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A COMPARATIVE STUDY OF DIPSI GTT VERSUS IADPSG GTT IN TERMS OF DIAGNOSTIC EFFICACY AND OUTCOME IN GESTATIONAL DIABETES MELLITUS

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ABSTRACT

Background: Diabetes in Pregnancy Study Group India (DIPSI) and International Association of Diabetes and Pregnancy Study Groups (IADPSG) recommendations are general diagnostic criteria utilized in our country for determining gestational diabetes mellitus (GDM). To diagnosis GDM, the IADPSG following Hyperglycaemia and Adverse Pregnancy Outcome (HAPO) recommends fasting plasma glucose (FPG) of 92 mg/dL, 1-h PG of 180 mg/dL, or 2-h PG of 153 mg/dL.

Aims: To compare DIPSI recommended GTT and IADPSG-2 phase strategy in terms of efficacy for diagnosing GDM.

Materials and methods: The study was undertaken on antenatal women in the Out Patient Department of our hospital. It was done to compare the efficacy of DIPSI recommended GTT and IADPSG2-phasestrategyin diagnosing GDM and also to study the neonates of the two groups in terms birth weight, presence of neonatal hyperbilirubinemia and presence of any respiratory distress.

Results: The data from 70 women in groups A and B was analysed. There is no statistically significant difference in the demographic distribution of the study groups. The number of GDM cases detected by the two diagnostic criteria did not differ significantly. When comparing the two groups, birth weight, respiratory distress, and neonatal hyperbilirubinemia are all negligible. When comparing groups, the type of labour and delivery are unimportant. In both study groups, there is no significant difference in the frequency of GDM patients who require either MNT or insulin +MNT.

Conclusions: We conclude that application of DIPSIGTT is comparable to the new IADPSG guidelines recommended by ADA in the diagnosis of GDM Even those who came under low-risk category for developing GDM according to ADA were found to develop GDM in the study population in both the groups.

Keywords: Diabetes mellitus, Diabetes in Pregnancy Study Group of India, (DIPSI) Glucose Tolerance Test (GTT)

INTRODUCTION

Diabetes mellitus is a metabolic disorder of varying severity involving carbohydrates, protein and fat, due to lack or deficiency of insulin resulting from destruction , dysfunction of beta

cells or due to peripheral resistance to insulin. An important aspect of this distribution metabolism is carbohydrate intolerance manifesting as fasting hyperglycemia, impaired glucose tolerance gestational diabetes mellitus or overt diabetes.

India has the second largest number of people with diabetes in the world (62.4 million) and this number is expected to reach 100 million by the year 2030. Rapid changes in lifestyle including unhealthy diet and physical inactivity may have contributed to this in prevalence of diabetes in general with a parallel increase in the rates of GDM.[1]

The effects of gestational diabetes (GDM) on both maternal and fetal health are well documented and have been recently confirmed recently confirmed by results from the hyperglycaemia and adverse pregnancy outcomes (HAPO)study.

Women diagnosed to have GDM are at increases risk of future diabetes predominantly type 2 diabetes mellitus)DM) as are their children. Thus GDM offers an important opportunity for the development , testing and implementing of clinical strategies for diabetes prevention. Timely action taken now in screening all pregnant women for glucose intolerance , achieving euglycemia in them and ensuring adequate nutrition may prevent in all probability , the vicious cycle of transmitting glucose intolerance from one generation to another.

The diagnosis of GDM has always been beset with problems related to differing diagnostic criteria with conflicting evidence regarding the maternal and fetal outcomes. Studies conducted in different populations and with different methodolgies , consistently reported an increase in GDM in all ethnic groups, suggesting that there is an increase in GDM prevalence. A true increase in the prevalence of GDM aside from its adverse consequences for the infant in the newborn period might reflect or contribute to the ongoing pattern of increasing diabetes and obesity.[2,3]

This implies that universal screening and care of women with GDM is paramount public health priority in population at high risk for GDM and diabetes, rather than risk factor screening. Compared to selective screening , universal screening for GDM detects more cases and improves maternal and neonatal prognosis. Hence universal screening for GDM is essential , as it is generally accepted that women of Asian origin and especially ethnic Indians are at a higher risk of developing GDM and subsequent type 2 diabetes.

