International Journal of Reproduction, Contraception, Obstetrics and Gynecology
Gowda SH et al. Int J Reprod Contracept Obstet Gynecol. 2021 Sep;10(9):3544-3548
www.ijrcog.org
pISSN 2320-1770 | eISSN 2320-1789

DOI: https://dx.doi.org/10.18203/2320-1770.ijrcog20213482

Original Research Article

Validation the sensitivity and specificity of diabetes in pregnancy study group of India recommended 75 g oral glucose challenge test by comparing with carpenter and couston 100 g oral glucose tolerence test

Shashikala H. Gowda, Tarigopula Swathi, Rakshitha B.*

Department of Obstetrics and Gynecology, Kempegowda Institute of Medical Sciences, Bangalore, Karnataka, India

Received: 30 June 2021
Revised: 29 July 2021
Accepted: 30 July 2021

***Correspondence:**
Dr. Rakshitha B.,
E-mail: rakshirakshitha0@gmail.com

ABSTRACT

Background: Diabetes is one of the most common non communicable diseases globally. India is considered as the world diabetes capital. Women detected with gestational diabetes mellitus (GDM) have an increased incidence of developing diabetes; especially type 2 diabetes mellitus in the later life, and future development of obesity and diabetes in the offspring. So the aim of this study is to validate the sensitivity and specificity of diabetes in pregnancy study group of India (DIPSI) recommended 75 g oral glucose challenge test (OGCT) by comparing with carpenter and couston 100 g oral glucose tolerance test (OGTT) and to note the prevalence of gestational diabetes in antenatal population attending Kempegowda Institute of Medical Sciences (KIMS).
Methods: All antenatal patients reporting to our hospital at or before 24 to 28 weeks period of gestation will be recruited for the study. Patients at random will be subjected to 75g glucose load according to DIPSI criteria and one week later to carpenter and couston 100 g OGTT. Blood glucose is estimated from venous blood using glucose oxidase and peroxidase (GOD-POD) method and patients diagnosed according to respective criteria.
Results: Most of the patients were in age distribution of 20–25 years. Among 100 patients in study group 28 were diagnosed as GDM by DIPSI criteria. Among 100 patients, 12 patients were detected as GDM by carpenter and couston GTT, 19 patients had impaired glucose tolerance. The incidence of GDM in the antenatal population attending KIMS hospital between gestational ages of 24–28 weeks is 12%.
Conclusions: DIPSI can be used as a diagnostic test for GDM as one step simple and easy procedure especially I low resource settings like India for improved pregnancy outcome.

Keywords: Intravenous iron sucrose, Iron carboxymaltose, Postpartum anaemia, Haemoglobin, Serum ferritin

INTRODUCTION

Diabetes mellitus is a group of metabolic disorders characterized by hyperglycemia resulting from defects in insulin secretion, insulin action or both.1 Several distinct types of diabetes mellitus exist and are caused by a complex interaction of genetics, environmental factors and life style choices.[1] The prevalence of diabetes mellitus in India, in adults was found to be 2.4% in rural and 4-11.6% in urban population. High frequencies of impaired glucose tolerance, shown by those studies, ranging from 3.6-9.1%, indicate the potential for further rise in prevalence of diabetes mellitus in the coming decades.[2] It is estimated that 1 out of every 200 pregnancies is complicated by diabetes mellitus and additionally that 5 in every 200 pregnant women will develop gestational diabetes.[3] Normal pregnancy is associated with altered maternal glucose homeostasis and metabolism. Pregnancy is considered to be a diabetogenic state characterized by

exaggerated rate and amount of insulin release, associated with decreased sensitivity to insulin at cellular levels. Many of the changes are a result of the progressive rise in the levels of oestrogen, progesterone, human placental lactogen, cortisol and prolactin as pregnancy advances. Many of these hormones are insulin antagonists, causing insulin resistance in the mother and cause abnormal glucose tolerance in some women rendering them prone for gestational diabetes.[4]

It is important to identify a pregnant woman with gestational diabetes mellitus because gestational diabetes mellitus (GDM) is associated with significant metabolic alterations, increased perinatal mortality and morbidity, maternal morbidity and exaggerated long term morbidity among the mothers and their off spring.[5]

