolerance Test and Its Impact on Maternal and Fetal Outcomes at a Tertiary Care Center in Jharkhand *Frontiers in Health Informatics, 13* (3), 7993-8004

Abstract

Objectives: *This study aimed to determine the incidence of gestational diabetes mellitus (GDM) using the 75g oral glucose tolerance test (OGTT) and to assess its impact on fetomaternal outcomes at a tertiary care center in Jharkhand.*

Methods: *This prospective observational study enrolled 100 pregnant women presenting for antenatal check-ups between May 31, 2020, and September 31, 2021. Participants underwent 75g OGTT and fetomaternal outcomes were recorded and analyzed.*

Results: *GDM prevalence was identified in 11% of participants. Compared to women without GDM, those diagnosed with GDM were older (29.5±3.9 years vs 25.3±4.2 years, P=0.002), had a higher body mass index (BMI: 28±5.14 kg/m^2 vs 22.81±2.97 kg/m^2, P=0.007), and were more likely to belong to the lower middle socioeconomic class (27.27% vs. 72.73%, P=0.0009). Additionally, a family history of diabetes (45.45% vs. 6.74%, P=0.0001) and a previous history of macrosomia (2 cases vs. 1 case, P=0.031) were more common among women with GDM. Multivariate regression analysis did not reveal any independent significant risk factor of GDM (P >.05). Women with GDM experienced higher rates of infection (27.27% vs. 5.62%, P=0.041), polyhydramnios (36.36% vs. 4.49%, P=0.005), and neonatal hypoglycemia (30% vs. 0%, P=0.0008).*

Conclusions: *The 75g OGTT is a suitable screening test for GDM in low-income regions such as India. Factors associated with GDM include advanced maternal age, higher BMI, lower socioeconomic status, a family history of diabetes and history of macrosomia. Timely screening, diagnosis and treatment are imperative to mitigate associated fetomaternal complications related to GDM.*

Keywords: *fetomaternal outcome, gestational diabetes mellitus, 75g OGTT screening test*

Introduction

Gestational diabetes mellitus (GDM) is defined as carbohydrate intolerance of variable severity with onset or first recognition during present pregnancy. The disorder usually presents after 20 weeks gestation because of an inability to compensate for the physiological increase in insulin resistance that develops progressively throughout pregnancy as a consequence of multiple factors, including placental hormone secretion such as human placental lactogen, increased caloric intake, and reduced physical activity [1].

The prevalence of GDM depends on population characteristics such as obesity, age, ethnicity, and prevalence of type 2 diabetes mellitus [2]. It also depends upon the method of diagnosis used [3].

Diabetes in Pregnancy Study Group India (DIPSI) recommends a two-hour plasma glucose evaluation after the use of 75 g glucose load irrespective of the timing of last meal as a single-step procedure for the diagnosis of GDM. GDM is diagnosed if the venous plasma glucose value exceeds 140 mg/dl.

Indian women are at an 11-fold increased risk of development of glucose intolerance in pregnancy [4]. In developing countries such as ours, many women receive antenatal care (ANC) very late in the pregnancy; therefore, it is crucial to screen all these women for GDM with a simple test which is one time. Screening and diagnosis of GDM and effective treatment not only prevent adverse maternal and perinatal outcomes but also future diabetes in both mother and child.

Hence, this study was conducted to measure the incidence of GDM at a tertiary care center in Jharkhand, with 75 g oral glucose tolerance test (OGTT) as a single-step screening test, and to evaluate the outcome of mother and fetus.

Materials & Methods

This prospective observational study was conducted at a tertiary care center in Jharkhand from May 31, 2020, to September 30, 2021, after clearance was received from the Institutional Ethics Committee. We followed 100 women coming to outpatient department (OPD) for ANC visits in the Department of Obstetrics and Gynaecology and included all antenatal women irrespective of presence or absence of risk factors for GDM. We excluded women with any medical condition or drug therapy that would alter blood glucose level and those with pregestational diabetes mellitus.

Sample size was calculated based on a study conducted by R. Tripathi et al. [5]. They found that 73 women (7.8%) had GDM based on DIPSI criteria. With this value as reference, the minimum required sample size with 5.5% margin of error and 5% level of significance was 92 patients. To reduce the margin of error, the total sample size taken was 100.

