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COMPARISON OF DIPSI GUIDELINES VS CONVENTIONAL OGTT FOR DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS

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ABSTRACT

INTRODUCTION: Gestational Diabetes Mellitus (GDM) is defined as carbohydrate intolerance with recognition or onset during pregnancy is associated with a higher rate of maternal and fetal compromise. OGTT is the current gold standard for screening for GDM. It is a two-step test which requires the pregnant woman to be in a fasting state for a long duration. DIPSI is a one-step procedure for diagnosing GDM does not require patients in a fasting state and is a simple, economical and feasible alternate in Indian scenario.

AIM: To compare DIPSI criteria based test with conventional OGTT for diagnosis of GDM.

Material & Methods: A hospital based screening study was conducted at Department of Obstetrics & Gyanecology, K J Somaiya Medical College & hospital, Mumbai for duration of 2 years (May 2015 to June 2016). A total of 200 consecutive pregnant women in the second and third trimester of pregnancy registered at our antenatal clinic and satisfying the eligibility criteria were taken in the study after informed consent. Pregnant women with 2-h PG ≥ 7.8 mmol/L (DIPSI criterion) were diagnosed as GDM and rest were classified as normal glucose tolerant (NGT) women. One week later all of them were made to undergo the conventional 75 gm OGTT. Data was analyzed using statistical software SPSS ver. 21.

RESULTS: The sensitivity and specificity of DIPSI was 86.8% and 98.8% with PPV and NPV of 94.3% and 97.0% and overall diagnostic accuracy was 96.5%.

CONCLUSION: The results of present study shows that DIPSI is a simple, single, convenient, economical screening test for GDM and can be used as both diagnostic as well as screening test with good diagnostic efficacy.

KEYWORDS

Gestational Diabetes Mellitus, OGTT, DIPSI

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INTRODUCTION

The maternal metabolic adaptation is to maintain the mean fasting plasma glucose of 74.5 ± 11 mg/dl and the post prandial peak of 108.7 ± 16.9mg/dl. This fine tuning of glycemic level during pregnancy is possible due to the compensatory hyperinsulinaemia, as the normal pregnancy is characterized by insulin resistance. A pregnant woman who is not able to increase her insulin secretion to overcome the insulin resistance that occurs even during normal pregnancy develops gestational diabetes [1].

Gestational Diabetes Mellitus (GDM) is defined as 'carbohydrate intolerance with recognition or onset during pregnancy', irrespective of the treatment with diet or insulin. The importance of GDM is that two generations are at risk of developing diabetes in the future. Women with a history of GDM are at increased risk of future diabetes, predominately type 2 diabetes, as are their children [1].

Studies have shown that there is a much higher rate of maternal and fetal compromise in diabetic pregnancies as compared with normal pregnancies [2]. Diabetic mothers are exposed to an increased risk of hypertension in late pregnancy [3]. Other obstetric complications such as polyhydramnios, preterm labour and abortions are also commonly encountered in pregnant diabetics. Infants of diabetic mothers are exposed to variety of problems such as, sudden intrauterine death, respiratory distress syndrome, hypoglycemia, cardiomyopathy, neonatal jaundice, impaired calcium and magnesium homeostasis and many more.

A number of studies have documented that the treatment of gestational diabetes as defined by WHO criterion reduced serious perinatal morbidity and also improved the woman's health-related quality of life [4-6].

American Diabetes Association (ADA) recommends two step procedures for screening and diagnosis of diabetes and that too in selective (high risk) population. ADA recommends 3 hour 100 gm OGTT and Gestational Diabetes Mellitus is diagnosed if any 2 values meet or exceed FPG > 95 mg/dl, 1 hr PG > 180 mg/dl, 2 hr PG > 155 mg/dl and 3 hr PG > 140 mg/dl [7].