The frequency of GDM and its associated maternal, perinatal and long term morbidity emphasize the importance of an appropriate screening method. Despite >30 years of research, lack of consensus remains regarding nearly every clinical aspect of GDM. The need to screen, diagnostic criteria, treatment and even the validity of GDM as meaningful diagnosis.[5] The screening of all pregnant women for GDM should be universal which is also recommended by the second and third international workshops on GDM and the World health Organization (WHO) expert committee on diabetes.[6,7]

Fourth international workshop conference on gestational diabetes emphasized on selective screening.[8] The American college of obstetricians and gynecologists (ACOG) the contrary, advocates selective screening.[8] However it has been observed that the selective screening based on traditional risk factors, 35% of GDM will be missed.[9] This study was planned with a aim to find the prevalence of GDM in the pregnant women at Kempegowda Institute of Medical Sciences (KIMS) hospital, Bangalore.

METHODS

Prospective study over a period of 18 months from 01 January 2016 to 30 June 2017. All antenatal women attending OBG clinic at or before 28 weeks gestational age at KIMS, Bangalore

A total 100 antenatal women at or before 28 weeks gestational age attending OBG clinic at KIMS hospital.

Inclusion criteria

All antenatal patients reporting for the first time at or before 28 weeks period of gestation.

Exclusion criteria

Antenatal patients reporting for the first time after 28 weeks period of gestation patients lost to follow-up after 1 week known case of diabetes mellitus.

Methodology

All antenatal patients reporting to our hospital for the first time at or before 28 weeks period of gestation will be recruited for the study. They will undergo screening for GDM for high risk factors like age >25 years, body mass index (BMI) >25 kg/m2, family history of diabetes, past obstetric history of GDM, macrosomia, and anomalous fetus.

Patients at random will be subjected to 75 g glucose load according to diabetes in pregnancy study group of India (DIPSI) criteria and one week later to Carpenter and Couston 100 g oral glucose tolerance test (OGTT) blood glucose is estimated from venous blood using glucose oxidase and peroxidase (GOD-POD) method and patients diagnosed according to respective criteria.

Statistical analysis

The study data will be analyzed using statistical package for social sciences (SPSS). Independent Chi square test will be used to correlate different methods of diabetes screening.

RESULTS

Most of the patients were in age distribution of 20–25 years. The mean age of study population is 25.41 years. Maximum numbers of patients were multipara. Most of the patients in the sample had pre obese BMI. The average BMI of the study group is 25.84. This classification is according to WHO Asian guidelines for BMI. The most common medical disorder was hypothyroidism. H/o abortion and family H/o GDM were most common risk factors in study population.

Most of the patients were taking mixed diet. Among 100 patients in study group 28 were diagnosed as GDM by DIPSI criteria. 8 people diagnosed as GDM were primipara and 4 were multipara. There is no evidence of statistically significant difference in the prevalence of GDM among different age groups.

Table 1: Sensitivity and specificity of DIPSI compared with GTT.

OGCT	GTT		Total
	Positive	IGT/negative	
Positive	11	17	28
Negative	1	71	72
Total	12	88	100

Sensitivity 91.7%, specificity-80.7%, positive predictive value-40%, negative predictive value-98.6%, diagnostic accuracy-82%

Among 100 patients, 12 patients were detected as GDM by carpenter and couston GTT, 19 patients had impaired glucose tolerance (Figure 3).

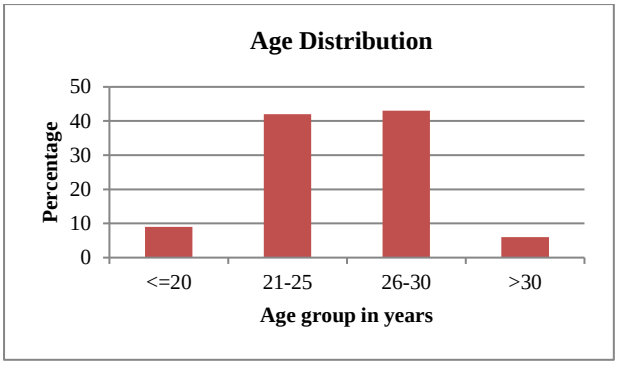

Figure 1: Age distribution.

