



International Journal of Current Research and Academic Review

ISSN: 2347-3215 Volume 4 Number 5 (May-2016) pp. 27-33

Journal home page: <http://www.ijcrar.com>

doi: <http://dx.doi.org/10.20546/ijcrar.2016.405.004>



Evaluation of Validity and Efficacy of DIPSI Criteria for Screening of Gestational Diabetes Mellitus

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KEYWORDS

Gestational Diabetes Mellitus,
Validity and efficacy of
DIPSI

A B S T R A C T

The main aim and objectives of this study includes, to compare the one step and two step procedure for diagnosis of GDM. This study was done at Deptt. Of Obst. & Gynaecology, S.N. Medical College, Agra between September 2013 to September 2015 with a total of 750 antenatal women irrespective of gestational age and gravidity and association of any clinical/historic risk factors for GDM. Out of these 150 women did not complete the study. A detailed history taking and clinical examination was done along with BMI. Routine investigation were done at 24-28 weeks gestation. Two step procedure which included 50gm GCT followed by 75gm OGTT for patients screened positive by 50gm GCT (WHO Criteria) was performed. All the patients also underwent 75gm 2hr OGTT(WHO Criteria) as the final diagnostic test. Mean 20.87+/-4.53 years, mean BMI 25.29+/-3.58 kg/m². 43 cases were diagnosed of GDM retrospectively. Only 26 (60.4%) of these women were GCT positive and rest 17 (39.6%) were GCT negative. Thus sensitivity and specificity of GCT is 60.4% and 78.5% respectively. For universal screening we favour a single GTT with a 75gm of oral glucose load and diagnosing women with a 2hr PPG \geq 140mg/dl as GDM. This method recommended by WHO serves both as a one step screening and diagnostic procedure and is east to perform besides being economical.

Introduction

Gestational diabetes mellitus (GDM) is carbohydrate intolerance that either begins or is first diagnosed during pregnancy. Its prevalence rate is between 2% and 18%¹. According to different geographical regions and ethnicity women with a history of GDM have a 3.5 fold increased risk of developing diabetes mellitus compared to normal population and it increases perinatal

morbidity and mortality². Therefore the identification and early diagnosis of GDM are important for both maternal and fetal health.

A worldwide consensus on the diagnostic criteria and recommended screening test for GDM has not yet been reached and new diagnostic criteria are being introduced over

time to avoid exposure of pregnant women to non physiological glucose loads for which DIPSI has come up with a simple test. Its still a dilemma about which test to apply to our Indian population. Therefore, this study was undertaken to evaluate and compare the two step and one step screening procedures (test propagated by DIPSI) & to find out a one step procedure which serves both as screening & diagnostic tool at the same time & which is acceptable, economical & feasible to perform in Indian context

Evaluation of two step procedure for diagnosis of GDM - 50 gm OGCT followed by 75 gm OGTT (WHO Criteria).

Evaluation of 75 gm OGTT for diagnosis of GDM as a single step procedure, (DIPSI guidelines, a modified version of WHO criteria).

Compare the above two screening procedures.

Materials and Methods

A randomised Prospective Study was conducted in the Department of Obstetrics & Gynaecology, S.N. Medical College, Agra between September 2013 to September 2015.

A total of 750 antenatal women having gestational age 24 to 28 weeks with or without risk factors for diabetes were included in the study.

Exclusion criteria included, diagnosed cases of diabetes mellitus, patients with gestational age <24weeks or >28weeks.

At first antenatal visit the patients were enrolled for the study. Detailed obstetric, family history & history for any other risk factor was taken.

NICE Clinical Guidelines 63 - Diabetes in Pregnancy

Body mass index above 30 kg/ml
Previous macrosomic weighting 4.5 kg and above

Previous gestational diabetes

Family history of diabetes

Family origin with high prevalence of diabetes.

South Asian (especially women whose country of family origin in India, Bangladesh and Pakistan).

Black Carribean

Middle eastern (especially women whose country of family origin in Sourth Arab USA, Iraq, Jordan, Siriya, Oman, Qtar, Qwait, Egypt).

General clinical and obstetrical examination was done and BMI was calculated (with pre-pregnancy weight(if available) or weight at first antenatal visit.Routine investigations done- ABO-Rh ,Hb, Urine routine & microscopy, HIV, VDRL, Serum T4 & TSH.