General diagnostic criteria used in our country for determination of gestational diabetes mellitus (GDM) involve Diabetes in pregnancy study group India(DIPSI) and international association of diabetes and pregnancy study group (IADPSG)guidelines. [4]DIPSI states that when a pregnant woman walks into the antenatal clinic she has to be given 75 g oral glucose load irrespective of fasting state , and if 2 h plasma glucose (PG) id >140 mg/dL, then it is considered to be a case of GDM . The IADPSG after the hyperglycaemia and adverse pregnancy outcomes (HAPO) study recommends any of the values of fasting plasma glucose (FPG)>92 mg/d, 1-h PG>180mg/dL, or 2 h PG >153 mg/dL to diagnose GDM. Hence this prospective study was undertaken to ascertain whether the present practice of diagnosing GDM by the guidelines recommended by Diabetes in pregnancy study group (DIPSI) which is feasible and cost effective can still be followed in our country or to adopt IADPSG recommendations.

MATERIALS AND METHOD

This Cross sectional study will be done in the Department of Obstetrics and Gynecology, GMC, Nizamabad. This study will be conducted in GGH Nizamabad fromOctober 2020 to June2021

Sample size

$$n = \frac{Z_{\alpha}^{2}\ p(p-1)}{d^{2}}$$

N= Sample size = 34

Z_α= standard normal variate=1.96
p= % of diagnosed with gestational diabetes as per DIPSI =74.34%
d= absolute precision =15%
Sample size is collected based on (pulkit vj;sujeet) study.[5]
Approximately 80 antenatal women attending the op for the first time will be included. They are divided into 2 groups.
40 cases allotted into DIPSI group and 40 cases allotted into IADPSG by simple randomization methods

Selection of Subjects

Inclusion Criteria :Singleton pregnancy ***in*** booked cases of pregnant women with BMI < 35 those pregnant women who gave informed consent

Exclusion Criteria:known diabetic**,** H/0 GDM in previous pregnancy , marked obesity(BMI > 35) , H/o previous baby > 4kg**,** H/o previous IUD**,** congenital anomalies**,** multiple pregnancy **and** pregnancy with comorbidities

METHOD
All the antenatal women who are attending the OPD , at first antenatal visit, after obtaining informed consent, and who satisfy the inclusion and exclusion criteria will be randomly allocated into two groups:Group-A and Group-B. Randomization will be done using simple random sampling method.
Antenatal women included under group A at the first antenatal visit will be given 75gm oral glucose load irrespective of last meal timing. And 2ml venous of venous blood will be collected and immediately analysed using auto-analyser for glucose level. If sugars are normal we will repeat again at 24-28 weeks and at 32-34 weeks. A 2 hour plasma glucose value between 140mg/dl and 199mg/dl is considered as diagnostic of GDM (DIPSI criteria).
Antenatal women randomized to group-B on first antenatal visit will besubjected to fasting plasma glucose testing. GDM is diagnosed if fasting plasma glucose (FPG) >92mg/dl but less than 126mg/dl. Those women who are not diagnosed as GDM,test will be repeated with 75 gm. OGTT between 24-28 weeks

DIPSI criteria
2hr plasma glucose value in pregnancy

->200 mg/dl	overt diabetes
140 -199mg/dl	GDM
120- 139 mg/dl	Gestational glucose intolerance
<120 mg/dl	Normal

IADPSG criteria

Fasting	92 mg/dl
1 Hour	180 mg/dl
2 Hour	153 mg/dl.

