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RESEARCH ARTICLE

TO EVALUATE THE UTILITY OF DIABETES IN PREGNANCY STUDY GROUP INDIA(DIPSI) CRITERIA FOR SCREENING OF GESTATIONAL DIABETES MELLITUS"

Shruti Arun Gavhane, Prof. S.N. Chaudhari, Dr. Kishor Hol and Dr. Shraddha Shastri

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Abstract

Background: The optimal strategy for screening and diagnosis of Gestational DiabetesMellitus (GDM) is still elusive. There is possibility of difference infetaland maternaloutcome depending on the diagnostic method used. This study highlights on the efficacy of two tests "100-gram oral glucose tolerance test with Carpenter Coustan Criteria'' and "Diabetes in Pregnancy Study Group India" and to find the prevalence of GDM using DIPSI criteria and to compare the screening outcomes between DIPSI and ACOG guidelines.

Methods: This study is a prospective cohort study done at tertiary care center 200 patientswhere enrolled in study between 12-16 weeks of gestation. exclusion criteria were History of GDM in previous pregnancy, known case of GDM and history of macrosomic baby. Women between 12-16 weeks of gestational age were subjected to screening for GDM by DIPSI criteria. Values more than 140 mg/dl were labelled as DIPSI positive. Positive cases were further subjected to 100gm of oral glucose tolerance test (OGTT) by Carpenter Coustan criteria at 12-16 weeks of gestation. All OGTT (Carpenter Coustan criteria) negative patients underwent repeat OGTT at 24-28 weeks of gestation. All DIPSI negative cases also underwent repeat DIPSI test at 24-28 weeks of gestation.OGTT (Carpenter-Coustan) positive cases were diagnosed as GDM and will be subjected to appropriate management.

Results: The prevalence of GDM by the DIPSI test was 16% and by the Carpenter and Coustan test was 12.5%. Maximum no. cases of GDM 20 i.e. 80 % where in age group of 21-25 . 76%-19 cases of GDM where having BMI of 18.5 to 24.99 kg/m2. 14 i.e 56% GDM cases where multigravida and 11(44%) were primigravida.The sensitivity ,specificity, positive predictive value and negative predictive value were 1005,96%78.12% and100% respectively.

Conclusion: DIPSI offers feasibility, convenience, simplicity and repeatability, while economizing universal screening and diagnosis of GDM .

Introduction:-

In India there are approximately 69 million people with diabetes, and according to WHO, developing countries are bound to bear the majority of the diabetes epidemic in the 21st century (rise estimated to 80 million diabetics by

Corresponding Author:- Shruti Arun Gavhane

year 2030) GDM represents around 90% of pregnancies complicated by diabetes [1], and it is known that women diagnosed with GDM have an increased risk of diabetes in future[1-2]. GDM represents primary prevention level to evaluate and possibly prevent Type 2 diabetes in two generations [3](FIGURE 1)

Gestational diabetes mellitus (GDM) is defined as carbohydrate intolerance of variable severity with onset or first recognition during pregnancy. Pregnancy is a diabetogenic state. The prevalence of GDM varies from 1 to 14%, in direct proportion to the prevalence of Type 2 diabetes in a given population .[4]

Indian population are catogerized in the high risk ethnic group for diabetes .The recent data on prevalence of GDM in India is 16.55% by WHO criteria of 2hr blood glucose level of 140mg/dl.[5]

Many tests for GDM have been performed, but a distinction is generally made between screening tests and diagnostic tests. In general, screening and diagnostic tests are performed between 24 and 28 weeks, as at this point of gestation the diabetogenic effect of pregnancy is manifested.

At present, the most utilized screening test is oral glucose challenge test with 50gm of glucose followed by Oral glucose tolerance test. Several screening procedure and diagnostic criteria (CDA, NDDG ,ADA, WHO, and Australasian criteria) are being trailed in different countries. American Diabetes Association (ADA) mentions screening for selective (high risk) population. But compared to selective screening, universal screening, universal screening for GDM identifies more cases and improves maternal and neonatal prognosis. Therefore universal screening for GDM is essential, as it is generally acknowledged that women of Asian origin and especially ethnic Indians, are at a higher risk of developing GDM and later type 2 diabetes.

Diagnostic test for GDM has always been the 100gm 3 hr oral glucose tolerance test (OGTT).Women who have even one higher value on the100-g, 3-hour OGTT have a significantly increased riskof adverse perinatal outcomes compared with womenwithout GDM [6]. Although a higher level of analysismay be focused on this subset of women, further researchis needed to clarify the risk of adverse outcomes inpatients with one abnormal value on the 100-g, 3-hourOGTT and whether they would benefit from treatment. At present most commonly used internationally OGTT is the 75gm glucose solution. This is the test recommended by the WHO and it is used in Europe. In the USA, the100gm. OGTT is still mostly used.

The study group's guidelines was taken up by Diabetes In Pregnancy Study Group India(DIPSI), which recommended that, a simplified "1-step" approach should be taken for the screening and diagnosis of GDM with 75 gm, 2 hr glucose challenge test irrespective of whether the women is fasting or not. A value of>140mg/dl was taken as diagnostic of GDM. This one step procedure of challenging women with 75gm glucose and diagnosing GDM is simple and feasible. This study will try and evaluate the effectiveness of DIPSI guideline in identifying GDM.(Table 1)

Diabetes in Pregnancy Study Group India (DIPSI), 75 gms oral glucose load irrespective of fasting state is given and after 2 hr venous blood sample is collected for assessing blood glucose level[7].