This procedure requires the pregnant woman to be in a fasting state. It is difficult for the pregnant woman to get up possibly with morning sickness, travel to a clinic and wait an additional two hours before eating. In developing countries such as India, particularly in rural areas, there are other challenges as well to screening for GDM. Some of these challenges include lack of trained phlebotomists, lack of standardized laboratories to do blood glucose estimations, and the problem of transportation.

DIPSI (Diabetes In Pregnancy Study Group India) recommends “A one step procedure with a single glycemic value”, to diagnose GDM in the community: It recommends 75g OGTT irrespective of fasting status and GDM is diagnosed if 2-hour plasma glucose is ≥ 140 mg/ dl. This test correctly identifies subjects with GDM, as well as woman with normal glucose tolerance [8].This one step procedure of diagnosing GDM is simple, economical and feasible in Indian scenario.

Hence this prospective study was undertaken to ascertain the validity of DIPSI criterion to diagnose GDM as compared to conventional OGTT and to know the effects of hyperglycemia towards maternal and fetal outcome.

MATERIALS AND METHODS

Study Design

A Hospital Based Screening Study

Study Duration

May 2015 to June 2016

Study Area
Department of Obstetrics & Gynecology in a tertiary care hospital in Mumbai.

Sampling Formulae:
n – Z2 Sensitivity (1-Sensitivity)/ L2 * P

n – Sample size
Z2 - alpha error (at 99% confidence Interval, value is 2.56)
L 2 – allowable error (taken as 5% of Sensitivity)
P - Prevalence of GDM taken as 20% [based on our pilot study]
Sensitivity of DIPSI – 40% [Herath et al.5]

n- (2.56)2 * (0.4 X 0.6)/ (0.02)2 *(0.2)
n – 196
A total of 200 consecutive pregnant women in the second and third trimester of pregnancy registered at antenatal clinic of K J Somaiya Medical College & hospital and satisfying the eligibility criteria were taken in the study after informed consent.

INCLUSION CRITERIA
1. Women with singleton pregnancy.
2. Women aged between > 18 years.
3. Women gestational ages ranging between 24 – 28 weeks.
4. Women previously undiagnosed with Diabetes, in present pregnancy or previous pregnancy

EXCLUSION CRITERIA:
1. Women diagnosed as diabetic in present or previous pregnancy.
2. Women with any comorbid condition such as PIH, Thyroid & Heart conditions.
3. Women with multiple gestation.

STUDY METHODOLOGY
A standardized questionnaire was used and details pertaining to their anthropometrics such as height, weight, BMI, family history, medical history, menstrual history, weeks of gestation (for patients not sure of their dates, the earliest ultrasonography scans were taken into consideration for gestational age), obstetric history, and other relevant information were collected. Their routine obstetric examination was done and after excluding those with multiple gestations or with fetal anomalies by ultrasonography, the subjects were selected according to inclusion and exclusion criteria.

After obtaining the informed consent, pregnant women were given 75 g oral glucose load irrespective of their last meal timing and venous plasma was drawn at 2 h. The plasma glucose was estimated in the central laboratory by the glucose oxidase peroxidase (GOD-POD) method. Pregnant women with 2-h PG ≥ 7.8 mmol/L (DIPSI criterion) [8] were diagnosed as GDM and rest were classified as normal glucose tolerant (NGT) women.

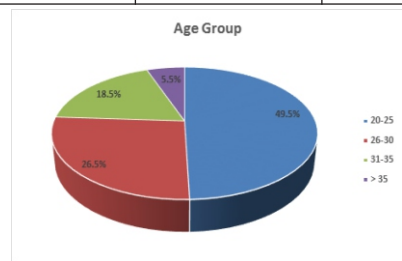
One week later all of them were made to undergo the conventional ADA recommended 75 gm OGTT. We administered a 75-g anhydrous glucose load after a 12 hours fast and obtained fasting, 1-h, and 2-h samples from an antecubital vein. We collected samples in tubes containing fluoride and kept them at 4°C until centrifugation up to 2 h later. Plasma measurements were performed with glucose oxidase peroxidase (GOD-POD) method. GDM was defined (ADA criteria) as at least two values greater than the following

Fasting glucose of > 95 mg%
1-h glucose of 180 mg%, or
2-h glucose of 155 mg%.

