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COMPARISON OF DIAGNOSTIC ACCURACY OF DIPSI, HbA1c AND WHO CRITERIA FOR THE DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS

Obstetrics & Gynaecology

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ABSTRACT

Successful maternal health shall be achieved with efforts to reduce maternal injury and disability. Gestational diabetes mellitus (GDM) is a serious health issue in many regions of the globe. According to the diagnosing approach, there is a large variance in the prevalence of GDM. Gestational diabetes mellitus is usually asymptomatic and is most diagnosed by routine screening during pregnancy. The present study entitled "Comparison of diagnostic accuracy of DIPSI, HbA1c with WHO criteria for the diagnosis of gestational diabetes mellitus" was conducted on 100 participants in the department of obstetrics and gynaecology, SMGS Hospital Jammu, over a period of one year. The diagnostic accuracy of non-fasting diabetes in the Pregnancy Study Group of India (DIPSI) and Haemoglobin A1c (HbA1c) with fasting WHO criteria for diagnosis of gestational diabetes mellitus were compared. It was found that DIPSI showed better agreement with gold standard WHO criteria in diagnosing the cases of gestational diabetes mellitus compared to HbA1c.

KEYWORDS

GDM; Diagnosis; DIPSI; HbA1c

INTRODUCTION

Maternal health refers to the health of women during pregnancy, childbirth, and the postnatal period. Although important progress has been made in maternal health in the last two decades, about 295000 women died during and following pregnancy and childbirth in 2017 **(WHO, 2017).** Although the maternal mortality ratio dropped by 38% worldwide between 2000 and 2017, the number of deaths is unacceptably high. 94% of all these maternal deaths are reported in low-income and lower-middle-income countries **(WHO, 2017).**

Gestational diabetes mellitus (GDM), often referred to as gestational diabetes, can be defined as 'glucose intolerance or hyperglycemia (high blood glucose concentration) with onset or first recognition during pregnancy **(WHO, 1999)**. Based on the methodology used for diagnosis, the variation of prevalence is significantly considerable. Indian women require universal screening as they experience an eleven times higher risk of development of GDM when compared to Caucasian women **(Sridhar GR *et al., 2003*).**

GDM in India is estimated to be 10-14.3. In the Indian setup easy, cost-effective, reliable diagnostic method is required as follow-up dropouts are common. The one-step 75gm 2-hour OGTT diagnostic criteria for hyperglycemia in pregnancy recommended by WHO in 1999 were not evidence-based, are over ten years old and required upgradation in light of new data. An ongoing issue that has been problematic with 1999 WHO criteria relate to (FPG) criterion. The diagnostic level (≥7.0) mmol/l is considered to be very high **(Chi *et al.*, 2018)**.

To assess the evidence quality and strength determination of diagnostic cut-off values for diagnosis of GDM, Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology was utilized. Some groups used only the 2-h plasma glucose (PG) measurement without measuring FPG, while others used both FPG and 2-h PG measurements. In the latter case, the cut-off value of ≥7.0 mmol/l or ≥ 6.1 mmol/l (levels diagnostic of impaired fasting glucose) has been used. Diabetes in pregnancy can be diabetes mellitus or gestational diabetes mellitus. The WHO, in its report, addressed the classification and diagnosis of gestational diabetes. Any of the following numbers, at any point during pregnancy, should be used to make the diagnosis of gestational diabetes mellitus.

- Fasting plasma glucose=5.1-6.9 mmol/l (92-125 mg/dl)
- 1-hr post 75g oral glucose load v>= 10.0 mmol/l (180 mg/dl) *
- Post 75g oral glucose load 8.5 – 11.0 mmol/l (153-199 mg/dl)

*There are no established criteria for the diagnosis of diabetes based on the 1-hour post- load value. The difference from IADPSG guidelines is that these new WHO guidelines set a range of plasma glucose levels to distinguish diabetes in pregnancy and GDM **(WHO, 2013).**

75-gram glucose challenge test has been recommended by the Diabetes in Pregnancy Study group India (DIPSI) for the diagnosis of GDM. This is a one-step procedure, feasible, economical, and simple to execute **(Seshiah V *et al.*, 2005).** Ministry of Health, Government of India has recommended DIPSI criteria for the diagnosis of GDM **(Mellitus GD, 2014)**. There is still a controversy over the specificity and poor sensitivity of DIPSI at present when compared to other tests **(Mohan V *et al.*, 2014; Herath M *et al.*, 2015 and Vij P *et al.*, 2015).** The current position of DIPSI remains controversial as few recent studies have reported its poor sensitivity and specificity compared to other tests **(Vij P *et al.*, 2015)**.

