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PREVALENCE OF GESTATIONAL DIABETES MELLITUS IN AN URBAN INDIAN COHORT USING DIABETES IN PREGNANCY STUDY GROUP IN INDIA (DIPSI) CRITERIA – VALIDATING ONE-STEP APPROACH

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Background. India is the “World’s Diabetes capital”, with half the diabetic population being women. Early detection of glucose intolerance during pregnancy offers a timely opportunity for screening, management and prevention of gestational diabetes mellitus (GDM) and prevents fetal complications.

Objective. The study assessed the prevalence of GDM in an Indian cohort using the Diabetes in Pregnancy Study group of India (DIPSI) criteria.

Methods. 200 pregnant women underwent two-phase testing with non-fasting 75-gram glucose challenge under Diabetes in Pregnancy Study group of India (DIPSI) criteria at <20 weeks and between 24-28 weeks period of gestation. A 3-hour 100-gm oral glucose tolerance test (OGTT) was used for confirmation. Repeat testing was done for women negative during the first-phase.

Results. Mean age was 24.26±3.75 years with 52.5% multigravidas. Mean Body Mass Index (BMI) was 20.7±3.07 kg/m². The prevalence of GDM in study cohort was found to be 15.5% using the DIPSI criteria while the prevalence of GDM after 100 g OGTT was 13.0%. GDM was mostly seen to occur in women of 26-30-year age group. Statistically significant associations for age and GDM, and BMI and GDM were evidenced.

Conclusions. Maternal age of ≥25 years should be adopted as a risk factor for the development of GDM. The DIPSI criteria offer a cost-effective and an evidence-based protocol for a single-step definitive glucose test for both screening and diagnosis of pregnant patients belonging to any socio-economic strata; furthering its implementation for public health obstetrics.

KEY WORDS: gestational diabetes mellitus; DIPSI criteria; screening; pregnancy; glucose tolerance test.

Introduction

Gestational Diabetes Mellitus (GDM) is established to be carbohydrate intolerance with onset or first diagnosis during pregnancy [1]. The WHO defines GDM as plasma glucose concentration of >140 mg/dl 2-hours by 75-gm oral glucose tolerance test (OGTT) similar to that of impaired glucose tolerance (IGT) test in a non-pregnant state [2]. With advancement of pregnancy, insulin resistance and diabetogenic stress caused by placental hormones necessitates compensatory increase in insulin secretion, the inadequacy of which leads to the development of GDM. The patients with GDM are at a risk group of future diabetes mellitus (DM) development, predominantly type-2 DM, as well as their children are [3]. In addition, untreated GDM may possibly lead to increased

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risk of large for gestational age fetus, plunge in blood sugar and jaundice in the offspring.

The prevalence of DM is increasing worldwide. Developing countries sustain a major proportion of world population translating to the epidemic proportions of DM being encountered by the healthcare fraternity in limited resource public health infrastructure. India is projected as the “World’s Diabetes capital”, with half the diabetic population being women. India is expected to contain the highest population of diabetics by 2025. The syndemic (synergistic epidemic) of DM and obesity compounding the problem of GDM exists under socio-epidemiological and anthropological perspectives of health disparity factored by poverty, living conditions, socio-economic status and dietary habits.

GDM is the most common metabolic disease of pregnancy worldwide. The prevalence of GDM reaches up to 14% of all pregnancies, resulting in approximately 200,000 cases annually in the United States. Asian and Indian

lifestyles are starkly different from Western lifestyles translating into 11.3 times higher relative-risk of GDM in Indian women compared to their western counterparts [4].

With the population experiencing a changing lifestyle and epidemiology of DM, it is pertinent to offer screening of GDM during the antenatal work-up. GDM holds out a significant opportunity for testing, development and implementation of clinical strategies for diabetes prevention in people [5]. Timely screening of the pregnant women for glucose intolerance, succeeding euglycemia and adequate nutrition may prevent presumably the pathological cycle of vertical transmission of glucose intolerance. This necessitates the universal mandatory screening for GDM during pregnancy, which is a resource intensive concept in the developing country perspective. Presently most institutions catering to women with adequate affordability are following the 2-phase procedure for screening GDM. The criteria by Diabetes in Pregnancy Study Group of India (DIPSI) recommend a simplified one-step approach for the screening and diagnosis of GDM irrespective of fasting state of expectant mothers, which is a promising protocol for underprivileged communities having limited healthcare accessibility during pregnancy.

Timely revealing of glucose intolerance in pregnancy offers an opportunity for screening, management and prevention of GDM on time and prevents fetal complications thus improves neonatal outcomes [6, 7]. This necessitates the general mandatory screening for GDM during pregnancy, which is a resource intensive testing modality. This study was carried out to assess the incidence of GDM in an Indian cohort using the DIPSI criteria [8].