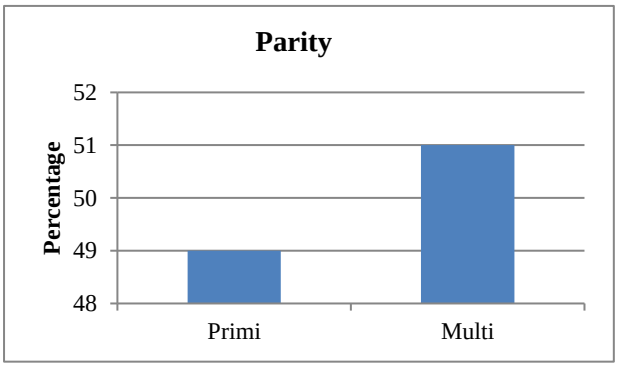

Figure 2: Parity.

Among 28 patients detected as GDM by DIPSI only 11 were confirmed by GTT, 11 had impaired glucose tolerance and 6 had normal GTT. Among 72 patients detected as normal by DIPSI, 1 had GDM according to GTT, 8 had impaired glucose tolerance and 63 were normal by GTT. The kappa value is 0.46 for agreement between DIPSI and GTT (Figure 4).

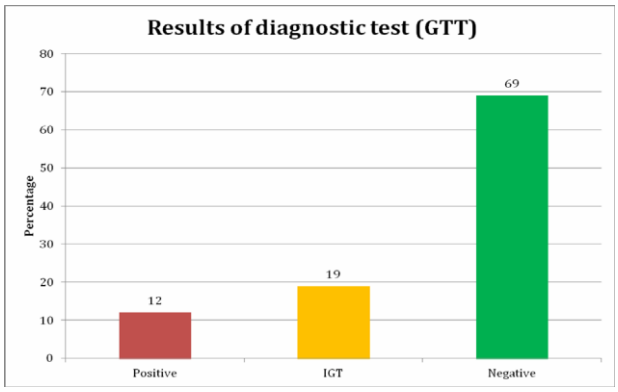

Figure 3: Results of diagnostic test (GTT).

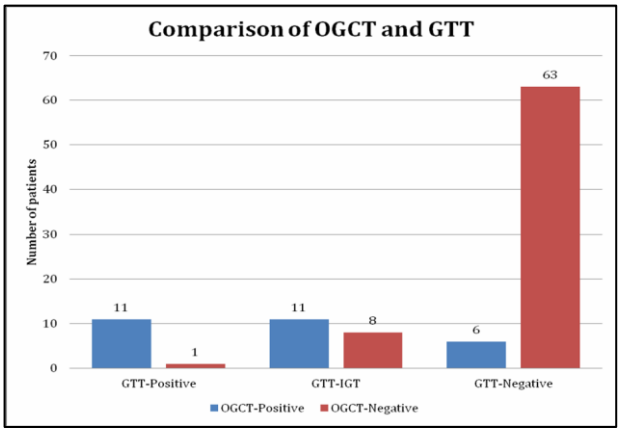

Figure 4: Comparison of OGCT and GTT.

Table 2: Association of GDM (GTT) with presence of risk factor.

Risk factor	GTT			
	Number of patients	Positive n (%)	IGT/negative n (%)	P value
Past history of GDM	4	3 (75.0)	1 (25.0)	<0.001
Family history of DM	26	4 (15.4)	22 (84.6)	0.5
H/o abortion	26	3 (11.5)	23 (88.5)	0.9
H/o Macrosomia	7	0 (0)	7 (100)	NA
h/o Anomalous baby	9	3 (33.3)	6 (66.7)	0.04
h/o Pre-term	5	3 (60)	2 (40)	0.001
Obesity (BMI≥30)	23	6 (26.1)	17 (73.9)	0.03

Among 12 patients diagnosed as GDM, 3 had past h/o GDM, 4 had family h/o diabetes, 3 had h/o abortion, 3 had history of anomalous baby, 2 had history of preterm labor, and 6 had obesity (Table 2).

Incidence

The incidence of GDM in the antenatal population attending KIMS hospital between gestational ages of 24–28 weeks is 12%.

DISCUSSION

There is an 11 fold increase in the risk of GDM in the Indian ethnicity. Among 27 million pregnant women per year in Indian population, only a fraction of women obtain

antenatal care. Due to increased risk universal screening is a mandatory approach for Indian context. Many women in developing countries avail antenatal care late in second or third trimester or may approach the health facility during labor without attending any antenatal clinic. In the last decade, as per the national data, health indicators including utilization of antenatal care services were as poor as 50–60% in rural areas, and there is a dropout of nearly one-third in the follow-up visits.

