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Role of DIPSI guidelines as a universal screening as well as diagnostic tool for gestational diabetes mellitus in rural tertiary health care centre

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Abstract
Aims & Objectives: This study aimed to evaluate validity of DIPSI guidelines as a universal screening as well as a diagnostic tool for Gestational Diabetes Mellitus. This study also estimated the incidence of Gestational Diabetes Mellitus and evaluated neonatal outcome in patients of Gestational Diabetes Mellitus.
Material and Methods: A total of 175 antenatal patients after excluding pre gestational diabetes were screened for GDM with 75 gm oral glucose irrespective of their last meal timing and venous plasma was drawn at 2 hours (DIPSI). Pregnant women with 2-hour plasma glucose ≥ 140 mg/dl underwent 100 gm Glucose Tolerance test as per Carpenter and Coustan criteria to diagnose Gestational Diabetes Mellitus and rest were classified as normal glucose tolerant (NGT) women.
Results: The incidence of GDM was 5.71 % using the DIPSI method and 3.43% using Carpenter and Coustan criteria. Age ≥25years, BMI ≥25 kg/m², family history of diabetes were the risk factors for GDM. GDM was more frequently associated with Pregnancy induced Hypertension, Polyhydramnios, NICU admission.
Conclusion: DIPSI recommended 75 gm oral glucose challenge test irrespective of the last meal is a very simple, cost effective and feasible procedure for universal screening and diagnosis of GDM.

Keywords: Gestational diabetes mellitus (GDM), diabetes in pregnancy study group India (DIPSI), screening, carpenter and coustan criteria

Introduction
Pregnancy is a diabetogenic state associated with increased insulin resistance. Gestational diabetes mellitus (GDM) is carbohydrate intolerance of variable severity with onset or first diagnosed during pregnancy [1]. According to Dornhorst A *et al*, Indian women have an eleven fold increased risk of developing glucose intolerance during pregnancy compared to Caucasian women [2]. There has been a lot of controversy regarding many aspects of GDM. Important being type of screening whether universal or selective, which screening tests and which diagnostic test to follow, about ideal cut off values, about the line of management and many more. In such circumstances, Diabetes in Pregnancy Study group of India (DIPSI) recommends universal screening for gestational diabetes in India [3]. This study is an attempt to evaluate how valid and effective DIPSI guidelines are in screening and diagnosing Gestational diabetes mellitus. This study will help us to diagnose Gestational diabetes mellitus at the earliest with a simple, feasible and economical test so that prompt measures can be taken to prevent further complications to both mother and the baby.

Materials & Methods
A prospective observational study was conducted in the Department of Obstetrics And Gynaecology in a tertiary care teaching hospital in rural Maharashtra, India. The study was initiated with the approval from the Institutional Ethics Committee. A total of 175 consecutive registered antenatal patients were screened for GDM after excluding pre gestational diabetes. Pregnant women were given a pre structurized questionnaire after obtaining an informed consent. Later, irrespective of their last meal, pregnant women were given 75 gm oral glucose load and venous plasma was drawn at 2 hours. The plasma glucose was estimated by the glucose oxidase peroxidase (GOD-POD) method. Pregnant women with 2-hour plasma glucose ≥ 140 mg/dl (DIPSI criterion) underwent 100 gm Glucose Tolerance test as per Carpenter and Coustan

Criteria to confirm Gestational Diabetes Mellitus and rest were classified as normal glucose tolerant (NGT). All women with GDM were followed up throughout pregnancy as per standard antenatal protocol. Appropriate treatment/ interventions for GDM were administered as per requirement. Their labour outcome and neonatal parameters were recorded. The parameters taken into account included age, family history of diabetes, gravidity, maternal BMI, blood pressure, blood sugar levels after DIPSI, BSL after Carpenter and Coustan criteria where relevant, mode of delivery, neonatal birth weight, APGAR score at 1 minute, requirement of NICU admission. The statistical analysis of the quantitative data was done using SPSS software version 17. Qualitative data was expressed in terms of percentages and was analysed using Chi-square test and Fischer exact test.