We used formula: - $N \geq (p(1-p))/(ME/z\alpha)^2$

Where Zα is value of Z at two sided alpha error of 5%, ME is margin of error and p is prevalence rate.

- n>= ((.078*(1-.078))/(.055/1.96)2=91.33=92 (approx.).

After giving informed consent, women presenting to the antenatal OPD were recruited and underwent a detailed history and thorough clinical examination. All participants were asked to undergo non-fasting 75 g OGTT testing. Diagnosis of GDM was made if 2 h post-glucose blood sugar was >=140 mg/dl. Patients were followed up until delivery to determine the fetomaternal outcomes in terms of incidence of GDM, maternal outcomes, fetal outcomes, risk factors of GDM and association of demographic characteristics with fetomaternal outcomes.

Microsoft Excel was used for data entry, and Statistical Package for Social Sciences (SPSS) software v. 21.0 (IBM, Chicago, USA) was used for the final analysis.

Categorical variables are presented by number and percentage (%). Quantitative variables were presented as the means ± SD and as median with 25th and 75th percentiles (interquartile range). The correlation of the quantitative variables was analyzed using independent t-test. Association of the qualitative variables was analyzed using a chi-squared test. If any cell had an expected value of less than 5, then Fisher's exact test was used. Multivariate logistic regression was used to find out risk factors of GDM. For statistical significance, P-value of less than 0.05 was considered statistically significant.

Results

In the present study, in the majority (89.00%) of study subjects, the result of 75g OGTT was negative. The Result of 75g OGTT was positive in only 11 out of 100 study subjects (11.00%) (Figure *1*).

Distribution of study subjects with GDM was comparable with parity (primi (7.89%, n=3) vs. multi (12.90%, n=8)) (P-value=0.526) (TABLE *1*). The proportion of study subjects with GDM was significantly higher in the upper middle percentile (50%, n=1) as compared to lower middle (27.27%, n=6), upper lower (2.99%, n=2), and lower (22.22%, n=2) (P-value=0.0009). Significant association was seen in age (years) and body mass index (kg/m^2) with GDM (P-value <.05). Mean ± SD of age and body mass index in study subjects with GDM was 29.55 ± 3.96, 28 ± 5.14, respectively, which was significantly higher than in study subjects without GDM (25.39 ± 4.2(P-value=0.002), 22.81 ± 2.97(P-value=0.007)), respectively.

Proportion of study subjects with GDM was significantly higher in patients with a history of diabetes in first degree relative (45.45%, n=5) than in patients without a history of diabetes in first degree relative (6.74%, n=6). (P-value=0.0001) (Figure*2*). Distribution of study subjects with GDM was comparable with a history of still birth or neonatal birth (No (10.11%, n=9) vs. Yes (18.18%, n=2)) (P-value=0.347). Distribution of study subjects with GDM was comparable with a history of recurrent abortion (No (9.78%, n=9) vs. Yes (25%, n=2)) (P-value=0.213). Distribution of study subjects with GDM was comparable with a history of congenital anomaly (No (11.11%, n=11) vs. Yes (0%, n=0)) (P-value=1).Proportion of study subjects with GDM was significantly higher in patients with a history of macrosomia (66.67%, n=2) than in patients without history of macrosomia (9.28%, n=9). (P-value=0.031). Distribution of study subjects with GDM was comparable with a history of polyhydramnios. (No (10.20%, n=10) vs. Yes (50%, n=1)) (P-value=0.209). None of the study subjects had history of glucose intolerance.

The proportion of study subjects with GDM had significantly higher incidence of infection and polyhydramnios than study subjects without gestational diabetes mellitus. (Infection: -27.27%, n=3 vs. 5.62%, n=5 respectively (P-value=0.041), Polyhydramnios: - 36.36%, n=4 vs. 4.49%, n=4 respectively (P-value=0.005)) (Figure 3).

Distribution of maternal outcome was comparable between study subjects without and with GDM. (Miscarriage: - 0% vs. 0% respectively, IUD: - 4.49%, n=4 vs. 9.09%, n=1 respectively (P-value=0.449), Pre-eclampsia:- 8.99%, n=8 vs. 18.18%, n=2 respectively (P-value=0.302)).