GDM is identified if 2-hour plasma glucose is ≥ 140 mg/dl. Advantages of DIPSI procedure are
•No fasting required.
• Causes least disturbance in a routine activities
• Both screening and diagnostic procedure
• Single step procedure has been approved by the Ministry of Health, Government of India and also suggested by the WHO[8].

Hence, diagnosis and management of GDM is very important. The optimal strategy for screening and diagnosis of GDM is still under debate. Universal versus Selective screening is controversial.

Methods:-

The present study was carried out at tertiary care hospital After the approval of the Institutional Ethics Committee.

The data collection was accomplished over a period of 2 years. It was a comparative study which included both OPD patients and admitted pregnant patients.

Sample Size:
200 patients attending antenatal OPD of Tertiary health

Care center.
Inclusion Criteria:
All pregnant patients between 12 – 16 weeks of gestation at antenatal OPD of tertiary health care center.

Exclusion Criteria:
All pregnant patients with
1. Previous history of GDM .
2. Known case of diabetes mellitus or family history of diabetes mellitus.
3. History of macrosomic baby.

Methodology:-

All pregnant women who fulfil the inclusion criteria were selected and subjected to thorough history taking, clinical examinations, routine antenatal investigations and obstericsonography.

Patients satisfying inclusion & exclusion criteria were selected and were subjected to a thorough history taking, general and systemic examination. Antenatal investigations at recruitment like Hb, ABO/Rh typing, Urine RE/ME, HBsAg, VDRL, HIV and obstetric USG were carried out.

Women between 12-16 weeks of gestational age were subjected to screening for GDM by DIPSI criteria. It was done by giving 75gm of oral anhydrous glucose regardless of fasting status and their blood sugar level were estimated by venous blood sampling after 2 hrs. During these 2 hrs patients were advised not to eat or drink anything including any addictive substance. Values more than 140 mg/dl will be labelled as DIPSI positive.

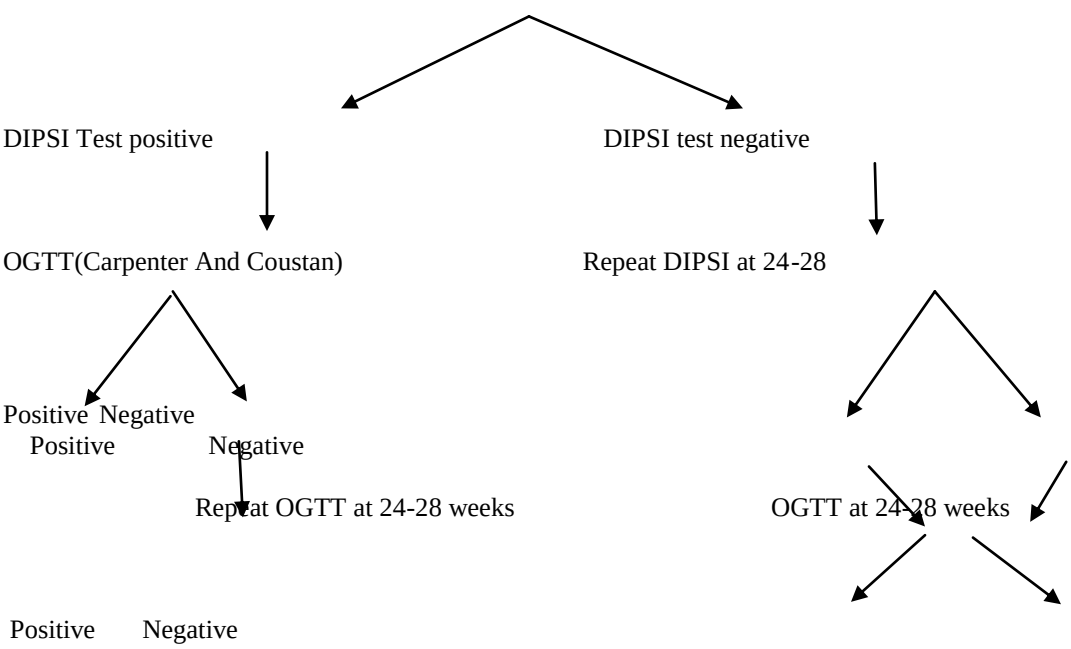
Positive cases were further subjected to 100gm of oral glucose tolerance test (OGTT) by Carpenter Coustan criteria at 12-16 weeks of gestation. Before conducting this test, patients were advised to be on their usual diet for 3 days and then they would come to the OPD in the morning in fasting state of at least 8 hours. A fasting venous blood sample were taken and then they were given 100gm of glucose dissolved in 200ml of water. Thereafter 1hr, 2hr and 3 hr (post load) samples were collected. During the test they were advised not to consume anything else. The patients was diagnosed positive if they met or exceeded the following values - Fasting 95mg/dl, 1 hr 180mg/dl, 2 hr 155mg/dl, 3hr 140mg/dl. All OGTT(Carpenter Coustan criteria) negative patients underwent repeat OGTT at 24-28 weeks of gestation.

All DIPSI negative cases also underwent repeat DIPSI test at 24-28 weeks of gestation.

OGTT (Carpenter-Coustan) positive cases were diagnosed as GDM and were subjected to appropriate management.

Flow Chart

200 patients attending antenatal OPD selected as per inclusion/exclusion criteria



Observations And Results:-

Statistical analysis:

Test of significance chi-square test.

Mean differing by $p < 0.05$ as observed from the tables accepted as significant.