A practical, cost-effective, easy, and convenient screening test is required so that the women can be tested during their initial visit even in a non-fasting state as many may not return subsequently in a fasting state. So accordingly diabetes in pregnancy study group India has designed a one-step non-fasting test which meets all the above criteria and this has been approved by ministry of health government of India. But there still is a lot of controversy about the sensitivity and specificity of this test in diagnosing GDM. Hence I have chosen this study to help clear up this dilemma surrounding DIPSI.

This study is conducted in KIMS hospital, Bangalore and 100 women between 24 to 28 weeks attending antenatal clinic. The mean age of study population in the present study was 25.41 compared to 25.02 in Sexana et al, 24 in Vishwanathan mohan et al, and 24.6 in Geetha et al.[10-12]

In the present study there is no statistically significant difference in incidence of GDM between different age groups. The prevalence proportion increased with age from 14.5% in the age group of 15-19 years to 25% in the age group >30 years in the study conducted by Seshiah et al but this was not seen in the present study.

The mean BMI of the study population in the preset study was 25.8 which was in pre obese range compared to 25.55 in Geetha et al, 24.89 in Saxena et al and 22.6 in Mohan et al.[10-12]

In the present study BMI >30 has been associated with increased chance of developing GDM. 50% of the patients who were diagnosed with GDM had BMI >30. So obesity is a very important risk factor for GDM. Similar conclusions regarding the relation between obesity and BMI have also been drawn in the studies by Saxena et al and Geetha et al.[10,12]

Age >25 years, past history of fetal loss, family history of diabetes, obesity are the most Common risk factors in the study population. These are compared to a similar Indian study in above table. The results of the present study are almost comparable to the study of Saxena et al.[10]

The most common risk factor in GDM population was past history of GDM, age >25 years, obesity, history of congenital anomalies. These have been compared to three other studies in the above table. They are comparable in most parts to Jindal et al which is an Indian study.[13]

Age is the most common risk factor in Western countries but not in India. Our study has the less number of GDM patients in risk age group as compared to Western studies and among Indian studies. This may be because our study population was younger as compared to other studies.

The sensitivity and specificity of our study is comparable to Saxena et al study which is conducted in 2017.[10] It is also similar in results to Badikallaya et al and Sharma et al studies.[14,15] The study which is by Mohan et al shows that DIPSI has low sensitivity and high specificity compared to WHO and International association of diabetes and pregnancy study groups (IADPSG) criteria.

In our study the positive predictive value of DIPSI was 40% and the negative predictive value was 98.6%. The accuracy of DIPSI was 82%. The kappa value for agreement between DIPSI and GTT was 0.46 which shows moderate agreement in values. So DIPSI can be used as a diagnostic test for GDM especially in Indian context where a single step diagnostic test is ideal.

Incidence

The incidence of GDM in our study was 12%.The prevalence of GDM in the present study comparable with that of study done by Bhattacharya et al (3%) and Gupta et al (3.05%).[16]

Prevalence found in study by Das et al (4%) is higher comparative Swami et al, was 7.7% and Seshaiah et al was 16.55% which is much higher compared to other studies.[17,18] All the above are studies on Indian women.

So, glucose testing in non-fasting state improves acceptability. The WHO has accepted the IADPSG criteria as the new WHO criteria in 2013 although it recognizes a few important and pertinent observations with regard to GDM testing. GTT is resource intensive, and many health services, especially in low-resource settings, are not able to routinely perform OGTTs in pregnant women. In these circumstances, many health services do not test for hyperglycemia in pregnancy. Taking multiple venous samples as recommended by ADA, IADPSG requires extra. So, glucose testing in non-fasting state improves acceptability. The WHO has accepted the IADPSG criteria as the new WHO criteria in 2013 although it recognizes a few important and pertinent observations with regard to GDM testing. GTT is resource intensive, and many health services, especially in low-resource settings, are not able to routinely perform OGTTs in pregnant women. In these circumstances, many health services do not test for hyperglycemia in pregnancy. Taking multiple venous samples as recommended by ADA, IADPSG requires extra cost, manpower, and resources. Doing a two-step test is also not feasible as many women may be lost to follow-up. Thus, diagnosing GDM with a single sample is practical and economical. Moreover, the pregnant women will not be pricked multiple times for taking venous samples.

