

COMPARISON BETWEEN DIPSI AND IADPSG OGTT CRITERIA AS DIAGNOSTIC TEST FOR DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS

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Abstract:

Background Gestational Diabetes causes several maternal and fetal complications. Recognizing and treating diabetes or any degree of glucose intolerance in pregnancy results in lowering maternal and fetal complications. DIPSI (recommended by FOGSI and validated by MoHFW, India) suggested a single step testing for GDM. Several studies done in India and abroad have suggested conflicting results as compared to the standard IADPSG 75 gm OGTT. This study compares the efficacy of the sensitivity and specificity of DIPSI OGTT as against gold standard IADPSG OGTT criteria. **Material and Method** A prospective Diagnostic Evaluation Study carried out on 450 Antenatal patients at a zonal hospital in Eastern India. All participants were subjected to OGTT test by both IADPSG & DIPSI criteria on two separate occasions 7 days apart in the 1st trimester as well as between 24 to 28 weeks. DIPSI results were compared between 75 patients who were positive & 75 patients who were negative by IADPSG criteria. Sensitivity and specificity were calculated. **Results** Sensitivity and Specificity of DIPSI OGTT as against IADPSG OGTT was found to be 90% and 100% respectively. **Conclusion** The best approach to screen for Gestational Diabetes is undoubtedly the IADPSG Criteria as recommended by WHO. However in resource poor and developing

countries like India, DIPSI criteria is also a good alternative to the IADPSG criteria. Larger multicentric multinational studies are required to establish the diagnostic efficacy of DIPSI as an equally efficacious alternative to the standard IADPSG OGTT.

Keywords: Gestational Diabetes Mellitus (GDM), DIPSI OGTT, IADPSG OGTTCriteria, Sensitivity and Specificity, Glucose Intolerance in Pregnancy

COMPARISON BETWEEN DIPSI AND IADPSG OGTT CRITERIA AS DIAGNOSTIC TEST FOR DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS

Introduction:

Diabetes is one of the most common metabolic disorder affecting pregnancy. Its prevalence is undoubtedly growing in parallel with the epidemics of overweight and obesity. Gestational diabetes is defined as glucose intolerance of any degree detected for the first time during pregnancy. Gestational Diabetes has had an increasing repertoire of causing maternal and fetal complications. These patients present higher risk for excessive weight gain, preeclampsia, cesarean sections, a high risk of developing type 2 diabetes and cardiovascular disease in the future. Neonates born to these mothers are at higher risk for macrosomia and birth trauma, and after delivery, these neonates are at a higher risk of developing hypoglycemia, hypocalcemia, hyperbilirubinemia, respiratory distress syndrome and polycythemia^{1,2}. Not just stopping at that, these neonates have a higher propensity to develop obesity and type 2 diabetes in their later life. Recognizing and treating diabetes or any degree of glucose intolerance in pregnancy results in lowering maternal and fetal complications.

Currently the diagnostic standard for Gestational Diabetes is the one suggested by the International Association of Diabetes and Pregnancy Study Groups (IADPSG). IADPSG recommended a single-step approach to the diagnosis of GDM in 2010, i.e. 75 g OGTT for all pregnant women. GDM is diagnosed if one or more plasma venous glucose values exceeded the following thresholds: fasting >92 mg/dl, one hour ≥ 180.0 mg/dl, or two hour ≥ 153 mg/dl³. However in majority of the low income nations, most of the ladies do not get sufficient exposure to health care

facility and they simply avoid visiting health care facilities as they are mostly daily wage earner. Travel to a health care facility is more often at the cost of hunger or loss of job. With this in view the Diabetes in Pregnancy Study Group of India (DIPSI) in India suggested the single step testing for GDM. DIPSI test involves administering 75 gm of oral glucose in 300 ml of water (to be consumed over 5-10 minutes) irrespective of the fasting status of the woman. It is also worth mentioning that Indians (South East Asian) ladies are 11 times more susceptible to Gestational Diabetes than Caucasian ladies. Hence DIPSI recommends screening in the first antenatal visit (even if it is First trimester) itself. This test is both screening as well as diagnostic for GDM.⁴ Although this method of testing has been validated and approved by Govt of India and is recommended by FOGSI and MoHFW, India, several studies done in India and abroad have suggested conflicting results as compared to the standard IADPSG 75 gm OGTT.

Despite multiple deliberation of the issue in various international workshops and a lot of research in the field, there is still no unique approach to diagnose and treat diabetes in pregnancy. This study compares the sensitivity and specificity of DIPSI OGTT as against the standard IADPSG OGTT.