One or more values greater than the threshold are treated as GDM.
All three values less than threshold are treated as normal.
FBS >126 mg/dl is Overt Diabetes
Antenatal women belonging to both the groups are followed up at subsequent antenatal visits and at the time of delivery for maternal and perinatal outcome. Maternal and neonatal

complications are related to euglycemic state.So it is important to diagnose early and treat meticulously. Various parameters will be noted in the pre-designed study proforma (attached).

Statistical Analysis

The data collected will be analysed and the results are presented as frequency and percentages. For the data such as age, BMI of woman at booking and birth weight of new-born are also presented as mean and standard deviation. The Chi-square test or fisher's exact test will be used to determine the Statistical significance of the difference between the groups in terms of number of GDM cases detected, number of subjects treated with only nutritional therapy or those required insulin and maternal complications etc.

RESULTS

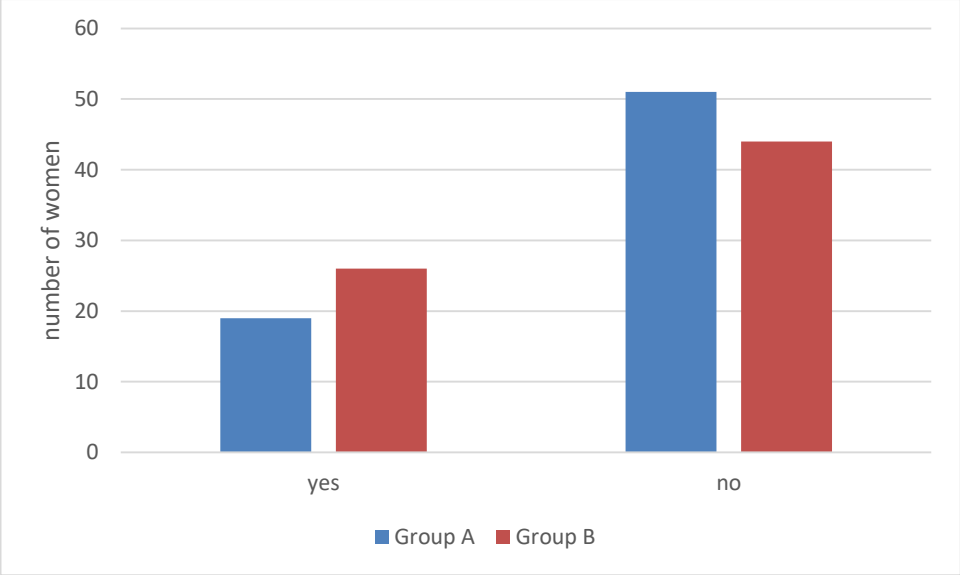
The data collected from 70 women each in group a and group b were analysed and the result are presented under different section.

Table-1: Demographic and health related characteristics

Age	**Group -A**		**Group-B**	
	Number of patients	**Percentages**	**Number of patients**	**Percentages**
<25	8	11.4	16	22.9
25-29	25	35.7	27	38.6
30-34	33	47.1	22	31.4
>35	4	5.7	5	7.1
Total	70	100	70	100
Parity				
Primi	28	40	37	52.8
Multi	42	60	33	47.2
BMI				
Underweight(<18.5)	3	4.2	3	4.2
Normal (18.5-24.9)	48	68.5	48	68.5
Over weight(25-29.9)	18	25.7	19	27.14
Obese (30-34.9)	1	1.4	0	0
Number of abortions				
1	14	20	12	17.14
2	2	2.85	1	1.4
3	0	0	1	1.4
Family history of DM				
Present	27	38.5	22	31.4
Absent	43	61.5	48	68.6
Previous LSCS				
Yes	9	12.8	11	15.7
No	61	87.2	59	84.3

The study subject in groups are comparable with P value was <0.05 indicates no significant difference in demographic distribution of the study groups.