Of 200 cases studied, 15 (7.5%) had age between 18 – 20 years, 161 (80.5%) had age between 21 – 25 years, 19 (9.5%) had age between 26 – 29 years and 5 (2.5%) had age above 30 years.

The mean ± SD of age of cases studied in the entire study group was 25.1 ± 3.4 years and the minimum – maximum age range was 18 – 37 years. Maximum no. cases of GDM 20 i.e. 80 % were in age group of 21-25 .(FIGURE 2)

Of 200 cases studied, 5 (2.5%) had BMI less than 18.50 kg/m2, 158 (79.0%) had BMI between 18.50 – 24.99 kg/m2, 31 (15.5%) had BMI between 25.00 – 29.99 kg/m2 and 6 (3.0%) had BMI above 30.00 kg/m2 in the study group.
76%-19 cases of GDM were having BMI of 18.5 to 24.99 kg/m2.(FIGURE 3)

Of 200 cases studied, 90 (45.0%) were primigravida and 110 (55.0%) had multigravida in the study group.14 i.e 56% GDM cases where multigravida and 11(44%) were primigravida.(FIGURE 4)

(TABLE 2) Of 200 cases studied, 19 (9.5%) had positive and 181 (90.5%) had negative GDM status as per DIPSI criteria at 12-16 weeks gestational period.

(TABLE 3)Of 200 cases studied for OGTT, 15 (7.5%) had positive and 185 (92.5%) had negative GDM status as per OGTT criteria at 12-16 weeks gestational period.

(TABLE 4)The assessment of GDM status by both OGTT and DIPSI criteria was done at 12-16 weeks of gestation. Distribution of GDM status at 12-16 weeks by OGTT is significantly associated with GDM status at 12-16 weeks by DIPSI (P-value<0.05) .

Diagnostic efficacy indices such as sensitivity, specificity, PPV, NPV and accuracy of DIPSI against OGTT as a Gold Standard at 12- 16 weeks of gestation is 100.0%, 97.83%, 78.9%, 100.0% and 98% respectively.(FIGURE 5)

(TABLE 5)Out of 200 cases 15 cases had both DIPSI and OGTT positive were diagnosed ad GDM. The further 185 cases were screened at 24-28 Weeks for both DIPSI and OGTT.
The above table shows prevalence of GDM by DIPSI test at 24-28 weeks period of gestation among 185 study subjects which had negative OGTT at 12-16 weeks were screened further .13 cases were DIPSI positive at 24-28 weeks. In this 13 cases 2 cases had a positive DIPSI at 12-16 weeks and DIPSI at 24-28 weeks was also positive.This 2 cases had negative OGTT at 12-16 weeks

(TABLE 6)The above table shows prevalence of GDM by GTT test at 24 – 28 weeks period of gestation among 185 study subjects which were negative at 12-16 weeks of gestation out of which 10 cases became positive.

Out of 10 OGTT positive cases ,2 cases which had Positive for DIPSI at both 12-16 weeks and 24-28 weeks and had negative OGTT at 12-16 weeks, became positive for OGTT at 24-28 weeks.(TABLE 7)

The assessment of GDM status by both OGTT and DIPSI criteria was done at 24-26 weeks of gestation. Distribution of GDM status at 24-28 weeks by OGTT is significantly related with GDM status at 24-28 weeks by DIPSI (P-value<0.05) .

Diagnostic efficacy indices such as sensitivity, specificity, PPV, NPV and accuracy of DIPSI against OGTT at 24-28 weeks of gestation is 100.0%, 98.29%, 76.92%, 100.0% and 98.38% respectively.(FIGURE 6)

(TABLE 8)The above table shows overall prevalence of GDM by DIPSI criteria and OGTT criteria done between 16 weeks and 28 weeks [32(16%) cases were GDM positive by DIPSI test 25(12.5%) cases were positive by OGTT test out of 200]. P- value<0.00001 is statistically significant.
(FIGURE 7)
DIPSI test Sensitivity (No. of true positive/ No. of true positive +No. of false negatives.) for GDM in comparison to OGTT is 100%
DIPSI test specificity (No. of true negative/ No. of true positive +No. of false negative) for GDM in comparison to OGTT is 96 %
Positive predictive value (No. of true positive/total no. of positive) of DIPSI test is 78.12%
Negative predictive value (No. of true negative/total no. of negative) of DIPSI test is 100%
Accuracy of DIPSI test in comparison to OGTT taken as standard for screening of GDM is 96.50 %.

Disscussion:-

Diagnosis ofGDM is important because treatment, including diet, insulin when indicated and antepartum fetal surveillance can reduce the perinatal morbidity and mortality. Yet there is no world-wide agreement on the screening policies and diagnostic criteria of GDM [(9)].DIPSI -A modified version of WHO guideline having proposed one-time plasma glucose level as a measure to detect GDM is an effort to predict future possibility and predisposition for gestational diabetes mellitus. Advantages of DIPSI are pregnant women need not to be fasting will not experience morning sickness, no nausea or vomiting, no waiting period, causes least disturbance in a pregnant women's daily activity, can diagnose pre GDM, works as screening as well as diagnostic tool. Recent concept is to screen for glucose intolerance in the first trimester itself as fetal beta cells recognizes and reacts to maternal glycemic level as early as 16 weeks of gestation. If negative at 16 weeks, the screening test is to be performed again at around 24-28 weeks and then at 32-36 weeks. [(10)]