Methods

The triple-blind study was conducted amongst 200 patients admitted to the antenatal outpatient department (OPD) of a tertiary-care hospital, containing 1600 beds, and medical teaching institute in Western India; the study was approved by the Ethics Committee of these medical facilities as well as the written informed consents were attained from the patients. All pregnant females at 20 weeks or less period of gestation (POG) were involved in the study that lasted for two years: from May 2012 to Apr 2014. The patients with GDM/Impaired Glucose Tolerance (IGT) in previous pregnancy, established morbidity of DM, DM in a first-degree relative or with a history of unexplained still-

birth, large for gestational age offspring, congenital anomalies or previous birth injuries, were excluded. Relevant history, general examination for calculating body-mass index and evidence of insulin resistance along with obstetric/gynecological examination were carried out. Triple-blinding of a patient, gynecologist and laboratory medicine specialist was ensured to eliminate bias and confounding.

The entire cohort of 200 patients was subjected to a two-phase testing at the POG of <20 weeks and for a second time at the POG of 24-28 weeks, a temporal separation was at least four weeks. In the first phase, all patients were given 75-gm anhydrous oral glucose at their first visit, irrespective of their fasting state, according to the DIPSI criteria. The levels of plasma venous blood glucose were evaluated by glucose oxidase-peroxidase method in 2 hours. The indices of ≥ 140 mg/dl were positive by the DIPSI criteria. A 3-hour 100-gm oral glucose tolerance test (OGTT) was used for confirmation. Any indices of ≥ 95 mg/dl fasting, ≥ 180 mg/dl in 1 hour, ≥ 155 mg/dl in 2 hours, ≥ 140 mg/dl in 3 hours were considered to be positive. Only one positive value in OGTT was considered as IGT while two positive values were considered for GDM.

In the second phase, women who were negative initially by DIPSI criteria were made to undergo a repeat test with non-fasting 75-gm at 24-28 weeks as per the DIPSI criteria. A 100-gm OGTT was used for confirmation.

Data was analyzed using SPSS (version 21; IBM Corporation) with χ^2 test or Fisher's exact test for categorical variables and Student's t-test for continuous variables. All statistical tests were two-tailed and P values <0.05 were considered significant. Clinicodemographic and diagnostic profiles were correlated for descriptive statistics and included frequency, percentages and 95% confidence intervals (95% CI).

Results

The study cohort comprised of young patients with mean age was 24.26 ± 3.75 years ranging from 20 to 28 years. Most patients were between 21 to 25 years of age (102/200, 51%, 95% CI 43.87% - 58.09%), followed by 49/200, 24.5%, 95% CI 18.83% - 31.17%, between 26 to 30 years (24.5%) (Table 1).

95/200, 47.5%, 95% CI 40.45% - 54.65% were primigravida while 105/200, 52.5%, 95% CI 45.35% - 59.55% were multigravida. Mean Body Mass Index (BMI) was 20.7 ± 3.07 kg/m², range

between 14.33 to 30.81 kg/m². Most of the pregnant females (108/200, 54%, 95% CI 46.83% – 61.01%) were having BMI between 21-25 followed by 92/200 (46%, 95% CI 38.99% – 53.17%), who had BMI ≤20 kg/m². There were no overweight or obese women in the cohort (Table 2). The study was carried out with a 100% follow up with no drop outs.

Out of the 200 pregnant females in the cohort, in the first phase, 31/200 (15.5%, 95% CI 10.93% – 21.44%) were tested positive by the DIPSI criteria prior to 20 weeks POG; 21/200 (10.5%, 95% CI 6.77% – 15.81%) of them were tested positive by 100-gm OGTT. In the second phase, the remaining 10 women tested positive by the DIPSI criteria and negative by 100-gm OGTT were again subjected to 100-gm OGTT at a 24-28-week POG, resulting in five more being found positive by 100-gm OGTT.

Out of the 169 women tested negative by the DIPSI criteria at less than 20 weeks POG, in the first phase, one aborted at 14 weeks POG and was excluded from the study. The remaining 168 women were again subjected to DIPSI and then validated by 100-gm OGTT at a 24-28-week POG. None tested positive with either DIPSI or 100-gm OGTT.

The prevalence of GDM in study cohort was found to be 15.5% using DIPSI criteria while the prevalence of GDM after 100-gm OGTT was 13% (Table 1). GDM was mostly seen to occur in women of 26-30-year age group (12/26, 46.15%, 95% CI 27.14% – 66.25%) followed by 9/26 (34.62%, 95% CI 17.95% – 55.64%) in the 21-25-year age group. Statistically significant association for age and GDM (p=0.003) was seen by Fisher’s exact test. Almost all (25/26, 96.15%, 95% CI 78.41% – 99.8%) GDM was seen with BMI >20 kg/m², with statistically significant (p=0.003) difference seen by Fisher’s exact test. However, the association of gravidity was not significant (p=0.207) using Chi square test.