STATISTICALANALYSIS
All the collected data was entered in Microsoft Excel Sheet 2007.The data was then transferred and analyzed using SPSS ver. 17. Qualitative data was represented in the form of frequency and percentage while quantitative data was represented using Mean +/- S.D. Appropriate statistical evaluation was carried out as per the type and distribution of data. Screening parameters (sensitivity, specificity, etc.) of DIPSI criteria as compared to gold Standard (ADA criteria) was calculated using standard formulae. A p-value of < 0.05 was taken as level of significance.

RESULTS
Table 1. Distribution of subjects based on Age group

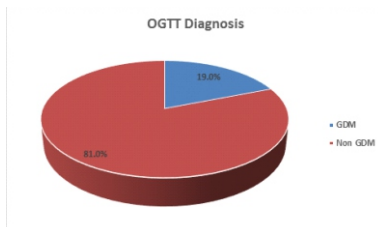
Age group (yrs)	N	%
20-25	99	49.5%
26-30	53	26.5%
31-35	37	18.5%
> 35	11	5.5%
Total	200	100.0%



Almost half of the females were between 20-25 years of age while 5.5% were over 35 years of age

Table 2. Distribution of subjects based on Diagnosis of GDM

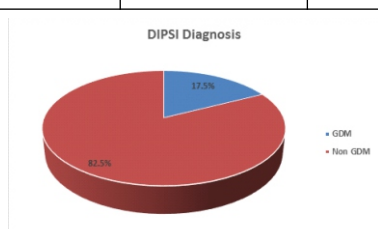
Diagnosis (OGTT)	N	%
GDM	38	19.0%
Non GDM	162	81.0%
Total	200	100.0%



The prevalence GDM as per OGTT was 19%.

Table 3. Distribution of subjects based on diagnosis of GDM as per DIPSI Criteria

Diagnosis (DIPSI)	N	%
GDM	35	17.5%
Non GDM	165	82.5%
Total	200	100.0%



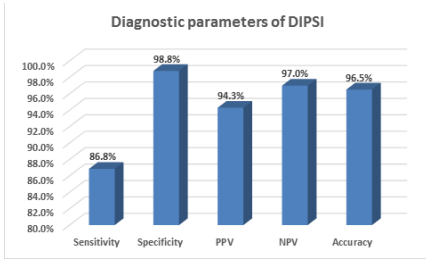
The prevalence GDM as per DIPSI was 17.5%.

Table 4. Comparison of DIPSI and OGTT Criteria for diagnosis of GDM

DIPSI	OGTT		Total
	GDM	Non - GDM	
GDM	33	2	35
Non - GDM	5	160	165
Total	38	162	200

Parameters	%
Sensitivity	86.8%
Specificity	98.8%

PPV	94.3%
NPV	97.0%
Accuracy	96.5%



The sensitivity and specificity of DIPSI was 86.8% and 98.8% with PPV and NPV of 94.3% and 97.0% and overall diagnostic accuracy was 96.5%.

DISCUSSION

Present hospital based screening study was conducted with the aim of comparing DIPSI criteria based test with conventional OGTT for diagnosis of gestational diabetes (GDM) and to compare maternal and perinatal outcome in diabetic and non-diabetic pregnancy.

Prevalence of GDM in community

TABLE 12. COMPARISION OF PREVALENCE ACC. TO VARIOUS STUDIES

Authors	Prevalence of GDM (%)
Seshiah et al. (2004) [10]	16.20%
Sridhar et al. [11]	12.70%
Balaji et al. [12]	13.40%
Present Study (by OGTT)	19%
Present Study (by DIPSI)	17.5%

In present study, the prevalence GDM as per OGTT was 19% while prevalence as per DIPSI was 17.5%.