HbA1c is another potential single test that can be done in a non-fasting state during the initial visit and gives an idea of sugar levels over three months. It has been used for diagnosing gestational GDM and pre-diabetes in pregnant women, and a high level of HbA1c has been seen to be closely associated with adverse outcomes in women with pre-diabetics and GDM **(Aldasouqi SA *et al.*, 2008)**.

The International Expert Committee appointed by the European Association for the Study of Diabetes, the American Diabetes Association (ADA), and the International Diabetes Federation, a cut point of HbA1C ≥6.5% was taken to diagnose diabetes. In 2011, WHO supported HbA1C >6.5% to be used for the diagnosis of diabetes. HbA1C 5.7- 6.4% before 20 weeks of gestation have shown to be at higher risk of developing GDM, according to some studies. As a diagnostic test for GDM, HbA1c has certain advantages for both physicians and patients. It can be done in a non-fasting state and is proved to be less cumbersome and more reproducible than OGTT **(Sacks DB, 2011).**

Therefore, the WHO criteria were chosen as the gold standard in this study as GDM based on this criterion has been shown to predict adverse pregnancy outcomes. The current study aimed to compare the diagnostic accuracy of DIPSI and HbA1c with fasting WHO criteria for diagnosis of GDM.

MATERIALS AND METHODS

The cross-sectional study was be undertaken in the department of

obstetrics and gynecology of SMGS Hospital, Jammu over a period of one year after proper institutional and ethical approval. The informed written consent from each participant was taken for the study.

Study tool: Proforma, siemens Autoanalyzer dimension RL max for venous blood sugar measurement and BIO-RAD D 10 to measure HbA1c. Study group included singleton pregnancy of gestational age less than 20 weeks. Exclusion criteria for study group were multiple gestations, Type 2 diabetes mellitus, incomplete Data, personal dissatisfaction or refusal for consent.

The study population was comprised of 100 singleton pregnancies with less than 20 weeks of gestational age, after written informed consent. Weight, height, BMI of each participant was measured. The blood sugar fasting, and blood sugar post prandial values of pregnant female were tested during first trimester. The patient was then called during 24 to 28 weeks of her gestational age. After informed consent and proper explanation, non-fasting pregnant women were given 75 gm glucose (anhydrous form) in 300 ml of water, that was supposed to be consumed within 5-10 minutes irrespective of their previous meal as recommended by DIPSI. Exactly after 2 hours, venous blood sample was taken, and the blood sugar was measured. Glycated haemoglobin (HBA1C) was also measured using venous blood sample. The participants were instructed to return after 72 hours with few instructions. The pregnant women were instructed to take unrestricted diet and do physical activity as she followed routinely. Patient was also instructed to keep fasting for 8 to 14 hours before the WHO GTT testing. Venous blood sample was taken to determine the blood sugar fasting value. 75 gm of anhydrous glucose in 250-300ml water was then given to the participant and venous blood sugar levels were measured after 1 hour and 2 hours of consumption of 75gm of anhydrous glucose. Details were recorded in the proforma devised for the study. The values obtained through DIPSI, HbA1C and WHO OGTT were evaluated and compared. The comparison based on these testing criteria were thus established. Further calculations were made to determine sensitivity, specificity, positive predictive value, negative predictive value, diagnostic accuracy, and other pertinent variables.. DIPSI ≥140 mg/dl was taken as positive and < 140 mg/dl as negative for GDM. The cut off value for HbA1c was taken as 5.7. The HbA1c ≥5.7% were taken as positive and <5.7 as negative for GDM. The cut off values for WHO OGTT test were taken as per WHO OGTT criteria for diagnosis of gestational diabetes mellitus. Fasting blood sugar 92-125mg/dl,1-hour post 75gm oral glucose load >=180mg/dl and 2-hour post 75gm oral glucose load 153-199mg/dl was taken as cut off values. Although there are no established criteria for diagnosis based on the 1-hour post load value, GDM was diagnosed if any one or more of above criteria were met. WHO OGTT test for diagnosis of gestational diabetes mellitus was taken as the gold standard test for this study.

2.1 Venous blood sugar measurement

The venous blood sugar levels were measured in Shri Maharaja Gulab Singh Hospital, Shalamar Jammu using Siemens autoanalyzer Dimension RLMax using Flex reagent cartridge. The procedure adopts the glucose (GLUC) method which if further an adaption of hexokinase-glucose-6-phosphate dehydrogenase method.

2.2 HbA1c value measurement

The HbA1c value was measured with Bio-Rad D10 testing system. The D-10 Dual program was employed for the measurement and calculation of HbA1c. The program is compatible only with the Bio-Rad D-10 hemoglobin testing system. It includes the analytes' separation by ion-exchange high-performance liquid chromatography technique. The analysis is done by chromatogram generation from the collected data and peak analysis. An algorithm is applied in the form of exponentially modified Gaussian technique to evaluate A1c peak area.