Figure-1: Incidence of GDM in study groups



There were 19 cases in group A and 26 cases in group B diagnosed as GDM by DIPSI GTT and IADPSG 2 phase protocol respectively. Of the 51 normal cases under group A , 8 were gestational glucose intolerance (GGI). The difference in the number of GDM cases detected by the 2 diagnostic criteria was not significant

Table-2: Neonatal outcome in groups

Birth weight	**Group -A**		**Group-B**	
	Number of patients	**Percentages**	**Number of patients**	**Percentages**
<1.5	1	1.4	0	0
1.5-2.49	4	5.7	8	11.4
2.5-3.99	63	90	62	88.6
>4.0	2	2.9	0	0
Respiratory distress				
Yes	9	12.9	8	11.4
no	61	87.1	62	88.6
Neonatal hyperbilirubinemia				
Yes	14	20	21	30
No	56	80	49	70

Birth weight , respiratory distress and Neonatal hyperbilirubinemia are insignificant when compared in both groups.

Table-3: Maternal outcomes in groups

Type of labour	**Group -A**		**Group-B**	
	Number of patients	**Percentages**	**Number of patients**	**Percentages**
Induced	15	78.9	15	57.7
Not induced	4	21.1	9	34.6
spontaneous	0	0	2	7.7
Mode of delivery				
LSCS	9	47.4	17	64.4
PTRM CS	1	5.3	1	3.8
Vacuum	2	10.5	0	0
Vaginal	7	36.8	8	30.8
Total	19	100	26	100

Type of labour and mode of delivery are insignificant when compare in groups.

Table-4: Patient needing therapy in groups

Only medical nutrition therapy(MNT)	**Group -A**		**Group-B**	
	Number of patients	**Percentages**	**Number of patients**	**Percentages**
Yes	15	78.9	21	80.8
No	4	21.1	5	19.2
Insulin and **medical nutrition therapy**				
Yes	4	21.1	7	26.9
No	15	78.9	19	73.1
Total	19	100	26	100

Among 19 patients diagnosed as GDM 15 patients required Only medical nutrition therapy and 4 required insulin and medical nutrition therapy in A group .
Among 26 patients diagnosed as GDM 21 patients required Only medical nutrition therapy and 7 required insulin and medical nutrition therapy in A group. There is no significant difference between the number of GDM patients requiring only MNT and insulin +MNT in both the study groups.

DISCUSSION

Identification and systemic management of the disease reduces both maternal and perinatal morbidity. Hence universal screening during pregnancy has become important in our country. For this we need a simple , reliable and cost effective procedure . Despite more than 30 years of research there is no consensus regarding the optimal approach to the screening of gestational diabetes.
Hence a prospective study of 140 pregnant women who reported to the hospital at booking was done to compare efficacy of DIPSI GTT and ADA GTT(IADPSG 2 phase) in identifying pregnant women with GDM and to findout if one step procedure which serves both as a screening and a diagnostictool is acceptable , economical and feasible to perform in the Indian context. This study also looked at the neonatal outcome in both the groups. This is comparative study of two groups consisting of 70 women each in the DIPSI GTT group A and ADA GTT group B. the women were allocated to either group using simple random sampling method.
The mean age of the patients studied was 29.1+3.28 years in the group A and 28+3.81 years in group B. According to ACOG risk stratification this age group belongs to the high risk group. There was no significant difference in the age between the two groups. The age groups is higher when compared to the two studies conducted by V Seshiah et al[6] where the mean age of study was 23+4 and 23.6+3.3. years. However , our study groups were younger in age as compared to women in study conducted by Pulokit Vij et al.[5]
Of the 60% women in group A and 43.2% in group Bwere multi gravidas. No statically significance was observed between the study groups. A study conducted by V Seshiah et al[6] reported parity as not directly linked to insulin sensitivity deterioration, fasting plasma glucose increases during pregnancy or to GDM appearance. They concluded that it might gain either before orduring pregnancy , when there is a sufficiently long time interval between pregnancies.
Araneta, M. R. et al concluded in a cross-sectional analysis that grand multiparity and diabetes in elderly women were associated . This relationship seemed to be confounded and

medicated by variation in body weight and sociodemographic factors by parity status. In older non diabetic women, higher parity does not pose an ongoing risk of developing diabetes.