Majority of patients in this study, that is, 20 GDM cases(80%) were in the age group of 21 to 25 years. In this study there was no significant association between age and GDM (p value >0.05). With mean age range of 18-37 years. A study conducted by Adel T et al showed Maternal age is strongly related with a positive OGCT and GDM[(11)]. It has been reported that the incidence of GDM increased markedly with increasing maternal age [(11-12)], they established that the incidence of a positive OGCT increased significantly with rising maternal age, from 2.2 % in women aged <25 years to 37.8% in women aged >35 years . Distribution of cases as per body mass index showed the majority 19 GDM Cases(76 %) were in the 18.5-24.9 BMI group. A study by William M, Susan Y. Chu, Callaghan et al quoted that risk of developing GDM is about two, four, and eight times greater among overweight, obese, and severely obese women, respectively, compared with normal-weight pregnant women [(13)].Present study shows that majority 14

GDM Cases(56 %) were multigravida and 11 (44%) were primigravida. Similar finding was observed in a study by Ke Manga Reddy.et al [(14)] they observed that, 59% women were multigravida. DIPSI guideline is "a one-step procedure with a single glycemic value", to diagnose GDM in the community. It is ideal for resource challenged settings like India. In this study prevalence of GDM by DIPSI test is 16 %, and it compares significantly well with the 12.5 % prevalence by OGTT (Carpenter and Coustan) criteria, which has been taken as standard for the diagnosis of GDM. This was parallel to the results found by study conducted by Sri RevathySadasivam et al in which, The incidence of GDM by 75 g single step OGTT was found to be 16.7%, whereas the incidence of GDM by Carpenter–Coustan method using 100 g OGTT was 13.3%, which goes in favour of high pick up rate in 75 g single step OGTT[(15)].

A study by Seshiahet al. had also found a sensitivity of 79.8% for this method. Any screening test with sensitivity more than 60% and specificity more than 90% can be used in a community for analysis and results of our study strongly favour and recommend the use of this one step procedure for the diagnosis of GDM. [(16-19)]

Indian studies stated the prevalence of GDM as between 16.55% and 22% using the DIPSI criteria, which is comparable to the prevalence of 16 % in our study [(20,21)]

Percentage of false negative result and NPV of the single step procedure was found to be 0% and 100%, which means in our study, this procedure recognised all the GDM Positive cases identified by carpenter coustan criteria. Percentage of false positive and PPV of this method was found to be 3.5% and 78.12%. which was similar to study of ofSri RevathySadasivam et[(15)]in which false positive were 3.85% and positive predictive value was 80%. Similar finding was observed by VijayalakshmiUdipiBadikillaya et al[(22)] .They assessed effectiveness of DIPSI recommended OGTT in diagnosing GDM in rural Indian females. They demonstrated that the DIPSI recommended 75 g OGTT was able to exactly detect GDM and had a higher sensitivity when compared to the 50 g OGCT (oral glucose challenge test) however the specificity was almost the same. Further studies are necessary to determine the effect of the timing of the OGTT on the plasma glucose value, in order to reduce the false positives. In a large multicentre study across India as part of a Federation of Obstetrics and Gynaecological Societies of India (FOGSI) initiative with a sample size of over 9000 women, DIPSI test identified 8% women with GDM exactly the same rate as described by Mohan et al. with the WHO (2009) 2-hour criterion [(23)].

Tables And Figures

Table 1:- Diagnostic Criteria for GDM.

Criteria	Glucose(gm)	Fasting Mmol/l (mg/dl)	1 -hour	2-hour	3-hour	Diagnosis (positive)
O'Sullvan and Mahan	100	105mg/dl 5.8mmol/l	190mg/dl 10.6mmol/l	165mg/dl 9.2mmol/l	145mg/dl 8.1mmol/l	>2
Carpenter coustan criteria	100	95mg/dl 5.3mmol/l	180mg/dl 10mmol/l	155mg/dl 8.6mmol/l	140mg/dl 7.8mmol/l	>2
WHO	75			140mg/dl 7.8mmol/l		
IADPSG	75	92mg/dl 5.1mmol/l	180mg/dl 10mmol/l	153mg/dl 8.5mmol/l		>1
DIPSI	75			140mg/dl 7.8mmol/l		

Figure 1:- Diabetes and Pregnancy.

