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ABSTRACT

BACKGROUND
Gestational diabetes mellitus is defined as carbohydrate intolerance with onset/recognition during pregnancy. There is an increase in incidence worldwide with a range of 0.4 - 10 %. Gestational Diabetes is often asymptomatic and associated with increased foetal and neonatal morbidity and mortality. Over the years there have been many controversies regarding the best screening and diagnostic test for GDM. The testing for GDM by appropriate method at the earliest detects women who need treatment with either diet alone or a combination of diet with insulin therapy. This helps in the prevention of maternal morbidity and mortality. Hence, an appropriate screening test for GDM has been much emphasized. This study was done to compare the non-fasting diabetes in pregnancy study group of India (DIPSI) criteria with the fasting state of the WHO 2018 for the diagnosis of GDM in our hospital setting.

METHODS
With this background, we conducted a single centric, prospective, observational study in our tertiary care hospital, after obtaining permission from the Institutional Ethics Committee. In this study, we enrolled 200 patients attending obstetric OPD in Basaveswara teaching and general hospital and Sangameshwar hospital attached to Mahadevappa Rampure Medical College, Kalaburagi with gestational age 24 – 28 weeks as per the inclusion and exclusion criteria. All participants were then subjected to screening and diagnostic tests as per DIPSI and WHO 2018 criteria.

RESULTS
Prevalence of GDM was 12.5 % in WHO 2018 group when compared to 10.5 % in the DIPSI group. The specificity of the DIPSI method in detecting GDM was 98 %. The highest incidence of GDM was observed in the age group of 26-30 yrs. Incidence of the highest prevalence of GDM was observed with BMI > 25 kg/m2. We studied the correlation between GDM with DIPSI and WHO 2018. True positive 16, False Negatives 9, True Negatives 179, False Positive 05.

CONCLUSIONS
Screening with DIPSI has 98 % specificity compared. DIPSI being a one-step procedure offers both a screening and diagnostic test for GDM. It avoids the need for multiple hospital visits, and multiple blood samples.

KEY WORDS
GDM, WHO 2018, DIPSI, Screening.
Diabetes Mellitus is a clinical syndrome characterized by hyperglycaemia due to absolute or relative deficiency of insulin. Lack of insulin whether absolute or relative affects the metabolism of carbohydrates, proteins, and fats.[1]

Pregnancy is characterised by mild fasting hypoglycaemia, postprandial hyperglycaemia, hyperinsulinemia and insulin resistance - diabetogenic stress. Normally pregnant woman elaborates an increased insulin production by 30% above her non-pregnant state. A woman who is unable to achieve adequate insulinogenic compensation develops gestational diabetes. Pregnancy un_masks the minor intolerance of carbohydrate metabolism in subjects with reduced pancreatic islet cell reserve.

The most common endocrine disorder to complicate pregnancy is diabetes. Gestational diabetes mellitus is defined as carbohydrate intolerance with onset/recognition during pregnancy. There is an increase in incidence worldwide with a range of 0.4–10%,[3] Gestational Diabetes is often asymptomatic and associated with increased foetal and neonatal morbidity and mortality. Good glycemic control reduces the risk of complications.[3]

Since the discovery of insulin, more women can carry their pregnancies to term, though stillbirths and birth defects are high. The incidence of GDM is higher in India and ranges from 10 to 17.8%. A national survey conducted recently reported the prevalence of impaired glucose tolerance (IGT) in the age group between 20–29 years at 12.2% and between 30–39 years at 15.3% respectively.[3] The prevalence of GDM in urban, semi-urban and rural areas is 17.8%, 13.8% and 9.9% respectively in a community-based survey by Seshiah et al.[4]

GDM has adverse outcomes in pregnancy including polyhydramnios, preeclampsia, macrosomia and shoulder dystocia. Long term risk includes childhood obesity and type II DM in mother and offspring which warrants an effective screening and diagnostic test for GDM. Over years there have been many controversies regarding the best screening and diagnostic test for GDM. The testing for GDM by appropriate method at the earliest detects women who need treatment with either diet alone or a combination of diet with insulin therapy. This helps in the prevention of maternal morbidity and mortality.

All complications of GDM are potentially preventable with early recognition and intense monitoring. Ethnically Indian women are prone to develop glucose intolerance by eleven-fold when compared to whites necessitating universal screening during pregnancy. Hence, an appropriate screening test for GDM has been much emphasized.