At 24-28 weeks , following tests were done-

II Step Test was done irrespective of any dietary preparation and meal status cases were given 50 gm glucose , in 200 ml of water to be consumed within 5 minutes and after next one hour her blood sample was taken to asses concentration of glucose in blood by glucose peroxidase method (cut-off value 130 mg/dl).All women were again called after 72 hours for 75 gm OGTT.

I Step Test- For this test , patient is advised to take unrestricted carbohydrate diet (almost 150 gm of carbohydrate per day) and then fasting for a minimum of 8-12 hrs prior to the test. 75 gm of glucose was given in 300 ml water to be consumed in 5 minutes. Blood sample collected after 120 mins and sent for glucose estimation by glucose peroxidase test (cut-off vlaue 140 mg/dl).

Principle of Glucose Peroxidase Test- Glucose Oxidase (GOD) catalyses the oxidation of glucose to gluconic acid. The formed hydrogen peroxide is detected by a chromogenic oxygen receptor phenol amino phenazone in the presence of peroxidase.

Results and Discussion

According to Table 1 mean age was 26.87 ± 4.53 years, majority of the patients were hindus and were residing in urban areas and belonging to Gr. III of socio economic class by B.G. Prasad classification.

Table II shows that there was nearly an equal distribution of amongst the gestational age groups 24-26 weeks and 26-28 weeks and table III says that the majority were gravida 3 or above. Fig 1 shows that the maximum number of patients had BMI <25. Fig 2 shows the risk factor distribution which says that 80% women in the study group did not have any risk factors while 20% women had risk factors out of which family history of diabetes was seen maximally followed by previously history of GDM and a bad obstetric history in the form of previous abortions , IUDs, and also a history of a previous macrosomic baby. As depicted in Table III, the screening result with 50gm GCT is positive in 24.8% cases while it is negative in 75.2% . According to the Table IV, 75gm OGTT by WHO criteria,

43 (8.6%) are positive while 457(91.4%) are negative. Table V shows on retrospective analysis out of these 43 cases only 26 cases were GCT positive. So had it not been for the 75gm OGTT, the remaining 17 cases would have been missed if the two step procedure was followed. Because OGTT is generally performed only for those who are GCT positive, so if this was followed, 17 (39.6%) potential cases of GDM would have been missed. This proves better sensitivity of the one step procedure (table V).

The importance of preventing GDM is that two generations, the woman herself and her children are at risk of developing diabetes in the future. Ethnically Indian women have high prevalence of diabetes, nearly eleven fold increased risk of developing gestational diabetes compared to caucasian women. Hence universal screening during pregnancy has become important in our country. For this we need a simple procedure that is economical and feasible for our population.

A number of investigators have found out that as age increases GDM increases 3, 4. According to our study, as age increases, the incidence of GDM increases from 11.6% in age group 18-20 yrs to as much as 41.8% in age group ≥ 31 yrs. Also prevalence of GDM increases with increase in maternal weight and it is seen in our study about 44.8% women with GDM have a BMI ≥ 30 . This is in correspondence with V. Seshiahld *et al.*

In our study first trimester BMI was considered as reference as all patients were enrolled in their early first trimester visit. There is also increase in prevalence with increasing gravidity from 44.2% in primigravida to 51% in gravida ≥ 4 .

Considering the risk factor association, it is seen in our study that in 67% women with GDM there were no risk factors while in the remaining groups, a positive family history

of diabetes (11.62 %), a bad obstetric history (9.3%), previous history of macrosomic baby (4.6%), previous history of GDM (6.976 %) was seen.

Table.1 Demographic Profile of Subjects Studied

Mean age (yrs)	26.87±4.53
Religion	Hindu (50.2%)
Inhabitation	Urban (58.8%)
Socio-economic class	Gr. III (28.6%)

Table.2 Distribution of Study Women on the Basis of Period of Gestation

Period	No.	PERCENTAGE
24-26 wks	241	48.2
26-28 wks	259	51.8
Total	500	100
mean±sd	26.04±0.10	

Table.3 Distribution of Study Women on the Basis of Gravidity

GRAVIDA	NUMBER	PERCENTAGE
Gravida 1	141	28.2
Gravida-2	163.6	32.6
Gravida-3 or above	186	47.2
Total	500	100
mean±sd	163.53±29.07	