Distribution of birth weight (kg) was comparable between study subjects without and with GDM. (<1.5 kg: 2.20%, n=2 vs. 9.09%, n=1 respectively, 1.5 to <2.5 kg: 29.67%, n=27 vs. 18.18%, n=2 respectively, 2.5 to 3.5 kg: 61.54%, n=56 vs. 45.45%, n=5 respectively, >3.5 kg: 6.59%, n=6 vs. 27.27%, n=3 respectively) (P-value=0.072). Mean ± SD of birth weight (kg) in study subjects without GDM was 2.62 ± 0.66 and in study subjects with GDM was 3 ± 0.96 with no significant association between them (P-value=0.092)[TABLE *II*]. Hypoglycemia was significantly higher in study subjects with GDM (30%, n=3) than in study subjects without GDM (0%) (P-value=0.0008). Distribution of other fetal complications was comparable between study subjects without and with GDM. Distribution of reason of admission in NICU was comparable between study subjects without and with GDM.

Maternal and fetal complications were less in our study because blood sugar was controlled in patients with GDM with medications.

Table I: -Association of socio demographic characteristics with GDM

Socio demographic characteristics	**Study subjects without GDM (n=89)**	**Study subjects with GDM (n=11)**	**Total**	***P* value**
Religion				
Christian	9 (100%)	0 (0%)	9 (100%)	0.504†
Hindu	71 (88.75%)	9 (11.25%)	80 (100%)	
Muslim	9 (81.82%)	2 (18.18%)	11 (100%)	
Parity				
Primi	35 (92.11%)	3 (7.89%)	38 (100%)	0.526†
Multi	54 (87.10%)	8 (12.90%)	62 (100%)	
Socioeconomic status				
Upper middle	1 (50%)	1 (50%)	2 (100%)	0.0009†
Lower middle	16 (72.73%)	6 (27.27%)	22 (100%)	
Upper lower	65 (97.01%)	2 (2.99%)	67 (100%)	
Lower	7 (77.78%)	2 (22.22%)	9 (100%)	
Age(years)				
Mean ± SD	25.39 ± 4.2	29.55 ± 3.96	25.85 ± 4.35	0.002*
Median (25th-75th percentile)	25(22-28)	30(26.5-32)	26(22-29)	
Range	19-37	24-36	19-37	
Body mass index(kg/m²)				
Mean ± SD	22.81 ± 2.97	28 ± 5.14	23.38 ± 3.63	0.007*
Median (25th-75th percentile)	22(21-23)	26(24-32.5)	22(21-24)	
Range	19-38	22-37	19-38	

Table II: -Association of fetal outcome with GDM .

Fetal outcome	Study subjects without GDM	Study subjects with GDM	Total	P value
Birth weight(kg)				
<1.5	2 (2.20%)	1 (9.09%)	3 (2.94%)	0.072†
1.5 to <2.5	27 (29.67%)	2 (18.18%)	29 (28.43%)	
2.5 to 3.5	56 (61.54%)	5 (45.45%)	61 (59.80%)	
>3.5	6 (6.59%)	3 (27.27%)	9 (8.82%)	
Mean ± SD	2.62 ± 0.66	3 ± 0.96	2.66 ± 0.7	0.092*
Median (25th-75th percentile)	2.5 (2.225-3)	3.3 (2.375-3.55)	2.6 (2.213-3)	
Range	1-4.4	1.25-4.4	1-4.4	
Fetal complications				
Congenital anomaly	2 (2.20%)	0 (0%)	2 (1.96%)	1†
Birth injury	1 (1.15%)	0 (0%)	1 (1.03%)	1†
Growth restriction	4 (4.60%)	0 (0%)	4 (4.12%)	1†
Hypoglycemia	0 (0%)	3 (30%)	3 (3.09%)	0.0008†
Admission in NICU	24 (27.59%)	4 (40%)	28 (28.87%)	0.468†
Reason of admission in NICU(n=28)				
Birth asphyxia	4 (16.67%)	0 (0%)	4 (14.29%)	0.35†
Birth injury	0 (0%)	1 (25%)	1 (3.57%)	
Congenital anomaly	1 (4.17%)	0 (0%)	1 (3.57%)	
Hyperbilirubinemia	5 (20.83%)	2 (50%)	7 (25%)	
IUGR	3 (12.50%)	0 (0%)	3 (10.71%)	
Low birth weight	2 (8.33%)	0 (0%)	2 (7.14%)	
Preterm	9 (37.50%)	1 (25%)	10 (35.71%)	