Results

It was a prospective observational study including 175 pregnant women of which 3 were twin pregnancies. The mean maternal age was 24.22 ± 3.9 years and the mean BMI was 23.7 ± 3.6 kg/m². Among 175 subjects, 5.71% had family history for diabetes mellitus and 64.57% subjects belonged to a gestational age group of 24 to 32 weeks. Mean birth weight of neonate was 2.65 ± 0.45 kg.

Out of 175 pregnant women, 10 women (5.71%) had OGCT positive as per DIPSI criteria. 6 out of these 10 DIPSI positive pregnant women had positive OGTT with 100 gm glucose (Carpenter and Coustan criteria) and were termed as Gestational Diabetes Mellitus, accounting for 3.43%. Thus the sensitivity, specificity, positive predictive value and negative predictive value of DIPSI OGCT is 100%, 97.63%, 60% and 100% respectively.

Among the DIPSI positive subjects, statistically significant association exists with factors like BMI ≥ 25kg/m^2 (p <0.0001), Family history of diabetes (p = 0.013), Polyhydramnios (p = 0.017), PIH (p = 0.002) and NICU admission (p <0.0001) as per protocol (of department of neonatology) for babies of GDM mothers. Majority were delivered by LSCS (60%) followed by normal delivery (40%) which was not statistically significant (p = 0.797). Mean birth weight of neonates of DIPSI positive subjects was 2.84 ± 0.79 kg. Incidence of macrosomic neonates was higher in DIPSI positive study group (20%) compared to DIPSI negative study group (3.57%) but was not statistically significant (p = 0.066).

Table 1: Association between various factors and DIPSI Positive subjects.

Factor	DIPSI Positive (n=10) (%)	DIPSI Negative (n=165) (%)	FET: p Value
Age ≥ 25 years	4 (40)	60 (36.36)	0.19
BMI ≥ 25 kg/m^2	8 (80)	36 (21.82)	<0.0001
Family history	3 (30)	7 (4.24)	0.013
Polyhydramnios	2 (20)	2 (1.21)	0.017
Twins pregnancy	0	3 (1.82)	1
PIH	3 (30)	3 (1.82)	0.002
NICU admission	8 (80)	36 (21.82)	<0.0001

FET: Fisher's exact test

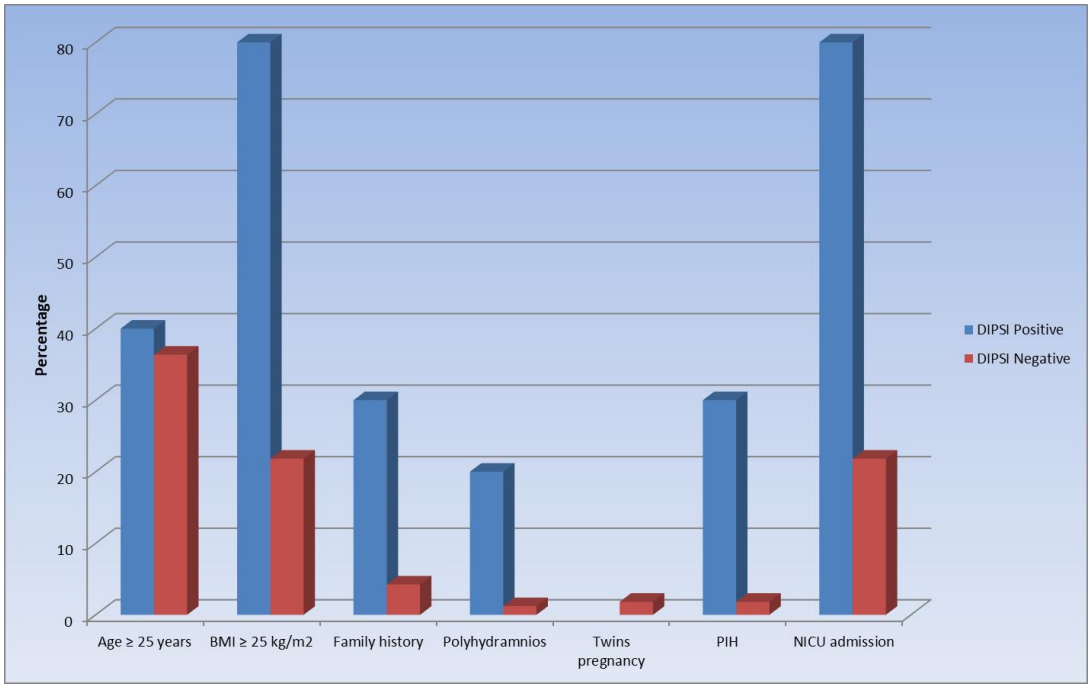

Fig 1: Association between various factors and DIPSI Positive subjects.