Discussion

Disorders of maternal glucose metabolism during pregnancy are two-pronged. Firstly, pre-existing type-2 DM accounts for 8% of DM in pregnancy. There is an increasing trend of type-2 DM in women of childbearing age group, attributable to sedentary lifestyles, dietary changes and the virtual epidemic of adolescent and childhood obesity.

GDM accounts for 90% of diabetes in pregnancy. GDM represents the “tip of an iceberg” for the overall prevalence of DM in the population, thus being representative screening target for timely intervention. The prevalence of GDM varies from 1-20% depending upon population sample and diagnostic criteria.

Risk factors of GDM include a high BMI (a measure of body fat), gaining weight or low physical activity in pregnancy, excessive dietary eating of polyunsaturated fats, glucose intolerance (a sign of diabetes) or delivery of a large baby in previous pregnancies, as well as a family history of diabetes. Excessive intake of saturated fat, low eating of polyunsaturated fat, and high gestational weight gaining may possibly increase the risk of GDM. A decreased risk of GDM is also associated with physical activity. Obesity is one of the most significant risk factors for GDM, its prevalence has been increasing much over the last decades [9, 10, 11].

The study revealed GDM among young pregnant females up to 30 years of age in contrast to the development of DM in later age. The risk of GDM increases significantly from 25 years onwards [12]. The most predictive factor of GDM is maternal age ≥25 years, according to the recommendations of the American Diabetes Association (ADA) on the age criteria of ≥25 years as a cut-off for screening for GDM. In population with lower diabetes prevalence, timing of screening depends on the risk profile. Women at high risk are offered screening at

Table 1. Age profile of pregnant patients (n=200)

Age (years)	Number of patients	Percentage (%)	95% confidence intervals
≤20	35	17.5	12.64-23.64%
21-25	102	51.0	43.87-58.09%
26-30	49	24.5	18.83-31.17%
>30	14	7.0	4.03-11.71%

Table 2. Body-mass index (BMI) profile of pregnant patients (n=200)

BMI (kg/m ²)	Number of patients	Percentage (%)	95% confidence intervals
≤20	92	46	38.99-53.17%
21-25	108	54	46.83-61.01%
>26	0	0	-

first antenatal visit, moderate risk at 24-28 weeks as per ADA guidelines. In general, screening and diagnostic tests are performed between 24 and 28 weeks, because at this point in gestation the diabetogenic effect of pregnancy is manifested. The study of Kaiser Permanente of Colorado (KPCO) proved a strong cohort influence on the prevalence of GDM. Regardless of the age and ethnicity, the women, who were born more recently, were at an increased risk for GDM diagnosis compare to those born earlier. This finding most likely reveals an increased exposure to risk factors taking place before childbearing age [13]. In clinical practice, maternal age of ≥ 25 years should be adopted instead of ≥ 35 years or ≥ 40 years as a risk factor for the development of GDM [14, 15].

The present study also proved that the increased prevalence of GDM was evidenced together with increasing BMI. Although the incidence of GDM in the pregnant females with normal weight (BMI 18.5-24.9) is 2.3%, it increased more than five-fold to reach 11.5% in extremely obese pregnant women with BMI 35-64.9 [16, 17, 18]. A systematic review of observational studies published over last 30 years, which elected maternal BMI as the only measure of obesity and where all diagnostic criteria for GDM were accepted; it revealed that for every 1 kg/m² increase in BMI, the prevalence of GDM increased by 0.92% (95% CI 0.73% to 1.10%) [19]. Indian women with GDM experience a higher risk of metabolic syndrome and diabetes [20].

The 15.5% prevalence of GDM by DIPSI criteria found in this study compares well to other Indian studies showing prevalence between 16.55% and 22%. In India the prevalence of GDM has been estimated at 16.55% by the WHO criteria of a 2-hour blood glucose level of 140 mg/dl. However, the prevalence for Kashmiri women was 3.8% [21, 22, 23, 24, 25]. GDM was proved to be more widespread in urban areas than in rural. For this population and ethnicity, the incidence of GDM corresponds to the incidence of IGT in non-pregnant adults within that population [26]. In Indian context the prevalence of GDM is steadily increasing from 2% in 1982 to 12% in 1991 to 16.55% in 2002. Variations in prevalence of GDM due to geography and ethnicity have similarly been reported in Mexico [27].