Aims and Objectives:

1. The aim of the study is to compare the efficacy of DIPSI OGTT as opposed to standard IADPSG OGTT in diagnosing Gestational Diabetes Mellitus.
2. The Objective of the study is to compare the sensitivity and specificity of DIPSI OGTT against standard IADPSG OGTT criteria

Methods and Material:

A prospective Diagnostic Evaluation Study was carried out at a zonal hospital in Eastern India amongst the Antenatal patients attending ANC OPD in the dept of Obstetrics and Gynaecology over a period of 2 years. The study spanned over 18 months starting from December 2020.

A total of 450 ladies enrolled for the study. To estimate sensitivity & specificity of DIPSI with respect to IADPSG (with sensitivity of 74% & specificity of 96% with 10% absolute error of margin & level confidence as 0.95), the minimum samples required was 73 positive & 14 negative by IADPSG criteria. However, we studied 75 positive & 75 negative by IADPSG criteria. 75 consecutive patients who tested positive for GDM by IADPSG criteria and 75 consecutive patients who tested negative for GDM were assessed for their results of DIPSI OGTT. To obtain these 150 patients, a total of 450 patients were screened. Guidelines as per declaration of Helsinki and Good clinical practice guidelines were followed while conducting the study⁵.

After obtaining written & informed consent from all pregnant ladies during first antenatal visit in first trimester (< 12 weeks of period of gestation), were subjected to OGTT test by both IADPSG & DIPSI criteria on two separate occasions 7 days apart. OGTT test by IADPSG criteria is not recommended in the first trimester. However in order to validate results of DIPSI OGTT done in first trimester, IADPSG OGTT was also done in the first trimester.

Those ladies who are not diagnosed to have diabetes, were subjected to OGTT test by both IADPSG & DIPSI criteria on two separate occasions 7 days apart again in second trimester during 24 – 28 weeks of period gestation.

IADPSG criteria: Blood sugar level fasting 92mg%, followed by consumption of 75 gm oral glucose & blood sugar level again measured at the end 1 hr >180 mg%, at the end 2 hr > 153mg

DIPSI criteria: Blood sugar level after consumption of 75 gm oral glucose > 140 mg% irrespective of meal status.

Data was collected in excel sheet and sensitivity and specificity were calculated using 2 by 2 table(Mc Nemmer's Method).

Results:

A total of 150 Antenatal patients were enrolled for this study. 75 of these were OGTT positive and 75 OGTT negative by IADPSG Criteria.

The mean age of the participating population was 27 years and 10 months, the youngest being 19 year old and the eldest being 44 year old.

The mean Gestational Age at delivery was 37 weeks 6 days , earliest being 26 weeks and 3 days and the latest being 40 weeks and 3 days. The demographic parameters are shown in Table 1.

Of the 150 participating ladies, 49 were primigravidas and 101 were multigravidas.

The average fetal weight at delivery was 2.85 kg, lowest being 1.2 kg and the heaviest being 3.85 kg.

71 patients had Vaginal delivery, 78 had CesareanSection , 1 had Intra uterine fetal demise and 1 had instrumental delivery. Out of the 149 live born neonates, 33 required NICU admission, mostly for Transient tachypnoea of newborn.

Out of the 75 IADPSG detected GDM patients, 58 of them were detected by DIPSI as well (True Positive). DIPSI failed to detect 17 GDM patients who were actually positive by IADPSG Criteria (False Negative).

Out of the 75 IADPSG declared non GDM patients, none were found to be positive by DIPSI criteria.

Arranging this data in a 2x2 table for statistical analysis (Table 2), sensitivity and specificity have been calculated.

Sensitivity of DIPSI compared against IADPSG is $a/(a+c) = 58/(58+6) \times 100\% = 90\%$

Specificity of DIPSI compared against IADPSG is $d/(b+d) = 75/(75+0) \times 100\% = 100\%$

Discussion:

This study was a prospective Diagnostic Evaluation study carried out at an East Indian Zonal Hospital with 150 participating Antenatal patients reporting to the Antenatal clinic. 75 of these women had tested positive for GDM by the IADPSG criteria and 75 of them were negative for GDM by the IADPSG criteria. These women were screened in the 1st trimester and between the 24th to 28th weeks of gestation as well. Those who tested positive for GDM in the 1st trimester were not subjected to repeat analysis in the second trimester. 3 days subsequent to their OGTT testing with IADPSG criteria, all of these ladies were given a glucose load of

75 gm irrespective of their last meal status. Considering the IADPSG criteria as the Gold Standard, the Sensitivity and Specificity of the DIPSI test were calculated using standard 2x2 table statistical analysis (Mc Nemmer's Method). In our study, we calculated the Sensitivity and Specificity of DIPSI as 90% and 100% respectively (With the consideration that Concurrent values by IADPSG are 100% accurate).