Among the pregnant women diagnosed with GDM, statistically significant association exists with factors like age≥ 25 years (p=0.025), BMI ≥ 25 kg/m^2 (p = 0.0001), Family history of diabetes (p = 0.002), Polyhydramnios (p = 0.006), PIH (p = 0.0001) and NICU admission (p = 0.0001) as per protocol (of department of neonatology) for babies of GDM mothers. 66.67% subjects in Gestational diabetes mellitus study group underwent LSCS which was not statistically significant (p = 0.77). Mean birth weight of neonates in GDM study group was 2.83 ± 0.48 kg. No neonate in GDM study group was macrosomic.

Table 2: Association between various factors and GDM subjects.

Factor	GDM (n=6) (%)	Non GDM (n=169) (%)	FET: p Value
Age ≥ 25 years	5 (83.33)	59 (34.91)	0.025
BMI ≥ 25 kg/m^2	6 (100)	38 (22.49)	0.0001
Family history	3 (50)	7 (4.14)	0.002
Polyhydramnios	2 (33.33)	2 (1.18)	0.006
Twins pregnancy	0	3 (1.78)	1
PIH	3 (50)	3 (1.78)	0.0001
NICU admission	6 (100)	38 (22.49)	0.0001

FET: Fisher's exact test

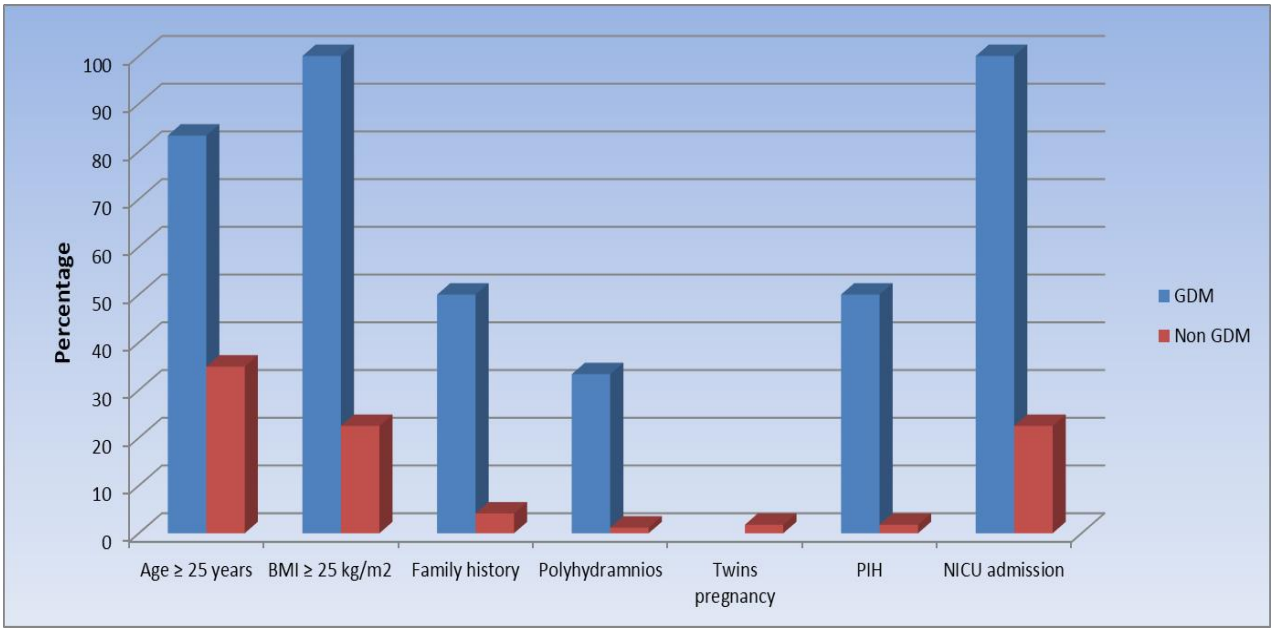

Fig 2: Association between various factors and GDM subjects.