RESULTS

83.3% of the patients with age >35 years ,80% of the women with age 31-35years, 81.4 % of women with age 26-30 years were found to be diagnosed as gestational Diabetes mellitus.95% of the patients who were post graduate ,71% who were graduate ,83.3% with secondary education, 75% with primary education and 70 % illiterate were diagnosed gestational diabetes mellitus.81.4% of urban residents and 73.3 % of rural residents were diagnosed gestational diabetes mellitus.83.3% of participants with BMI ≥30 kg/m^2 ,79.4 % study group with BMI 25-29.9 kg/m^{2}and 73.7% study participants with BMI 18.5-24.9kg/m^2 were diagnosed with gestational diabetes mellitus. Statistically age, educational status, residence and BMI were found insignificant in this study with p value >0.05 .82.3% of multigravida and 73.7% of primigravida were diagnosed with gestational diabetes mellitus. Statistically there is no association of gestational diabetes mellitus with gravida (p value >0.05) 85.5% of study group with family history of Diabetes mellitus were diagnosed with gestational diabetes mellitus. 64% of study group without family history of diabetes mellitus were diagnosed with gestational diabetes mellitus. In this study family history of diabetes mellitus in patients with gestational diabetes mellitus is statistically significant with p value 0.017. (p value <0.05 ***Statistically Significant (P-value<0.05).**85% of patients with history of large for gestational age babies or macrosomia were diagnosed as gestational diabetes mellitus while 75.9 % patients without this history had gestational diabetes mellitus.76.5% of participants with history of polyhydromnios were found to be gestational diabetes mellitus while 74.5% without history of polyhydromnios were diagnosed as gestational diabetes mellitus. 84.2 % participants with history of spontaneous abortions and 73 % of patients without history of spontaneous abortions were diagnosed with gestational diabetes mellitus.75 % patients with history of congenital malformations and 74.4 % without history of congenital malformations were gestational diabetes mellitus. History of LGA/macrosomia, polyhydromnios, preterm labour, spontaneous abortions, congenital malformations were found to be statistically insignificant with p value>0.05. 93.7% of patients who were diagnosed as gestational diabetes mellitus with gold standard WHO OGTT criteria were found to be positive with DIPSI as well while, only 9.5% were false positive.6.3% of women were found to be negative with DIPSI as diagnostic criteria but were positive with WHO OGTT test. DIPSI diagnosed 90.5 % of patients as negative for gestational diabetes mellitus who were also negative with WHO OGTT test.9.5% of patients were found to be negative by standard WHO OGTT test but DIPSI diagnosed them as positive for gestational diabetes mellitus.

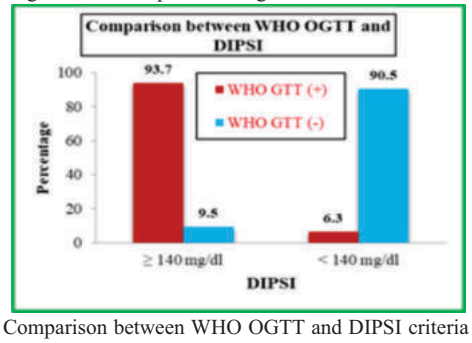

Fig. 1 Comparison between WHO OGTT and DIPSI criteria for the diagnosis of GDM

Fig. 2 depicts various parameters predicting the diagnostic accuracy of DIPSI taking fasting WHO OGTT as gold standard.

- Sensitivity of non-fasting DIPSI as a diagnostic test for gestational diabetes mellitus is 93.7 % with 95% confidence interval 86.1-97.3 in this study.
- Specificity of DIPSI as a diagnostic test was found to be 90.5% with 71.2-97.4 as 95% confidence interval in this study.
- Positive predictive value of DIPSI was calculated as 97.4 % with 95% confidence interval of 90.9-99.3 in this study.
- Negative predictive value of DIPSI was found to be 79.2% with 95% confidence interval of 59.5-90.8 in this study.
- Diagnostic accuracy of DIPSI as a diagnostic test for diagnosis of gestational diabetes mellitus was calculated as 93 % with 95% confidence interval of 86.3-96.6 in this study.

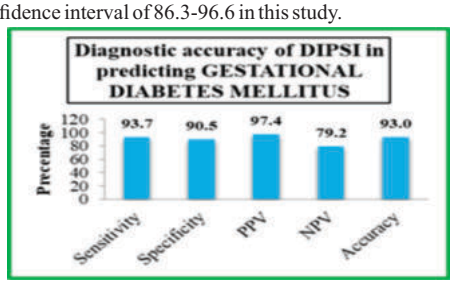

Fig. 2 Percentage diagnostic accuracy of DIPSI in predicting GDM

Fig. 3 illustrate comparison of HbA1c with WHO OGTT in diagnosing gestational diabetes mellitus.57% of patients diagnosed as gestational diabetes mellitus by HbA1c were positive by WHO OGTT criteria.