The International Association of the Diabetes and Pregnancy Study Groups (IADPSG) criteria have more sensitivity, are universally accepted and even isolated fasting glucose levels have a higher incidence of poor maternal and foetal outcomes. In 2010, the hyperglycaemia and adverse pregnancy outcome (HAPO) study suggested that fasting blood sugar values could be used to diagnose GDM. Seventy-five gm of oral glucose load is given and after 1-hour and 2-hours venous blood glucose is to be taken. If fasting plasma glucose ≥ 92 mg/dl (5.1 mmol/l), 1-hour plasma glucose ≥ 180 mg/dl (10 mmol/l), 2-hour plasma glucose ≥ 153 mg/dl (8.5 mmol/l), GDM is diagnosed.[5]

Recent WHO recommendation 2018 has been integrated from WHO 2013 publication “Diagnostic criteria and classification of hyperglycaemia first detected in pregnancy”. It stated that GDM should be diagnosed if one or more of the following criteria are met: fasting plasma glucose 92-125 mg/dl, 1-hour plasma glucose 180 mg/dl and 2-hour plasma glucose 153-199 mg/dl following a 75 g oral glucose load.[6]
**Method of Data Collection**

With the approval of the ethical committee, a standardized questionnaire was used and details pertaining to the patient’s 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 the subjects were selected according to inclusion and exclusion criteria.

After obtaining the informed consent, patients were then subjected to the DIPSI screening method. According to DIPSI [7] screening: 75 grams of glucose in 200 ml water was given to patients irrespective of being in a fasting state or having consumed food, and 2 hours later a venous sample was drawn from the patient in a fluoride container and plasma glucose value was measured using GOD POD method, values > 140 gm/ml were considered as DIPSI POSITIVE and diagnosed as GDM and rest were classified as normal glucose tolerant (NGT) women.

To estimate the sensitivity and specificity of this test, one week later all the patients who underwent the DIPSI test irrespective of being tested positive or not were made to undergo the conventional WHO 2018 criteria recommended 75 gm OGTT for diagnosis of GDM. We administered a 75-g anhydrous glucose load after 12 hour fast and obtained fasting, 1 hour, and 2 hours samples from an antecubital vein. We collected venous samples in tubes containing fluoride and kept them at 4°C until centrifugation up to 2 hours later. Plasma measurements were performed with the glucose oxidase peroxidase (GOD-POD) method. According to WHO 2006 Criteria - Gestational diabetes mellitus should be diagnosed at any time in pregnancy if one or more of the following criteria are met:[8]

- Fasting plasma glucose 5.1-6.9 mmol/l (92-125 mg/dl) - 1-hour plasma glucose ≥ 10.0 mmol/l(180 mg/dl) following a 75g oral glucose load* - 2-hour plasma glucose 8.5-11.0 mmol/l (153 -199 mg/dl) following a 75g oral glucose load
  *there are no established criteria for the diagnosis of diabetes based on the 1-hour post- load value

Patients who were diagnosed with GDM were advised management by a combination of diet therapy, and insulin therapy according to their plasma glucose levels.

**Data Management**

All the data collected from patients were compiled in a Microsoft Office Excel spreadsheet and analysed. Results are displayed in tabular and graphical format. The appropriate test is applied wherever necessary.

**Statistical Analysis**

All the variables were evaluated. For qualitative data analysis, chi-square test was applied for significance. Epidemiological screening tests were calculated for confirmation. P-value < 0.05 was considered statistically significant.

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**RESULTS**

We enrolled 200 patients attending obstetric OPD, all the participants were subjected to both DIPSI and WHO 2018 screening. At the end of the study, we got the following results.

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>Number (%)</th>
<th>DIPSI</th>
<th>WHO 2018</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 - 25</td>
<td>84 (42%)</td>
<td>09</td>
<td>75</td>
<td>09</td>
</tr>
<tr>
<td>26 - 30</td>
<td>92 (46%)</td>
<td>07</td>
<td>85</td>
<td>12</td>
</tr>
<tr>
<td>31 - 35</td>
<td>17 (8.5%)</td>
<td>04</td>
<td>13</td>
<td>03</td>
</tr>
<tr>
<td>36 - 40</td>
<td>07 (3.5%)</td>
<td>01</td>
<td>06</td>
<td>01</td>
</tr>
<tr>
<td>Total</td>
<td>200 (100%)</td>
<td>21</td>
<td>84</td>
<td>25</td>
</tr>
</tbody>
</table>

**Table 1. Category Wise Age Distribution in the Study Population and Its Co-relation with DIPSI and WHO 2018 (N=200)**

**Socio-Economic Status**

According to Modified Kuppuswamy Socioeconomic Scale in the Study Population and Its Correlation with DIPSI and WHO 2018 (N=200)