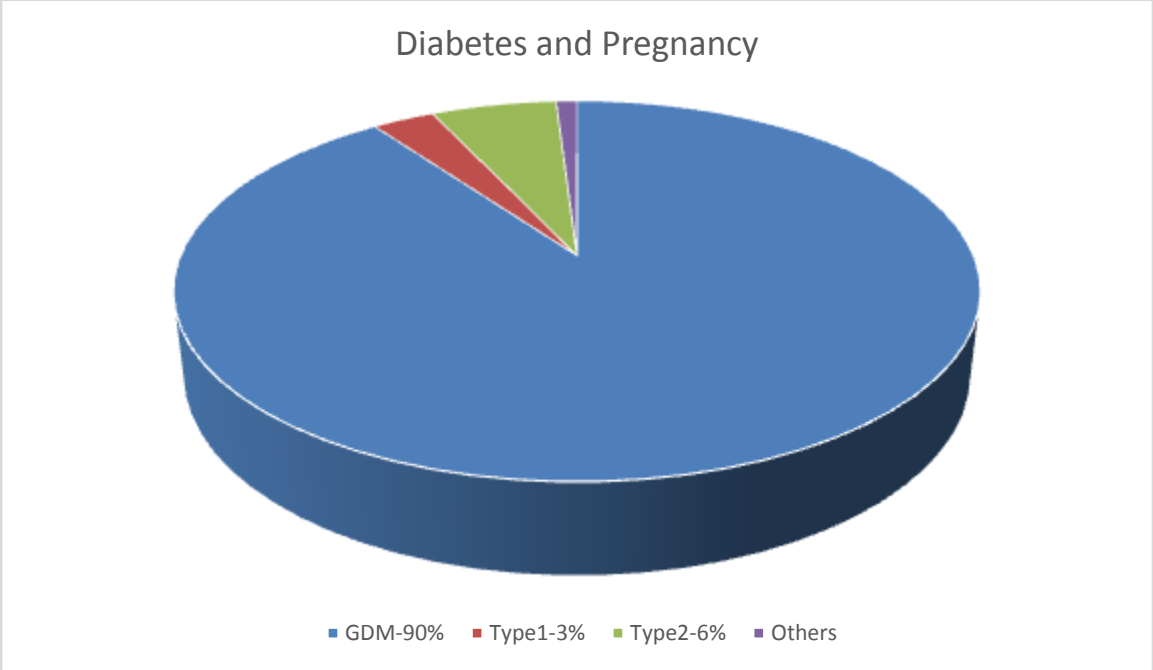


Figure 2:- Age distribution of cases studied in the study group.

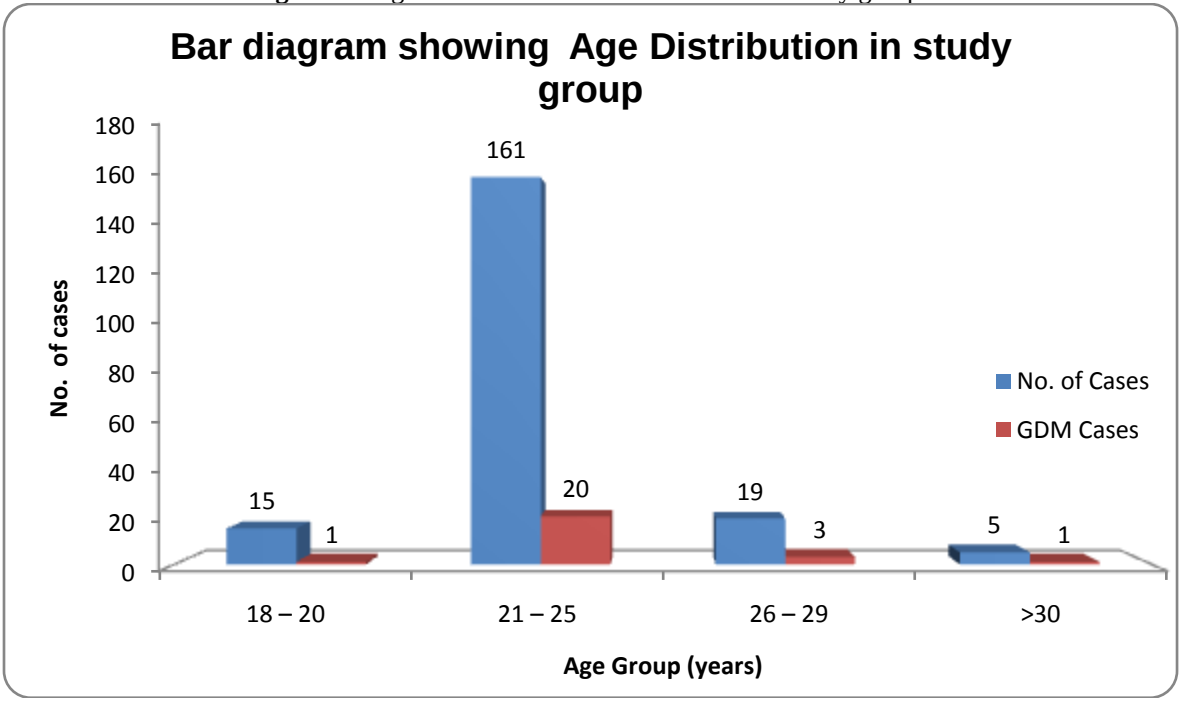


Figure 3:- Distribution of body mass index (BMI) among the cases studied in the study group.