The mean BMI of was similar in both groups . The study done by Pulkit et al[5] among north Indian women, the mean BMI was reported as 25+3.2 $kg/m^{2.}$

It was observed that the study groups were not significantly different in the number of abortions they had in the past.

38.5 women in group A and 31.4% women in group B had family history of diabetes. In women diagnosed to have GDM none of them had history of diabetes in the family in group A whereas group B , one woman had family history of diabetes. History of diabetes in the family, which is an established risk factor for the occurrence of GDM , was similar in both the study groups.

There were 27% cases in group A and 73% in group B diagnosed as GDM by DIPSI GTT and IADPSG 2 phase protocol respectively in the present study. Of the 51 normal cases in groups A , 8 were gestational glucose intolerance . the difference in the number of GDM cases detected by the two diagnostic criteria was not statically significant , indicating both testsare equally effective in detecting GDM cases.

Similar results were reported by Seshaiah V et al[6] utilizing both DIPSI and IADPSG criteria to ascertain the prevalence of GDM , and they reported that there was no significant difference in the diagnostic capability between these 2 guidelines. Anjalakshi et al also reported similar results comparing DIPSIversusWHO GTT. In their study of 800 pregnantwomen diagnosed as GDM by 75gm GCT(DIPSI GTT) irrespective of the last meal, reported similar results found showed a 100%% sensitivity and specificity using 75 gm GCT values no statistical difference ($p>0.005$) between plasma glucose.This according to DIPSI criteria. On the contrary, there were reports showing that DIPSI as an inferior procedure for detecting GDM cases.Some studies showed DIPSI as having higher detection rate indicating falsepositivecases.Aprospective studyof 200 women, 11% were tested positive for the DIPSIrecommended 75 g OGTT, whilethe ADArecommended diagnosed with GDM. However, by using the IADPSG diagnostic criteria, 134 (88. 15 %) subjects re found to have gestational diabetes. Nevertheless, based on isolated fasting glucose , it was 22.3% higher than the pregnancies currently diagnosed with GDM in India by DIPSI guidelines. Theyfound that there exist significant differences between the two guidelines as $P<0.05$ betweenthe discordant pair of differences diagnosing.

The mean birth weight of new-borns in the studygroupswere similarin group A, it was it was 3.0+0.46 and in groupB; 3.0+0.45 (p-0.94). No significant difference was found between the mean birth weight of new-bornsof women with GDM (2.95+0.70) and that of womenwithoutGDM (3.12+0.33) in group with GDM (2.95+0. 0576) and in group B, it was 3.12+0.53 and 2.940.38 for new-borns of won men with and without GDM respectively(p-0.104).(both groups together : Mean birth weight of new-borns of GDM was 3.05+0.61 and that of non-GDM was 2.98+0.36 (p=0.419). 26.7%of women with GDM and 10.5%of women who had no GDM had new-borns whose weight was more than 3.5 kg. This difference was significant at p-0.023.Similarfindingswere reportedby the HAPO studydone on 19.885new-borns, an analysis was performed of the link betweenmaternal hyperglycaemia, neonatal body composition and fetal hyperinsulinism. The results show that there is a linearand continuous relationship between percentage body fat in new-borns(evaluated by anthropometric and skin fold measurements),maternal 81ycaemia(fasting,and at 1 and 2 hours after 75 g test). These results were similar to the outcome of the study done by TurkiGasim et al[8]on outcomeof patientswith GDM had a significantly higher incidence of highermeanthat patients come of pregnancy in 220 patients with GDM which identified weight ($p<0.0001$) of babies; large for gestational age infants (p-