<table>
<thead>
<tr>
<th>Socio-Economic Status</th>
<th>Number</th>
<th>Percentage (%)</th>
<th>DIPSI</th>
<th>WHO 2018</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower</td>
<td>48</td>
<td>24</td>
<td>2</td>
<td>46</td>
<td>3</td>
</tr>
<tr>
<td>Upper Lower</td>
<td>22</td>
<td>11</td>
<td>7</td>
<td>15</td>
<td>9</td>
</tr>
<tr>
<td>Lower Middle</td>
<td>122</td>
<td>61</td>
<td>11</td>
<td>111</td>
<td>8</td>
</tr>
<tr>
<td>Upper Middle</td>
<td>08</td>
<td>4</td>
<td>1</td>
<td>7</td>
<td>5</td>
</tr>
</tbody>
</table>

**Table 3. BMI Categories in the Study Population and Their Correlation with DIPSI and WHO 2018 (N=200)**

On studying the co-relation of BMI with DIPSI and OGTT, the majority of our patients who tested positive for GDM from both DIPSI and GDM belonged to the BMI category of >25. Hence we inferred that the prevalence of BMI increases with an increase in BMI and there is no statistically significant difference in the DIPSI and OGTT co-relation with BMI.

In our study population out of 200 participants, 21 patients were tested DIPSI positive amounting to 10.5 % of patients who tested positive for GDM by DIPSI method and 89.5 % of patients were tested negative for GDM.

**Diagnosis (DIPSI)**

<table>
<thead>
<tr>
<th>Diagnosis (DIPSI)</th>
<th>Number</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GDM</td>
<td>21</td>
<td>10.5</td>
</tr>
<tr>
<td>NON-GDM</td>
<td>179</td>
<td>89.5</td>
</tr>
<tr>
<td>Total</td>
<td>200</td>
<td>100</td>
</tr>
</tbody>
</table>

**Table 4. Distribution of Patients Based on Diagnosis of GDM as per DIPSI in the Study Population (N = 200)**

We also tested patients who were tested with DIPSI and were again tested with the standard WHO 2018 within 1 week. 25 patients out of 200 tested positive for GDM by WHO
OGTT and 175 tested negative for WHO 2018 amounting to 12.5 % of positive cases.

Hence DIPSI could identify 98.89 % of patients who did not have GDM
Positive Predictive Value of DIPSI = TP/TP+FP = 76.19 %
Negative Predictive Value of DIPSI = TN/TN+FN = 95.21 %

We studied the co-relation between GDM with DIPSI and WHO 2018. Out of the 21 patients who tested positive for DIPSI, 16 tested positive with WHO 2018 and 5 tested negative. Hence, true positive with DIPSI 16 (Positive GDM on both DIPSI and WHO 2018) and false positive with DIPSI 05 (GDM positive on DIPSI but negative on WHO 2018). Out of the 25 patients who tested positive with WHO 2018, 16 patients were detected true positives with DIPSI method, whereas 9 patients were missed on DIPSI method but tested positive on WHO 2018. Hence making the false negatives with DIPSI method to be 09 (GDM absent on DIPSI and WHO 2018) True Negatives 179 (GDM absent on both DIPSI and WHO 2018).

Using these values we calculated the following data:
We studied the co-relation between GDM with DIPSI and WHO 2018.
Sensitivity of DIPSI = TP/TP+FN = 74 %
Hence DIPSI could detect 74 % of patients who had GDM
Specificity of DIPSI= TN/TN+FP = 98.89 %

### Table 5. Distribution of Patients Based on Diagnosis of GDM as per WHO (2018) in the Study Population (N = 200)

<table>
<thead>
<tr>
<th>Diagnosis (WHO 2018)</th>
<th>Number</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GDM</td>
<td>25</td>
<td>12.50</td>
</tr>
<tr>
<td>Non-GDM</td>
<td>175</td>
<td>87.50</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>200</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

### Table 6. Comparison of Mean Blood Sugar Values by DIPSI Method with WHO 2018 Test at 1 Hour and 2 Hours in the Study Population (N=200)

<table>
<thead>
<tr>
<th>Method</th>
<th>Mean</th>
<th>SD</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO - 2018 (Fasting)</td>
<td>93.81</td>
<td>18.58</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>WHO - 2018 (1 hour)</td>
<td>99.01</td>
<td>31.73</td>
<td></td>
</tr>
<tr>
<td>WHO - 2018 (2 Hours)</td>
<td>141.01</td>
<td>33.91</td>
<td></td>
</tr>
</tbody>
</table>

### Table 7. Comparison of DIPSI WHO 2018 Criteria for Diagnosis of GDM in the Study Population (N = 200)

<table>
<thead>
<tr>
<th></th>
<th>GDM</th>
<th>WHO 2018</th>
<th>Non - GDM</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GDM</strong></td>
<td>16</td>
<td></td>
<td>5</td>
<td>21</td>
</tr>
<tr>
<td><strong>Non - GDM</strong></td>
<td>9</td>
<td></td>
<td>170</td>
<td>179</td>
</tr>
</tbody>
</table>