* **Independent t test,** † **Fisher's exact test**

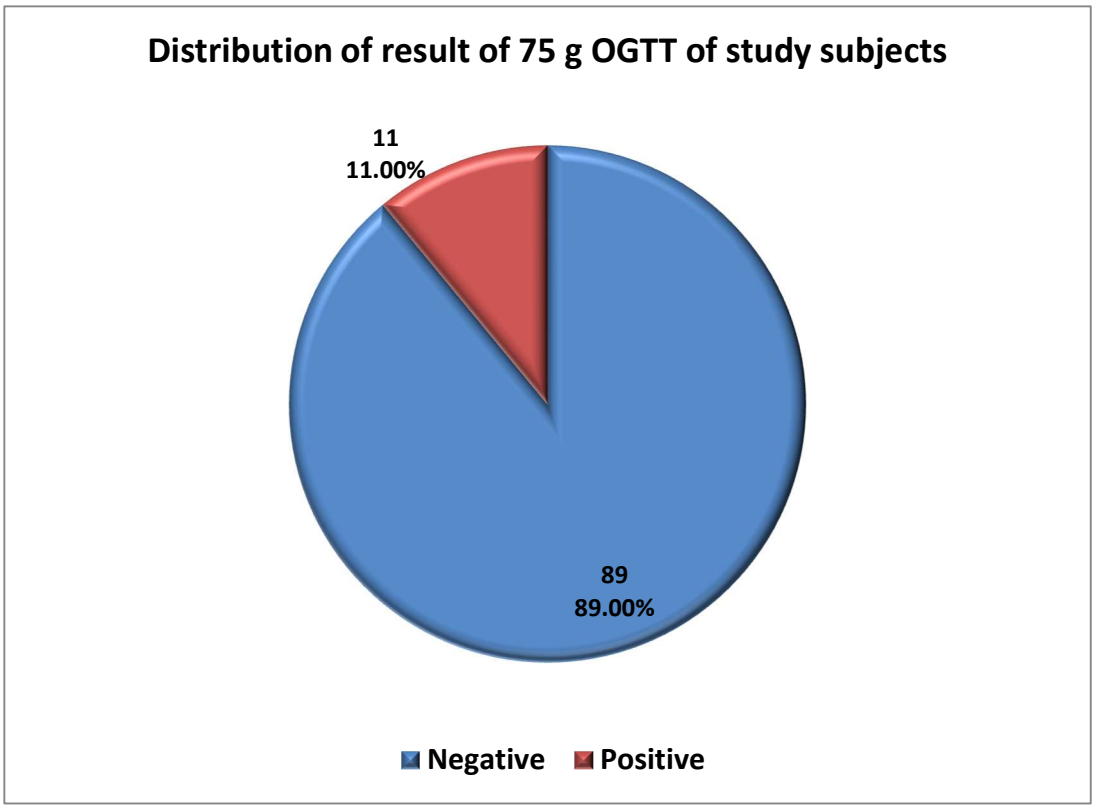

Figure 1: - Distribution of result of 75 g OGTT of study subjects

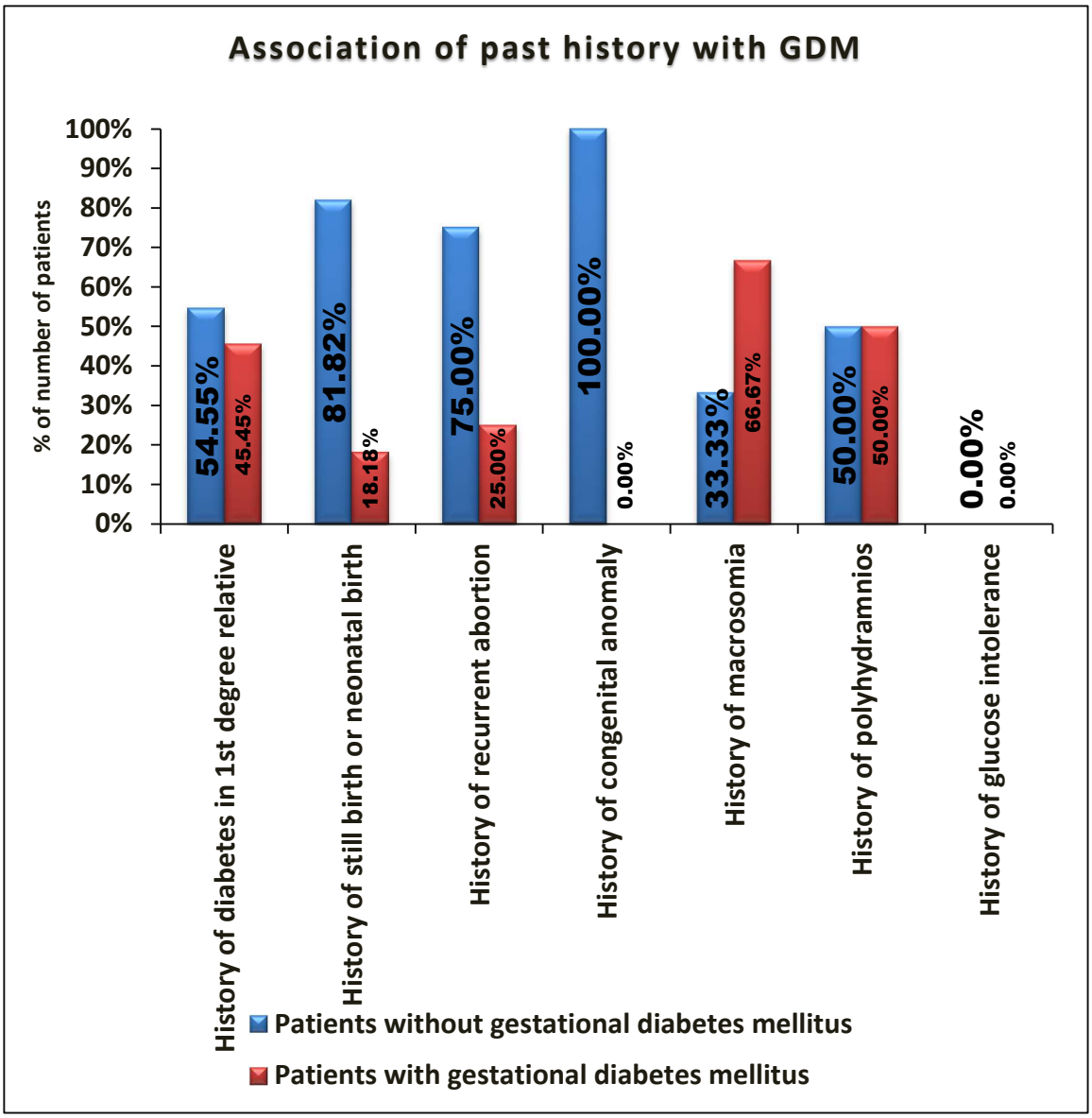

Figure 2: -Association of past history with GDM

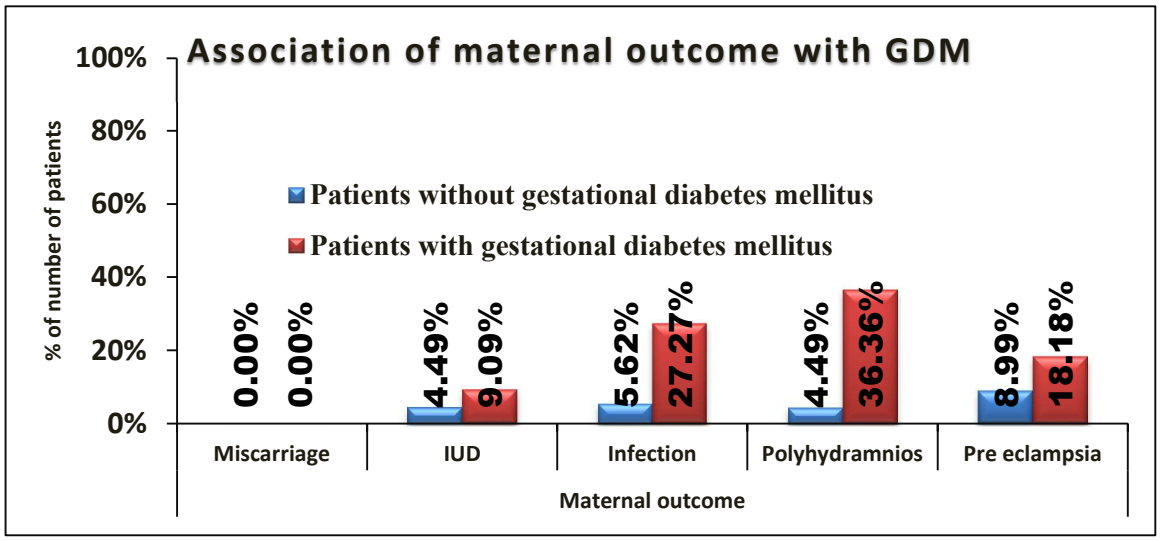

Figure 3: -Association of maternal outcome with GDM

Discussion

The present hospital-based prospective study was conducted on 100 pregnant women with the aim of determining GDM prevalence based on the DIPSI criteria. In the present study, GDM was seen in 11 cases (11%) as per the DIPSI criteria. In the study by Desai et al. [6], (n=200) GDM as reported by DIPSI was 17.5%. In another study by Tripathi et al. [7] (n=936) 73 women (7.8%) were identified as GDM on DIPSI criteria. Prevalence of GDM can vary as per population type.

The median age of the mothers in our study was 26 years. In a recent study by Muche et al. [8], the mean age of the women was 27.69 years. In our study, when compared with the women without GDM, women with GDM were significantly older (29.55 ± 3.96 vs. 25.39 ± 4.2, p=0.002). Song et al. [9] also found that women with GDM were significantly older than those without GDM (29.6 vs. 28.3, P < 0.001). Similarly, Muche et al. [8] reported that women with GDM were significantly older (30.93 vs. 27.01, P< 0.001). Advanced maternal age is reported to be an independent risk factor for GDM [10].