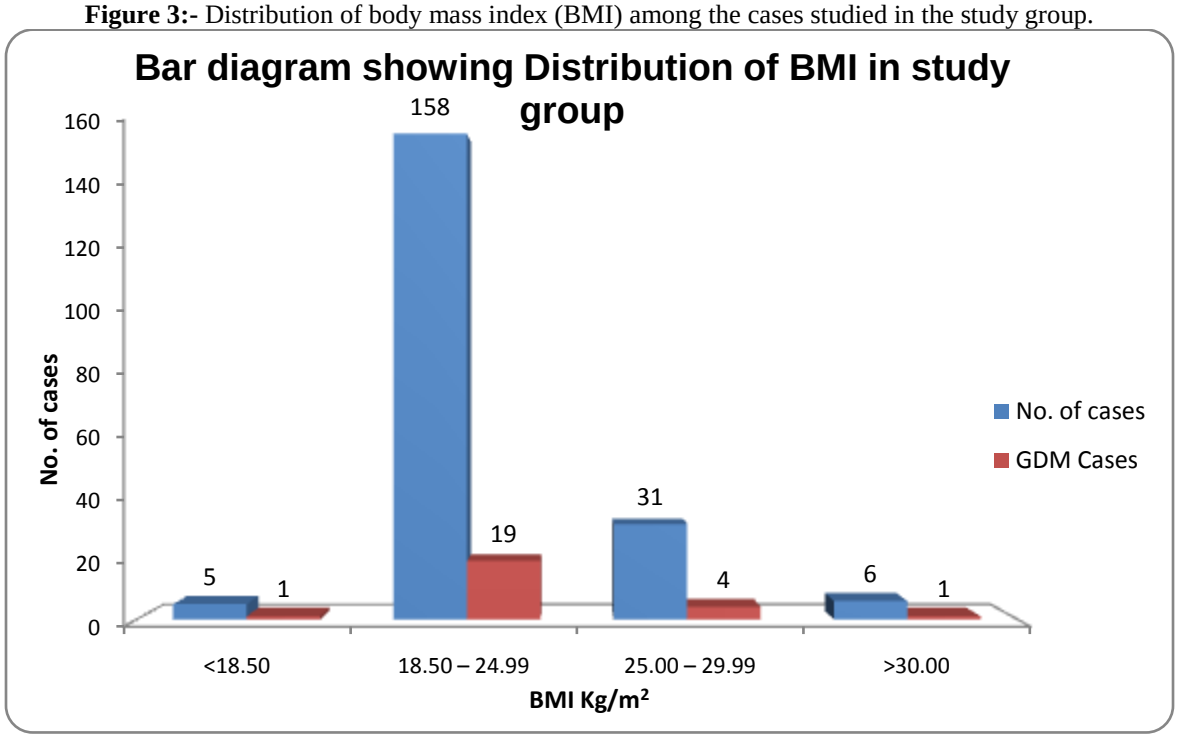


Figure 4:-Gravidity distribution of cases studied in the study group.

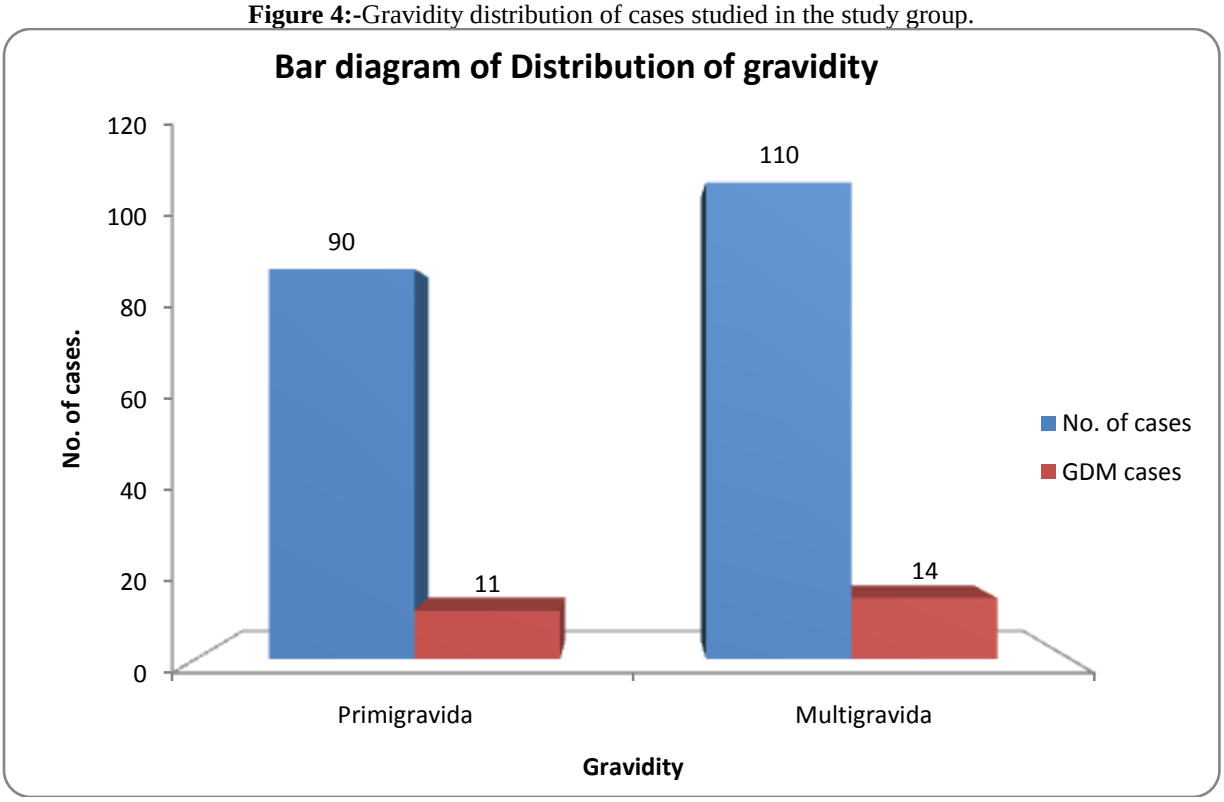


Table 2:- Prevalence of GDM by DIPSI test at 12-16 weeks period of gestation.

GDM by DIPSI	No. of cases	% of cases
Positive	19	9.5
Negative	181	90.5

Total	200	100.0

Table 3:- Prevalence of GDM by OGTT test at 12-16 weeks period of gestation.

GDM by OGTT	No. of cases	% of cases
Positive	15	7.5
Negative	185	92.5
Total	200	100.0

Table 4:- Association between prevalence of GDM by DIPSI and OGTT at 12-16wks period of gestation:

	GDM by OGTT at 12-16 weeks						
	Positive		**Negative**		**Total**		**P-value**
GDM by DIPSI at 12-16 weeks	N	%	n	%	N	%	
Positive	15	7.5	4	2	19	9.5	<0.00001
Negative	0	0	181	90.5	181	90.5	
Total	**15**	**7.5**	**185**	**92.5**	**200**	**100.0**	

Figure 5:- Diagnostic efficacy indices of DIPSI against OGTT as a Gold Standard at 12- 16 weeks of gestation in the study group.