The results of our study are very much in congruence with those of the 2015 C Anjalakshi etal⁶ and 2018 Shazia Khan etal⁷ studies. In 2015 C Anjalakshiet al compared the efficacy of DIPSI OGTT against IADPSG OGTT in 800 pregnant women. They concluded that there was no statistically significant difference in the results between the Glucose Challenge Test(GCT) and WHO OGTT when used in the diagnosis of GDM. They recommended GCT performed irrespective of the last meal timing as a patient-friendly method for screening for GDM. Likewise in 2018 Shazia Khan et al studied the sensitivity and specificity of DIPSI against Carpenter Coustan standards. In this study, they compared results in 100 patients using the DIPSI criteria and the Carpenter Coustan standard. The sensitivity and specificity of the DIPSI test were 100% and 97.14% respectively, as against the Carpenter Coustan Standards. The positive and negative predictive values of the DIPSI test were found to be 83.87%, and 100% respectively as against the Carpenter Coustan Standards. The positive likelihood ratio and negative likelihood ratio were 35.8 and 0. Diagnostic accuracy was found as 97.56%. They concluded that DIPSI (having high sensitivity, specificity, negative predictive value, and diagnostic accuracy) is a simple, feasible, convenient, and economical test for universal screening and diagnosis of GDM on a mass scale.

Gestational Diabetes is a major complication in Pregnancies across the globe. India being the Diabetes Capital of the World, shares a massive load of such patients.

Time and again this condition has been implicated in a large number of fetomaternal and neonatal complications including a substantial number of fetal losses. Although the disease burden is quite high, the effects can be well controlled with timely institution of diet control, therapy, and decision for delivery. This makes timely screening and diagnosis the cornerstone in the management of the illness.

India being a developing country has a large load of low and middle-income groups of patients. Health care for such patients more often than not is always at the cost of foregoing daily wage. Hence such poor patients cannot afford multiple visits during pregnancy. While the developed world is racing towards establishing sophisticated antenatal screening in the community level, the situation in developing nations like ours is pretty much the opposite. We are still struggling to fulfill the basic three antenatal visits as mandated by WHO. In such a situation it is beneficial to the patient and the health care system to have such tests in their armament that are cost and time effective and require minimal or no pre-test preparation.

DIPSI fulfills the criteria of such a test as it is a single prick, single visit test. The patient requires no pre-test preparation for this test. The result of our study and that of Shazia Khan et al and that of Anjalakshiet al bear testimony to the fact that DIPSI is as specific and sensitive as IADPSG OGTT. However over the years time and again various studies have also proved to the contrary like those conducted by Pulkit Viz et al⁸, Reva Tripathi et al⁹, Viswanathan Mohan et al¹⁰ and Kavita et al¹¹. Hence the vacuum still exists in establishing the diagnostic efficacy of DIPSI to be usable as the standard test on a global scale.

Conclusion:

Gestational Diabetes and its associated complications are still a major contributor to maternal and neonatal/fetal morbidity and mortality. There have been several types of screening processes recommended for its diagnosis. The best approach as adopted by WHO is undoubtedly the IADPSG Criteria. However, in resource-poor and developing countries like India, the DIPSI criteria is also a good alternative to the IADPSG criteria. Because of a single-step, cheap, and patient-friendly approach, this screening method can be safely recommended for use in the screening as well as diagnosis of Gestational Diabetes in India. In resource-adequate set-up it will be worthwhile to continue using the IADPSG criteria as it is the Gold Standard. Larger multicentric multinational studies are required to establish the diagnostic efficacy of DIPSI as an equally efficacious alternative to the standard IADPSG OGTT in the Global scale.

Tables:

Table 1 : Demographic Parameters		
Parameter	Range	Mean
Age	19 – 44 years	27years 10 months
Gestational Age	26 weeks 3 days- 40 weeks 3 days	37 weeks 6 days
Fetal Weight at	1.2 kg – 3.85 kg	2.85 kg

delivery		
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Table 2: 2x2 Table for statistical analysis		
GDM by IADPSG	GDM PRESENT	GDM ABSENT
GDM PRESENT by DIPSI	58 (a)	0 (b)
GDM ABSENT by DIPSI	17 (c)	75 (d)

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