Limitations

One of the limitations of this study is that maternal and fetal outcomes based on these recommendations are not available.

CONCLUSION

This study proves that DIPSI can be used as one step diagnostic test especially in a low resource setting like India since the incidence of diabetes is very high which makes universal screening mandatory.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Kasper D, Braunwald E, Hauser S, Longo D, Jameson JL, Fauci A. Harrison's Principles of Internal Medicine. 16th ed. McGraw-Hill. 2005;II:2152-3.
2. Park K. Park's Preventive and Social Medicine. 18th ed. Banarsidas Bhanot. 2005;312-4.
3. Albert RE. Diabetes in pregnancy obstetrics and gynaecology. Clinics of North America. WB Saunders Company. 1996;23(1):10.
4. Danilenko-Dixon DR, Winter V, Nelson RL, Ogburn PL. Universal versus selective gestational diabetes screening: Application of 1997 American Diabetes Association Recommendations. Am J Obstet Gynecol. 1999;181:798-802.
5. First International Workshop. Conference on Gestational Diabetes: Summary and recommendations. Diabetes Care. 1980;3:499-501.
6. American Diabetes Association. Summary and recommendations of Second International Workshop Conference on Gestational Diabetes mellitus. Diabetes. 1985;34(2):123-6.
7. Metzger BE. The organising committee: Summary and recommendations of Third International Workshop. Conference on Gestational Diabetes Mellitus. Diabetes. 1991;40(2):197-201.
8. Metzger BE, Coustan DR. Summary and recommendations of the fourth international workshop conference on gestational diabetes mellitus. Diabetes Care. 1998;21:161-7.
9. Coustan DR. ALOG practice bulletin no 30 gestational diabetes. Am J Obstet Gynecol. 2001;525-37.
10. Miller HC. The effect of prediabetic state on survival of the fetus and the birth weight of the new born infant. N Engl J Med. 1945;233:376-8.
11. Mohan V, Mahalakshmi MM, Bhavadharini B, Maheswari K, Kalaiyarasi G, Anjana RM. Comparison of screening for gestational diabetes mellitus by oral glucose tolerance tests done in the non-fasting (random) and fasting states. Acta Diabetol. 2014;51(6):1007-13.
12. Geetha N, Sangeetha KG. Comparison of IADPSG And DIPSI Criteria for Diagnosis of Gestational Diabetes Mellitus. IOSR J Dent Med Sci. 2016;15(9):1-4.
13. Jindal A, Ahmed F, Bhardwaj B, Chaturvedi B. Prevalence, clinical profile and outcome of gestational diabetes mellitus. J Obst Gyn of India. 2001;30(4):333.
14. Badikillaya VU, Adusumalli P, Venkata RG, Pernenki S. Effectiveness of Diabetes in Pregnancy Study Group India (DIPSI) diagnostic criterion in detecting gestational diabetes mellitus—a pilot study in a rural population. Indian J Basic Appl Med Res. 2013;2(6):614-8.
15. Sharma K, Wahi P, Gupta A. Single glucose challenge test procedure for diagnosis of gestational diabetes mellitus: a Jammu cohort study. J Assoc Physicians India. 2013;61:558-9.
16. Gupta A, Gupta YV. Screening of Gestational Diabetes with Glucose Challenge Test in high risk group. JK Science. 2006;8(2).
17. Das V, Kamra S. Screening for Gestational Diabetes and Maternal and Fetal outcome. J Obstet Gynecol India. 2004;54(5):449-51.
18. Swami SR, Mehetre R, Shivane V, Bandgar TR, Menon PS, Shah NS. Prevalence of carbohydrate intolerance of varying degrees in pregnant females in western India (Maharashtra)--a hospital-based study. J Indian Med Assoc. 2008;106(11):712-4.

Cite this article as: Gowda SH, Swathi T, Rakshitha B. Validation the sensitivity and specificity of diabetes in pregnancy study group of India recommended 75 g oral glucose challenge test by comparing with carpenter and couston 100 g oral glucose tolerence test. Int J Reprod Contracept Obstet Gynecol 2021;10:3544-8.