Depending on the type of population and the diagnostic criteria used, gestational diabetes is said to complicate 1–16% of all pregnancies [9]. A random survey performed in India in 2008 in urban population in Chennai showed prevalence of GDM in our country 16.2% [10]. Shridhar et al. in a study from Vishakhapattanam observed the prevalence of GDM as 12.7% [11]. While when DIPSI recommendation as a diagnostic test was used, prevalence of GDM was 10.2%. In a study by Balaji et al. [12] using DIPSI criterion 13.4% of women were identified as GDM. The recent data on the prevalence of GDM in our country was 16.55% by WHO criteria of 2 hr PG ≥ 140 mg/dl.2

DIAGNOSTIC ACCURACY

In present study, sensitivity and specificity of DIPSI was 86.8% and 98.8% with PPV and NPV of 94.3% and 97.0% and overall diagnostic accuracy was 96.5%. The study showed almost all women diagnosed as GDM by 75 g glucose non fasting test also satisfied the diagnostic criteria of 75-g oral glucose test performed in the fasting state recommended by WHO.

In a recent study, Seshiah et al. [13] done on pregnant women with no previous history of GDM/ pre GDM showed no significant difference in diagnosing GDM by the two criteria -by DIPSI criterion, the prevalence was 13.4%, applying IADPSG recommendation the prevalence of GDM was 14.6% and concluded that there was little difference in the diagnostic accuracy of the two tests. Thus DIPSI method is a suitable test for screening and diagnosing GDM in Indian population.

Similar results were also observed by Sharma et al. where sensitivity and specificity of DIPSI was observed as 90.2% and 97.5% respectively [14]. Polur et al. [15] observed a sensitivity and specificity of DIPSI as 82.5% and 93% respectively. Balaji V et al. in their study concluded that DIPSI criterion is cost-effective and evidence-based procedure meets our responsibility of offering "a single-step definitive glucose test" to every pregnant woman belonging to any socio-economic status.

TABLE 13. COMPARISION OF STUDIES FOR SENSITIVITY AND SPECIFICITY

Authors	DIPSI	
	Sensitivity	Specificity
Sharma A et al. [14]	90.20%	97.50%
Polur et al. [15]	82.50%	93.00%
Present Study	86.80%	98.80%

SUMMARY

A hospital based screening study was conducted at Department of Obstetrics & Gynecology in a tertiary care hospital for duration of 2 years (May 2015 to June 2016). The aim of the study was to compare the DIPSI criteria based test with conventional OGTT in diagnosing gestational diabetes (GDM) and to compare maternal and perinatal outcome in diabetic and non-diabetic pregnancy. A total of 200 consecutive pregnant women in the second and third trimester of pregnancy registered at antenatal clinic of the hospital and satisfying the eligibility criteria were taken in the study after informed consent.

FOLLOWING OBSERVATIONS WERE MADE DURING THE STUDY:

1. Almost 50% of the females were between 20-25 years of age while 5.5% were over 35 years of age.
2. The prevalence GDM as per OGTT was 19% while prevalence as per DIPSI was 17.5%.
3. The sensitivity and specificity of DIPSI was 86.8% and 98.8% with PPV and NPV of 94.3% and 97.0% and overall diagnostic accuracy was 96.5%.

CONCLUSION

Gestational diabetes mellitus is highly prevalent in mothers attending our antenatal clinics. The results of present study shows that DIPSI is a simple, single, convenient, economical screening test for GDM and can be used as both screening as well as diagnostic test with good diagnostic efficacy. So, it can replace OGTT as gold standard and can be used in routine practice to diagnose GDM.

Also, as gestational diabetes mellitus is associated with myriad of adverse maternal and fetal outcomes like hypertensive disorders in pregnancy, vaginal candidiasis, post-datism, polyhydramnios, high birth weight, shoulder dystocia and hypoglycemia in neonates and still birth. Thus routine screening for Gestational Diabetes and its associated complications is paramount to reduce GDM related morbidity and mortality among mothers and the neonates

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