Glycemic control with medical nutrition therapy was possible in one subject with GDM (16.67%) and four subjects with DIPSI positive OGTT negative (100%). 66.67% subjects in GDM study group required insulin with MNT for good glycemic control. Metformin was used in one GDM patient (16.67%).

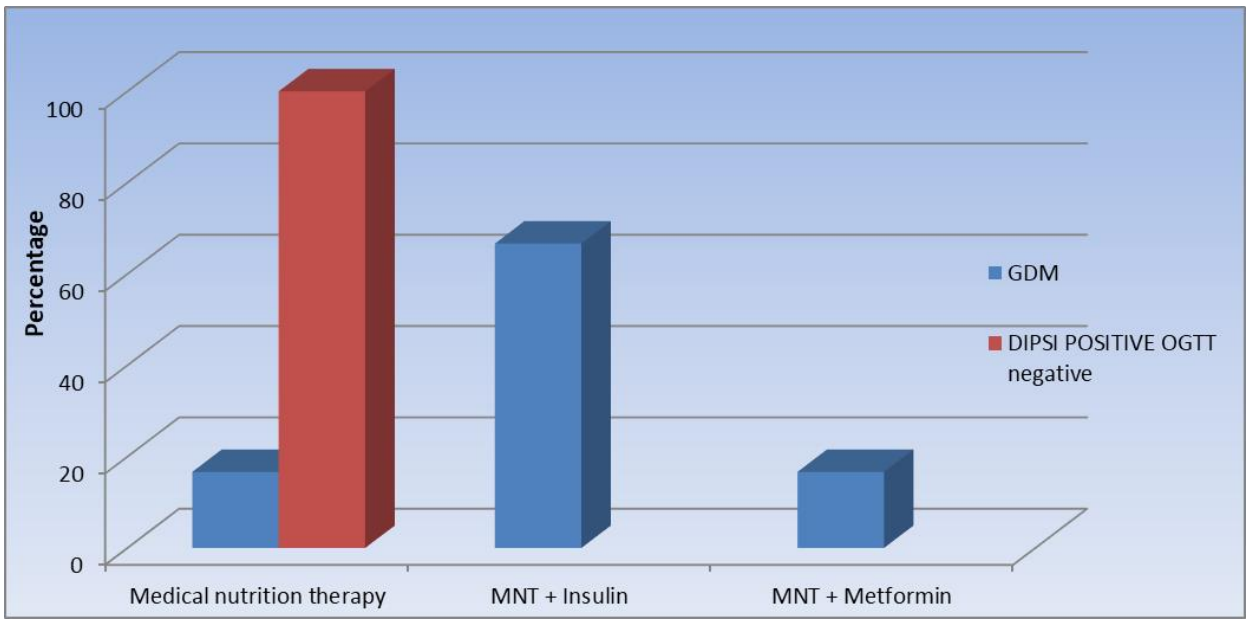

Fig 3: Management

Discussion

As per World Health Organization (WHO) impaired glucose tolerance outside pregnancy is plasma glucose >140mg/dl at 2 hours with 75gms OGTT [4]. Diabetes in pregnancy study group India (DIPSI) procedure of diagnosis is a modified version of the WHO criteria. The only difference is DIPSI procedure is performed irrespective of the last meal timing, whereas WHO procedure requires the women to be fasting [5].

Depending on the geographical locations and diagnostic methods used, the prevalence of GDM in India varied from 3.8 to 21%. GDM is more prevalent in urban areas compared to rural areas [6]. Our study population belonged to rural area. The incidence of GDM in our study population was found to be 5.71 % by using 75 gm OGCT (DIPSI) and 3.43 % by using standard 100 gm OGTT (Carpenter and Coustan). This high pick up rate by 75 gm OGCT test may help us in providing extra care to the patients at risk, though it may lead to increased cost and intervention to the patient, especially people living in rural areas of our country.