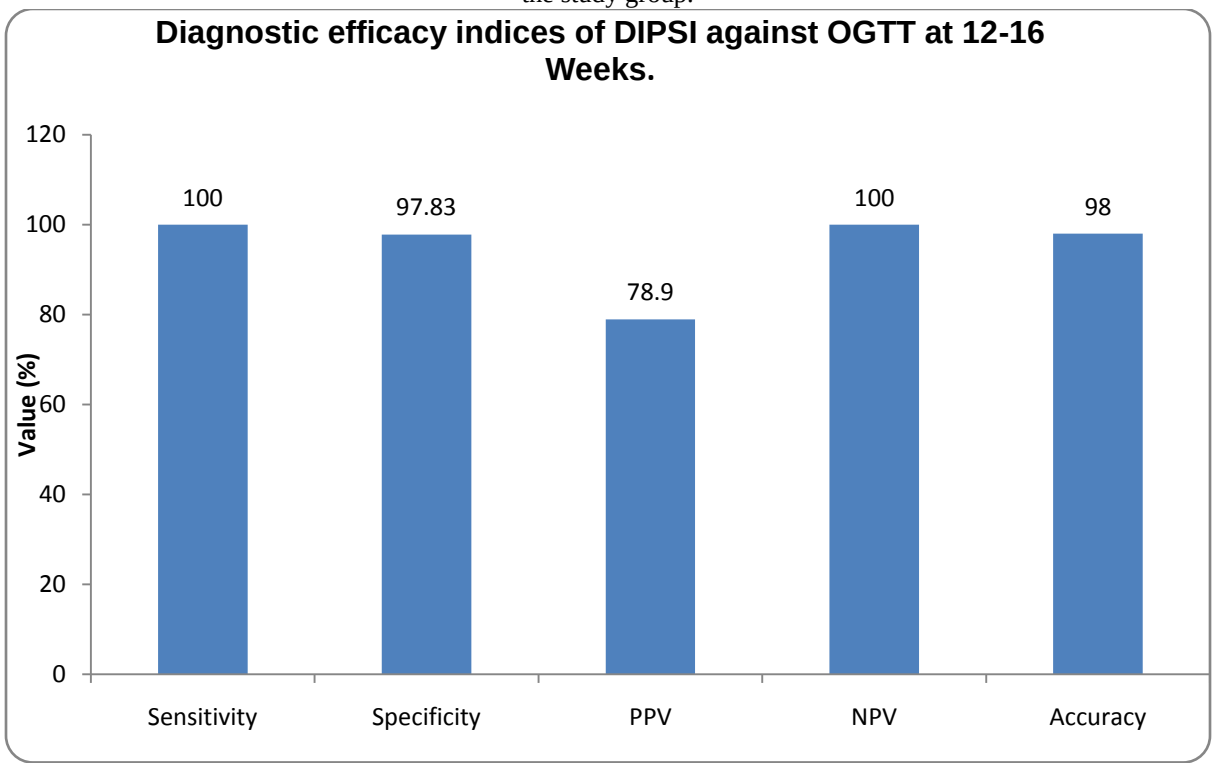


Table 5:- Prevalence of GDM by DIPSI test at 24 – 28 weeks period of gestation:

DIPSI at 24-28 Weeks	No. of cases	% of cases
Positive	13	7.03%
Negative	172	92.97%
Total	185	100.0

Table 6:- Prevalence of GDM by OGTT at 24 – 28 weeks period of gestation.

OGTT at 24-28 Weeks	No. of cases	% of cases
Positive	10	5.4%

Negative	175	94.6%
Total	185	100.0

Table 7:- Comparison of GDM status at 24-28 weeks of gestation based on DIPSI and OGTT criteria among the cases studied in the study group.

	GDM by OGTT at 24-28 weeks						
	Positive		**Negative**		**Total**		**P-value**
GDM by DIPSI at 24-28 weeks	N	%	n	%	N	%	
Positive	10	5.40	3	1.7	13	7.1	<0.00001
Negative	0	0	172	92.9	172	92.9	
Total	**10**	**5.4**	**175**	**94.6**	**200**	**100.0**	

Figure 6:- Diagnostic efficacy indices of DIPSI against OGTT at 24-28 weeks of gestation in the study group.