Certain ethnically diverse subpopulations have a much higher rate of GDM which renders them the susceptibility of a greater predispo-

sition to DM in later age. The incidence of GDM differs in direct share to the incidence of type-2 DM for tis ethnic group or population. In Asian population, GDM reflects the prevalence of IGT in the population. Therefore, the general screening for GDM is necessary for Asian and Indian population [28]. In comparison to the selective screening, the general one for GDM distinguishes more patients and improves neonatal and maternal prognosis. Currently, and after extensive deliberation, universal screening of all pregnant women is recommended by some professional associations. Nevertheless, there exist challenges in quality control of laboratory testing in developing countries catering to mass-screening in resource limited laboratories, which needs to be taken into account for clinical decision making [29, 30].

In pregnancy, the choice to carry out a placebo-controlled trial involves clinical equipoise [31]. Hence, there was no control group of unmanaged pregnant women in this study, as there are some publications confirming that management of GDM women, as defined by the WHO criteria, was associated with a decreased risk of pregnancy outcome. As the routine screening for glucose intolerance during pregnancy was not done initially, probably the undiagnosed glucose intolerance that was occurring in the past has resulted in the increased prevalence of diabetes in India.

DIPSI criteria are a major advance as they cater diagnosis and screening of all pregnant women regardless of the fasting state by a single-step approach with a 75-gm of a 2-hour glucose test and a cut-off of >140 mg/dl for diagnostics. The study revealed 31 patients through DIPSI criteria at ≤ 20 weeks POG, 21 of which were detected by 100-gm OGTT at ≤ 20 weeks POG and five were detected between 24-28 weeks POG. If the 75-gm criterion was reapplied at 32-34 weeks POG as recommended by DIPSI, it is likely that even the five women, who tested negative, when validated with 100-gm OGTT, could have tested positive for GDM. DIPSI is very economical, practical, convenient and feasible for patients and obstetric health-care practitioners [32, 33].

Conclusions

The incidence of Gestational diabetes mellitus in the study cohort using DIPSI criteria was significantly high (15.5%) and is comparable with other Indian studies. In clinical practice, the maternal age of ≥ 25 years instead of 35

years or ≥ 40 years should be adopted as a risk factor for GDM development. The DIPSI criteria offer a cost-effective and an evidence-based protocol for a single-stage complete glucose

test for both screening and diagnosis of pregnant patients of any socio-economic strata; furthering its implementation for public health obstetrics.

ПОШИРЕНІСТЬ ГЕСТАЦІЙНОГО ЦУКРОВОГО ДІАБЕТУ СЕРЕД КОГОРТИ МІСЬКОГО ІНДІЙСЬКОГО НАСЕЛЕННЯ ЗА КРИТЕРІЯМИ DIPSI – АПРОБУВАННЯ ОДНОЕТАПНОГО ПІДХОДУ

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Вступ. Індія є «столицею діабету у світі», при чому половину населення, хворого на діабет, складають жінки. Раннє виявлення порушення толерантності до глюкози під час вагітності дає можливість своєчасно проводити скринінг, лікування та профілактику гестаційного цукрового діабету (ГЦД) та запобігати розвиткові ускладнень вагітності.

Мета дослідження – встановити частоту розвитку ГЦД серед жінок з використанням критеріїв DIPSI.

Методи дослідження. Обстежено 200 вагітних жінок, яким проводили двофазне тестування навантаженням глюкозою (75 г глюкози натще серце) відповідно до критеріїв DIPSI на термінах <20 тижнів та між 24-28 тижнями вагітності. Тригодинний пероральний глюкозотолерантний тест (ПГТТ) (з навантаження 100г глюкози) використовували для повторного дослідження, яке проводили в тому числі і жінкам з негативними результатами, отриманими під час першої фази обстеження.

Результати. Середній вік обстежуваних вагітних жінок склав (24,26 \pm 3,75) років, з них з 52,5 % – мали кілька вагітностей. Середній індекс маси тіла (ІМТ) становив (20,7 \pm 3,07) кг/м². Встановлено, що поширеність ГЦД у досліджуваній когорті становила 15,5 % відповідно до критеріїв DIPSI, тоді як поширеність ГЦД після 100 г ПГТТ становила 13 %. ГЦД в основному спостерігався у жінок вікової групи 26-30 років. Встановлено статистично достовірні кореляції між показниками віку та ГЦД, індексу маси тіла та ГЦД.

Висновки. Вік майбутньої матері більше 25 років повинен розглядатися як фактор ризику розвитку ГЦД. Критерії DIPSI – це економічно ефективний і обґрунтований протокол для використання глюкозотолерантного тесту для скринінгу та діагностики вагітних пацієнток, що належать до будь-яких соціально-економічних верств, який може бути рекомендований для подальшої імплементації у клінічну практику.

КЛЮЧОВІ СЛОВА: гестаційний цукровий діабет; критерії DIPSI; скринінг; вагітність; глюкозотолерантний тест.

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