0.0011); weight birth macrosomia (p-0.0186)12.85 % of new-bornin groupA and 11.42% of women with GDM in group B had respiratory distress. Theseresultswere statistically not GDM womenwith GDM in group B had respiratory distress. significant.8 new-borns of women with GDM in group A and 3 new-bornsof 24.4% of women with GDM and 6.3% without GDM had respiratory distress. This difference was statistically significant (p=0.004). In the study by Crowtheret al[9](ACHOIS), the risk of respiratory distress,definedby the need for supplemental oxygenbeyondfour hoursafter birth, did not increase in the absence of treatment.ln the study by Esakoff et al [10] on pregnant women with GDM, therewas a particularly high risk of respiratory distress in new-bornswith a birthweight>4,000g, compared to thosewith a birthweightof less than 4,000 g (OR = 3.1 [1.11-8.65]

Neonatalhypoglycaemia in new-born with GDM In the studyconducted by Langer et al."on 555 womenwith untreated GDM diagnosed after 37 weight 1,110with treatedGDM and 1,110 non-diabeticControlsubjects, the rates of hypoglycaemia for the three groups were 18%. 6% 5 and 2% respectively.In the study done by Esakoff et al[10]. onpregnant women with GDM, there was a higherrisk of hypoglycaemia in new-bornswith a birth weight>4,000 g, comparedto those with a birth weight of less than 4,000g. However in the present study group had no new-born developed hypoglycaemia. The reason for this finding may be that only two new-borns of women in the Control in the antepartum and intrapartum period

20% of new-born of women in group A and 30% of women in group B ha neonatalhyperbilirubinemia. 36.8%of new-born of women with GDM in group A and 30.8% of womenwith GDMin group B had neonatal hyperbilirubinemia. These results were not statistically significant.

Similar findings were noted in the HAPO study, wherehyperbilirubinemia was foundto be weakly associated with maternal blood glucose levels at one hour using the 75 g test and at two hours.

New-borns of 33.3%of womenwith GDM and 21.1% without GDM in not statisticallyresults in study had hyperbilirubinemia. These results were not statisticallysignificant (p-0.144). In the studyby Crowther et al.[9](ACHOIS), the Proportion of infants with hyperbilirubinemia requiring phototherapy was 9% proportion there was no differencein the rate of hyperbilirubinemia 128 n both the treatment and the routine-care group(p = 0.98). In the study by Landon et al[11]between the two groups is 9.6% in the treatmentgroupversus12.9%in the control group.

CONCLUSION

Gestational diabetes mellitus (GDM) increasesthe risk of adversematernal and neonataloutcomeif untreated.From our studywe conclude that applicationofDIPSIGTT is comparable to the new IADPSGguidelines recommended by ADA in the diagnosis of GDM Even those who came under low-risk category for developing GDM according to ADA were found to developGDM in the study populationin both the groups. Thus this study also shows the importance of universal screening in Indian population even when they have a normal BMI, no family history of Diabetesmellitusor other risk factors There was better compliance in the patients of groupA DIPSI recommended 75 g OGTT as it is done irrespective of fastingstateand requiresonly one sample of blood. Even though the test has to be repeatedin each trimester, the cost in performing the procedure will be 66% less than the cost of performing IADPSG recommended procedure. Therefore, our population being at risk ethnically,we advise all pregnant women to report to the hospital in the first trimester to undergodiagnostictest for the detectionof GDM, improvement in awareness amongst e women and increasingtheiraccessibilityto medical facilities With proper management with strict adherenceto Medical nutrition therapy(MNT), frequent S to the hospitalfor treatment

with insulin if required, maternaland fetal morbidity and mortality in GDM can be minimized.

DIPSI guidelinesinclude a third trimestertesting for GDM which is very important in our population which is ethnically at risk for GDM and DM as we would otherwisemiss a small cohort of patientsin whom GDM probably be recognizedonly after 28 weeks.

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