When compared with the women without GDM, women with GDM had significantly higher BMI (28 ± 5.14 vs. 22.81 ± 2.97 kg/m2, P=0.007). Song et al. [9] also found that women with GDM had significantly higher BMI than those without GDM (21.5 vs. 20.5, P< 0.001). Even Fareed P et al. [11] found that women with GDM had significantly more cases with BMI 26-30 kg/m2 (61 vs. 20) and >30 kg/m2 (17 vs. 1) (P= 0.0000001). Higher maternal BMI is associated with a higher frequency of complications. Moreover, “clustering of metabolic abnormalities in obese women at early pregnancy may be another pathophysiology for the link between obesity and GDM” [12].

When compared with the women without GDM, women with GDM were significantly more likely to be lower

middle class (27.27% vs. 72.73%) and significantly less likely to be upper-lower class (2.99% vs. 97.01%) (P=0.0009). In previous similar studies, Swaminathan et al. [13] reported that majority of the women with gestational diabetes were upper class (35%). Al-Shaikh G et al. [14] reported that when GDM pregnant women were compared with without GDM women in terms of three variables (monthly income, ownership of house and car), there was a significant difference between two groups (p<0.001). Women who have higher income can afford more food in pregnancy, resulting in obesity [10]. Knowler et al. [15], however, found significant association of GDM with lower socioeconomic status.

Patients with GDM had significantly more history of diabetes in the family (45.45% vs. 6.74%, P=0.0001) and more macrosomia history (2 vs. 1, P=0.031), whereas history of still birth or neonatal birth, recurrent abortion, congenital anomaly, polyhydramnios, and