Table.4 Screening Result for Gdm with 50 Gm Gct in Women Studied

50 gm gct (mg/dl)	NUMBER	PERCENTAGE
Screening positive (≥130 mg/dl)	124	24.8
Screening negative (<130 mg/dl)	376	75.2
Total	500	100

Table.5 Statistical Comparison of Glucose Challenge Test (GCT) Oral Glucose Tolerance Test (OGTT)

	OGTT +ve (N=43)	OGTT -ve (N=457)	TOTAL
GCT +ve	26/43 (a) (60.4%)	98(c)	124(a+c)
GCT -ve	17/43(b) (39.6)	358(d)	376(b+d)
Total	43(a+b)	457(c+d)	500(a+b+c+d)

Figure.1

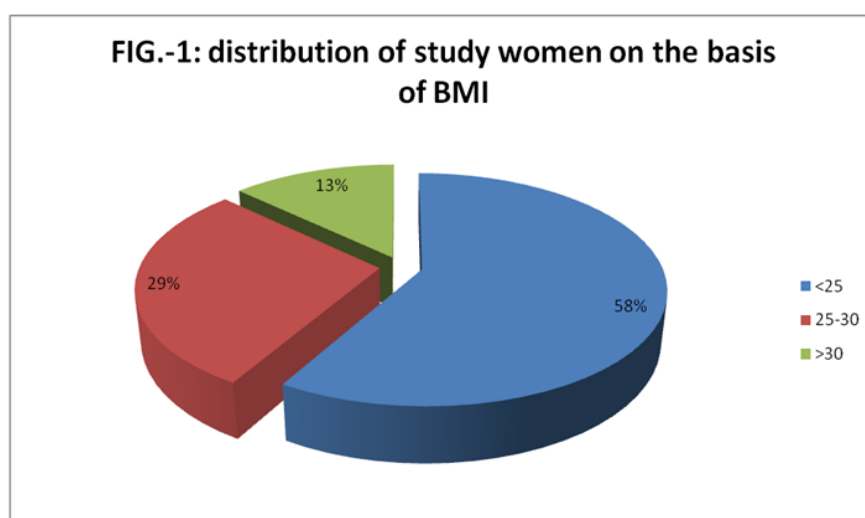


Figure.2A

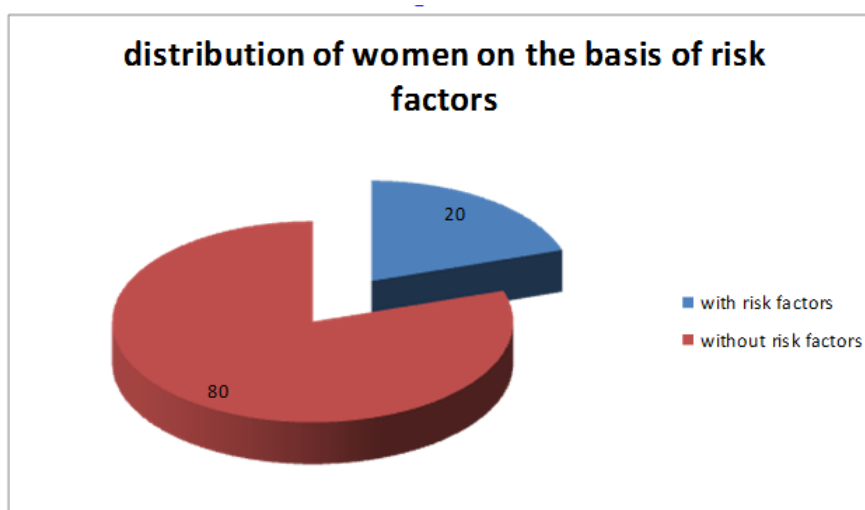


Figure.2B

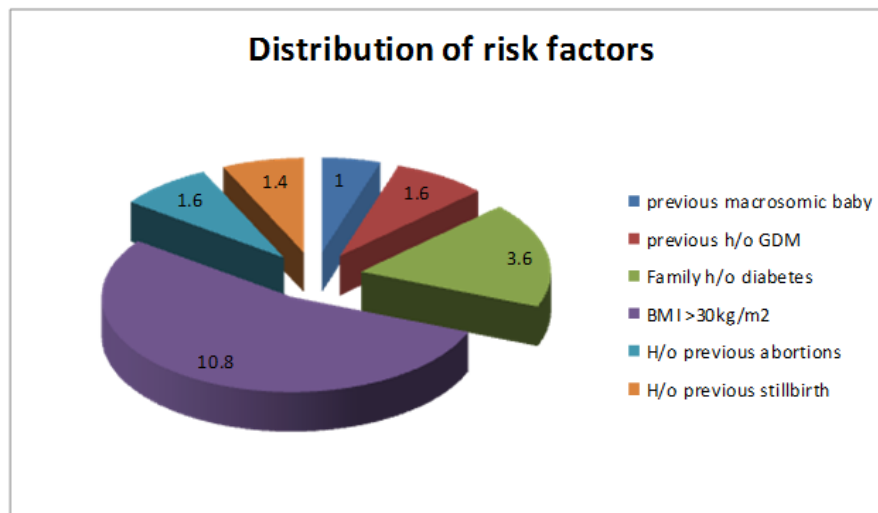
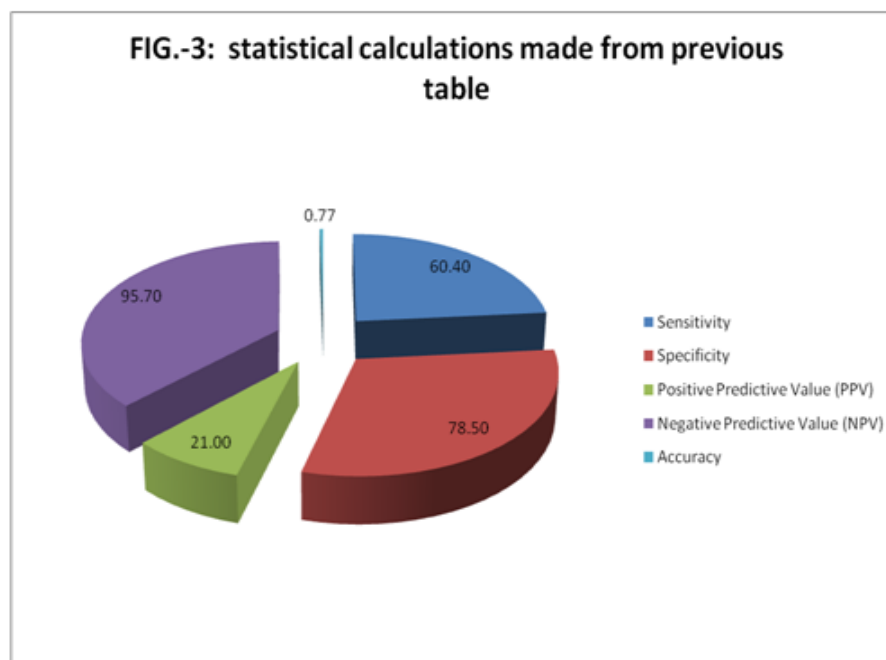


Figure.3



The incidence of GDM in different studies were, carpenter and couston *et al.*, - 1.5%, Vinita das *et al.*, - 4.0%, Green *et al.*, - 4.5 % and the incidence in our study was 8.6%. The higher incidence is probably due to the fact that ours is a tertiary care centre with all sorts of referral cases.

In our study incidence of GDM was 8.6% by I step method while it comes to be 5.2% by

II step method and the diagnostic pick up rate 1.6 times more with WHO criteria than with two step criteria which is in accordance with other studies by other workers like Shmidt *et al.*, who reported 3 times more pick up rate with WHO criteria than II step criteria and Seshiahld *et al.*, who reported 4 times more pick up rate with WHO criteria than II step criteria.

Thus the II step procedure not only has a low sensitivity but also the compliance of patients is very less and cost is increased of testing and repeat visit, thereby making the single step procedure by DIPSI as a cost effective and clinically reliable screening as well as diagnostic method for GDM.

Conclusion:

For universal screening in our Indian setting a single OGTT (oral glucose tolerance test) recommended by WHO (with 75 grams glucose and cut off ≥ 140 mg/dl after 2 hours) serves both as a one step screening and diagnostic procedure with high sensitivity and is easy to perform besides being economical.

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How to cite this article:

Meenal Jain, Shikha Singh, Latika Pant and Garima Singh. 2016. Evaluation of Validity and Efficacy of DIPSI Criteria for Screening of Gestational Diabetes Mellitus. *Int.J.Curr.Res.Aca.Rev.4(5): 27-33*. doi: <http://dx.doi.org/10.20546/ijcrar.2016.405.004>