According to Jovanovic L *et al*, advanced maternal age, family history of diabetes and obesity are established risk factors for GDM [7]. In our study, the prevalence proportion increased with age from 0.9% to 7.81% with a cut off age ≥ 25 years. Similarly studies by Seshiah *et al* and Kalra *et al* proved age ≥ 25 years as a risk factor for GDM [8-9]. So as the age advances the incidence of GDM increases. In clinical practice, maternal age of 25 years should be considered as a risk factor for the development of GDM. Several authors have suggested that prepregnancy overweight or obesity predisposes to GDM. Das *et al* [10] found that 25% of women with GDM had BMI > 27 kg/m2, while Seshiah *et al* [8] and Kalra *et al* [9] found that 21.4% and 67% of women with GDM, respectively, had BMI ≥ 25 kg/m2. In our study, all women with Gestational diabetes mellitus had BMI ≥ 25 kg/m2 (100%) which confirms that increased BMI is a risk factor for GDM. Of all the independent risk factors for GDM, BMI has emerged as a modifiable risk factor. GDM also increases the risk of women developing diabetes in the future. Hence they are the ideal group to be targeted for lifestyle modification or pharmacologic intervention in order to delay the onset of overt Type 2 diabetes mellitus in later life. Family history of diabetes mellitus was found in 50% of our GDM women. In studies by Bhattacharya *et al* [11], Das *et al* [10] and Kalra *et al* [9], 33.33% of GDM women had family history of diabetes mellitus.

Our study showed that the most common complications seen in GDM mothers were pregnancy induced hypertension (PIH) (50%) followed by Polyhydramnios (33.33%). While Gajjar *et al*[12] and Jindal *et al* [13] found that 60% and 48% of GDM mothers, respectively, had PIH. In the study by Kalra *et al* [9] the most common complications seen in GDM mothers were gestational hypertension (36.4%), vaginal candidiasis (24.2%), premature rupture of membranes (PROM; 18.1%) and abruption placentae (12.12%).

Cesarean delivery rate in the study by Kalra *et al* [9] was 78.8% amongst the GDM patients, with arrest of labor being the most common indication. While the rate of cesarean section in a study by Gorgal *et al* [14] was 19.5%. The results of our study were consistent with those of previous studies with a cesarean section rate of 66.67% among GDM women. Naylor *et al* [15] reported cesarean section rates of 20% for glucose-tolerant women, 29.6% for untreated GDM women and 33.6% for treated GDM women. The high rate of cesarean section among women with GDM is possibly a consequence of the diagnosis and not the condition.

In our study, none of the newborn of GDM mothers was macrosomic as compared to 4.65% in the non-GDM group. This can be attributed to good glycemic control in antenatal period. Balaji *et al* [16] and Kalra *et al* [9] reported 9.9% and 18% incidence of macrosomia in GDM mothers respectively. At our centre, newborns of GDM mothers were observed in NICU as per protocols of department of neonatology.

The present study was an attempt to evaluate validity of DIPSI guidelines as a universal screening as well as a diagnostic tool for Gestational Diabetes Mellitus. The positive predictive value of the test was 60%. Using Carpenter and Coustan criteria we would have missed 40% subjects with GDM. Hence, for universal screening and diagnosis of GDM, DIPSI guidelines, a single step test with 75 gm of oral glucose, irrespective of last meal timing is recommended.

Conclusion

In resource limited countries like India, DIPSI recommended 75 gm oral glucose challenge test irrespective of the last meal is a very simple, cost effective and feasible procedure for universal screening and diagnosis of GDM. Advanced maternal age, family history of diabetes and obesity are important risk factors for GDM.

Pregnancy induced hypertension and polyhydramnios are commonly associated complications in women with GDM. Increased rate of cesarean delivery in women with GDM contributes to increased maternal morbidity. Adequate glycemic control in antenatal period might reduce the incidence of macrosomic infants.

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