glucose intolerance were comparable (P>0.05). Muche et al. [8] also found that women with GDM had significantly more cases with family history of diabetes (21.5% vs. 4.2%, P< 0.001) and comparable previous history of adverse pregnancy outcome (45.6% vs. 35.8%, P=0.109). The significant association of GDM with family history of type 2 diabetes mellitus can be explained by the high genetic susceptibility for T2DM among Asian populations such as Indians.

In a meta-analysis by Lee et al. [16], the risk factors of GDM were “history of previous GDM (OR: 8.42, 95% CI: 5.35-13.23); macrosomia (OR 4.41, 95% CI: 3.09-6.31), and congenital anomalies (OR: 4.25, 95% CI: 1.52-11.88). Other risk factors were BMI ≥25 kg/m2 (OR: 3.27, 95% CI 2.81-3.80); pregnancy-induced hypertension (OR: 3.20, 95% CI: 2.19-4.68); family history of diabetes (OR 2.77, 95% CI: 2.22-3.47); history of stillbirth (OR: 2.39, 95% CI: 1.68-3.40); polycystic ovary syndrome (OR: 2.33, 95% CI: 1.72-3.17); history of abortion (OR: 2.25, 95% CI: 1.54-3.29); age ≥ 25 (OR: 2.17, 95% CI: 1.96-2.41); multiparity ≥2 (OR: 1. 37, 95% CI: 1.24-1.52); and history of preterm delivery (OR: 1.93, 95% CI: 1.21-3.07)”. In a similar study by Li G et al. [17], the risk factors for GDM were “advanced age (≥30 years, OR: 1.24; 95% CI: 1.05-1.46, P=0.0116), gestational BMI gain from pre-pregnancy to 15-20 weeks of gestation (25-30 kg/m2: OR: 1.04; 95% CI: 1.01-1.07, P= 0.0040), history of GDM (OR: 7.74; 95% CI: 6.42-9.32; P<0.0001) and thyroid diseases (OR: 1.47; 95% CI: 1.11-1.96; P=0.0073)”.