**DISCUSSION**

Gestational diabetes mellitus (GDM) is defined as "glucose intolerance first discovered in pregnancy". The definition applies to whether insulin or only diet modification is used for treatment and whether or not the condition persists after pregnancy. It does not exclude the possibility that unrecognized glucose intolerance may have antedated or begun concomitantly with the pregnancy. Approximately 7 % of all pregnancies are complicated by GDM, resulting in more than 200,000 cases annually. The prevalence may range from 1 to 14 % of all pregnancies, depending on the population studied and the diagnostic tests employed.

All complications of GDM are potentially preventable with early recognition and intense monitoring. Ethnically Indian women are prone to develop glucose intolerance by eleven-fold when compared to whites necessitating universal screening during pregnancy. Hence, an appropriate screening test for GDM has been much emphasized. The average age of the patients in our study was 26.61 ± 3.64 years with the range of 20 – 40 years. The majority of the participants, 85, were in the age group of 20 to 25 years. Similar results were obtained in a study conducted by Phulpagar et al.[9] the majority of patients were in the age group of 18 – 30 years with a mean age of 24.8 ± 3.48 years. Another study conducted by Wahi et al.[10] in which the average age was 27 ± 2.3 years and a study by Seshiah et al. had 22.5 ± 3.09.[11] In the present study, the prevalence of GDM as per WHO 2018 was 12.5 % while the prevalence as per DIPSI was 10.5 %. Using DIPSI criteria, the prevalence was marginally lower than WHO 2018 criteria in the present study. Depending on the type of population and the diagnostic criteria used, gestational diabetes is said to complicate 1–16 % of all pregnancies.

In our study, maximum patients belonged to the lower middle class (61 %) category according to the Modified Kuppuswamy scale followed by 24 % in the lower socioeconomic class. Socioeconomic status was inversely associated with the risk of GDM. The risk of GDM was higher in women with upper lower socioeconomic status. According to Timothy D. Dye et al.[12] women of higher socioeconomic status who were obese and did not exercise had a high risk of GDM compared to their counterparts of lower socioeconomic status. In this study, the incidence of GDM was high in women belonging to lower socioeconomic status (52.38 % with DIPSI and 36 % with...
WHO 2018) this could be because our study was conducted in a rural population and the majority of patients belonged to lower socioeconomic and middle-class status.

In our study, the majority of diabetic patients had BMI of > 25 kg/m² (73 %) and 23 % patients had BMI of > 30 kg/m². There is a strong association between high BMI and GDM which is similar to an earlier study by Seshiah et al.[11] and Shin Y Kim et al.[12] The proportion of GDM cases that belong to overweight, obesity and extreme obesity was 73 % and 20 % summing up to 93 %. Lifestyle intervention to reduce BMI can lower GDM risk. Established risk factors for GDM are advanced maternal age, obesity and family history of diabetes.

In the present study, the sensitivity and specificity of DIPSI were 74 % and 98.89 % with PPV and NPV of 76.19 % and 95.21 % and overall diagnostic accuracy was 93.30 %. The study showed almost all women diagnosed with GDM with a 75 g glucose non-fasting test also satisfied the diagnostic criteria of a 75-g oral glucose test performed in the fasting state recommended by WHO 2018.

In a recent study, Seshiah et al.[11] done on 1463 consecutive pregnant women with no previous history of GDM/ pre GDM showed no significant difference (P > 0.05) in diagnosing GDM by the two criteria -by DIPSI criterion, the prevalence was 196 (13.4 %), applying IADPSG recommendation the cumulative prevalence of GDM was 14.6 % (n=214) and concluded that the disagreement in diagnosing GDM by both criteria was not significant (P = 0.21). Thus, the DIPSI method is a suitable test for screening and diagnosing GDM in the Indian population.

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

CONCLUSIONS

The prevalence of diabetes is increased worldwide by 40 % over the past 10 years. All complications associated with GDM are potentially preventable by early identification, monitoring and proper treatment.

Screening and subsequent treatment started in the early weeks of pregnancy have the potential to detect cases early and can prevent or minimise adverse obstetric and perinatal outcomes.

Screening with DIPSI has 98 % specificity compared. DIPSI being a one-step procedure offers both a screening and diagnostic test for GDM. It avoids the need for multiple hospital visits and multiple blood samples.

This one-step procedure (DIPSI) of challenging pregnant women with 75-gram oral glucose appears to be a simple, feasible and easily reproducible screening method for GDM.

REFERENCES