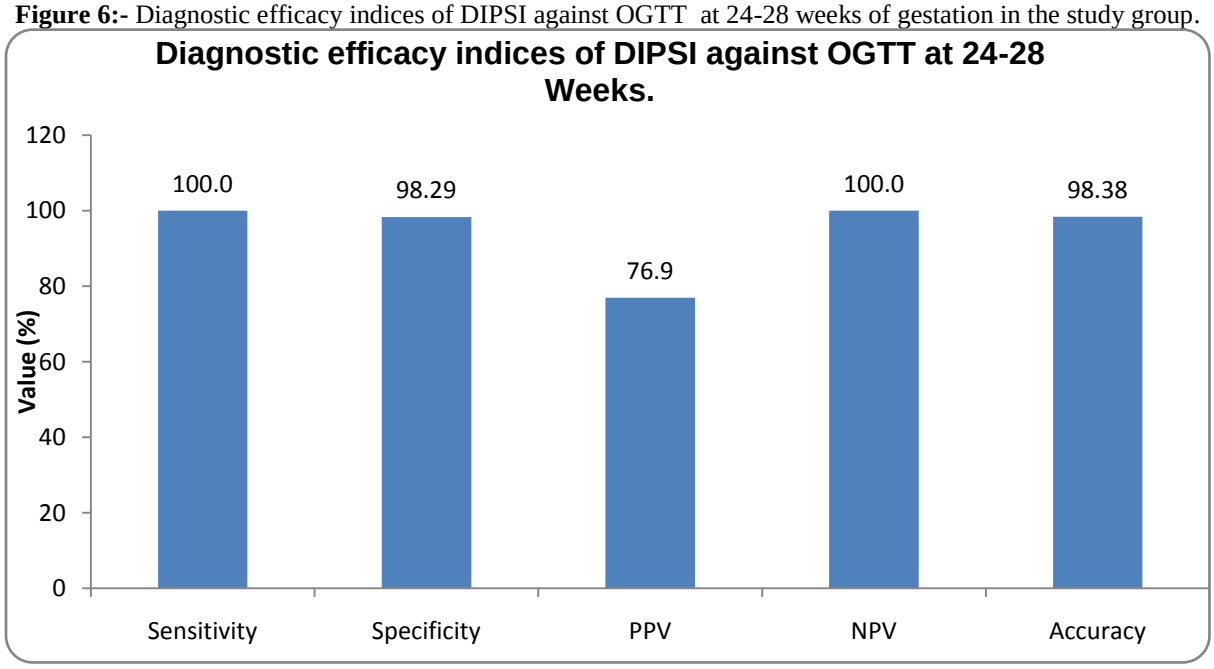
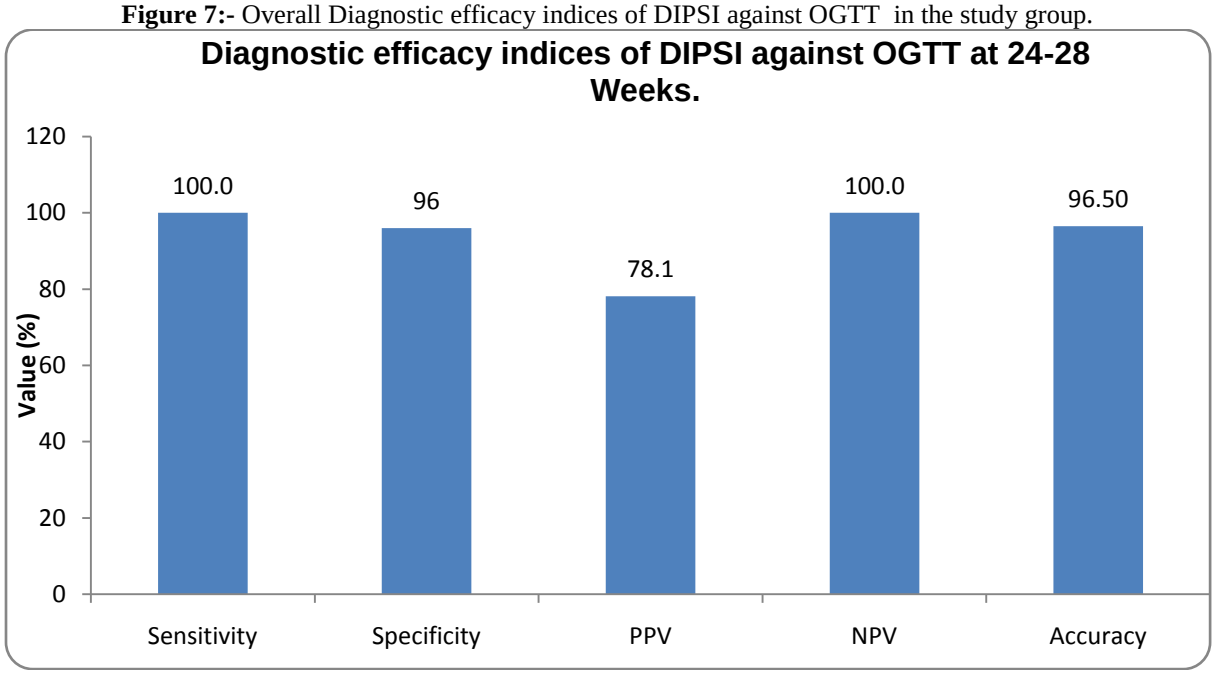


Table 8:- Overall prevalence of GDM by DIPSI and OGTT in study group:

GDM by DIPSI	**GDM by OGTT**				**Total**		
	Positive		**Negative**				**p-value**
	n	**%**	**N**	**%**	**n**	**%**	
Positive	25	12.5	7	3.5	32	16	<0.00001
Negative	0	0	168	84	168	84	
Total	**25**	**12.5**	**175**	**87.5**	**200**	**100.0**	

Figure 7:- Overall Diagnostic efficacy indices of DIPSI against OGTT in the study group.



Conclusion:-

All antenatal cases irrespective of their age, BMI, Gravidity, Family history, High risk factor should be screened for GDM in our country.

DIPSI is simplicity, feasibility, convenience, and repeatability, while economizing universal screening and diagnosis of GDM an mass-scale.

The sensitivity of DIPSI test was 100% and specificity 96 %. Positive predictive value(PPV) of DIPSI test was 78.12% and Negative predictive value(NPV) was 100%.

The DIPSI test can be utilized for screening of GDM in Indian Population.

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