In the present study, when compared with the women without GDM, women with GDM had significantly more infection (27.27% vs. 5.62%, P = 0.041), significantly more polyhydramnios (36.36% vs. 4.49%, P=0.005), and comparable pre-eclampsia and IUD. Fareed P et al. [11] found that compared with women without GDM, those with GDM had more polyhydramnios (47 vs. 3), preterm labor (23 vs. 5), pre-eclampsia (44 vs. 6), APH (6 vs. 1), IUGR (3 vs. 1), PPH (1 vs. 0), and wound infection (1 vs. 1); however, the difference was not significant (P=0.3451).The women with GDM more possibly develop preeclampsia because of the nature of coexisting mutual risk factors, including advanced maternal age, obesity and hypertension.

When compared with the women without GDM, women with GDM had higher but comparable mean birth weight (3 ± 0.96 vs. 2.62 ± 0.66, P=0.092) in our study. Fareed et al. [11] found that women with GDM had significantly more cases with weight >4 kg (17 vs. 2, P= 0.0007).When compared with the women without GDM, women with GDM had significantly more hypoglycemia (30% vs. 0%, P=0.0008), and their neonates had comparable congenital anomaly (0% vs. 2.20%, P=1), birth injury (0% vs. 1.15%, P=1), and growth restriction (0% vs. 4.60%, P=1). Fareed et al. [11] found that more neonatal complications were present in neonates of diabetic women. Prematurity and neonatal hypoglycemia was present in 31% and 27% in babies in

the GDM group. 11% had birth asphyxia and 6% had jaundice. Fetal macrosomia was present among 17% of the neonates of GDM group and among 2% of the non-GDM group. Congenital deformity was present in 2% of the babies of the GDM group and 1% in those of the non-GDM group (P= 0.2597).

The women with GDM required more ICU admission than those without GDM (40% vs. 27.59%, P=0.468); however, the difference was not significant statistically. When compared with the women without GDM, women with GDM had comparable reasons for admission in NICU, such as preterm (25% vs. 37.50%), hyperbilirubinemia (50% vs. 20.83%), birth asphyxia (0% vs. 16.67%), IUGR (0% vs. 12.50%), low birth weight (0% vs. 8.33%), and birth injury and congenital anomaly (P=0.35). Fareed et al. [11] found that the neonatal admission requirement was higher in the GDM group with 53% babies compared with 11% in non-GDM women. Overall, the presence of GDM carried an adverse fetomaternal outcome.

Limitations of the study are that as the present study was a hospital-based study; it may not reflect the prevalence of GDM at the community level. Our study was conducted in a setting which caters primarily to patients in the lower or middle socioeconomic strata, and the data primarily reflects the situation in this cohort.

Conclusions

The 75g OGTT is a suitable screening test for GDM in low-income regions such as India. The factors related to GDM were advanced age, higher BMI, lower middle socioeconomic class, history of diabetes in the family, and macrosomia history. Women with GDM had more adverse fetomaternal outcomes, such as more cases of infection, polyhydramnios, and hypoglycemia; however, the occurrence of pre-eclampsia, IUD, higher birth weight, congenital anomaly, birth injury, growth restriction, and admission in NICU were comparable. Overall, multivariate regression showed that none of the variables was an independent significant risk factor of gestational diabetes mellitus. Timely screening, diagnosis, and treatment are imperative to mitigate associated fetomaternal complications related to GDM.

Given the advantages of DIPSI it seems appropriate and practical for using as a screening alternative in developing countries as ours. However, further investigations are required for universal implementation of this test as GDM screening in India.

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