43% of patients diagnosed as non-gestational diabetic with HbA1c were actually found to be gestational Diabetes with WHO OGTT criteria. 100% patients who were diagnosed as negative for gestational Diabetes with HbA1c were actually negative with standard WHO OGTT test.

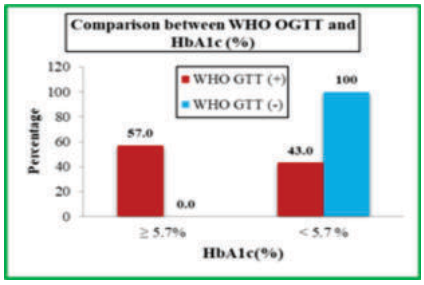

Fig. 3 Comparison of WHO OGTT and HbA1c in diagnosing GDM

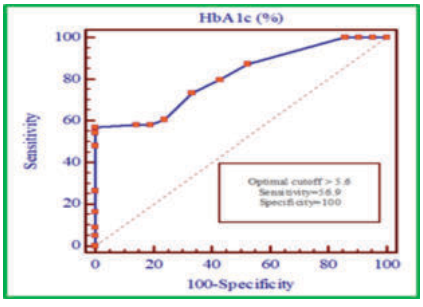

Fig. 4 ROC curve depicting optimal cut-off, sensitivity and specificity of HbA1c (%) for prediction of gestational diabetes mellitus

The ROC curve (Fig. 4) depicts the optimal cut-off value of HbA1c that can be taken to diagnose gestational diabetes mellitus. The optimal cut-off value obtained was ≥5.7%.The sensitivity of the test at cut-off value of ≥5.7% was found to be 56.9 % with 95%confidence interval value was 45.9-67.3.The specificity of the test was found to be 100 % with 95%confidence interval value 84.5-100.Positive predictive value of the HbA1c value ≥5.7% was 100 with 95%confidence interval of 92.1-100.Negative predictive value of HbA1c test at cut-off≥5.7% was calculated as 38.2% with 95%confidence interval of 26.5-51.4.Accuracy of HbA1c test at cut-off value ≥5.7% was calculated to be 66 % with 95%confidence interval of 56.3-74.5.Area under ROC curve with HbA1c value ≥5.7% was 0.809 with 95%confidence interval of 0.719-0.881.In this study P value calculated for HbA1c ≥5.7% as a diagnostic test for diagnosis of gestational diabetes mellitus taking WHO OGTT as gold standard was <0.001 which is statistically highly significant (Fig.5).

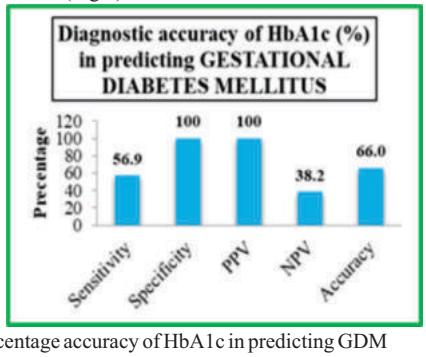

Fig. 5 Percentage accuracy of HbA1c in predicting GDM

HbA1c showed a low positive correlation (r = 0.415, P<0.001) with blood sugar fasting value, low positive correlation (r=0.456, p<0.001) with one hour post load blood sugar value and a high positive correlation (r = 0.614, P<0.001) with 2 hours post load blood sugar value of WHO GTT criteria. On the other hand, DIPSI showed high positive correlation (r = 0.617, P<0.001) with WHO criteria of blood sugar fasting, 1 hour post load (r=0.456, p<0.001), and even higher positive correlation (r = 0.739, P<0.001) with 2 hours post load blood sugar value of WHO GTT criteria.

DISCUSSION

Based on the methodology used for diagnosis, the variation of prevalence rates is significantly considerable. Prevention of complications in pregnancy and in later life of both mother and baby, can be done by early detection and thereby achieving normoglycemia.

In my study, the mean age of the participants was 27.8±4.65 years, mean gestational age was 25.7±0.98 weeks, and mean BMI was 27.2±2.81.

In another study conducted by **Hinkle SN *et al.* (2018)** 17% patients belong to <25 years of age, 56% patient belongs to 25-34 years of age and 27% patients belongs to ≥35.

In my study 20 (20%) participants with a post-graduation qualification, 31 (31%) with graduation, 19 (19%) with secondary education, 20 (20%) with primary education, and 10 (10%) participants were illiterate.

Findings are not consistent with the study conducted by **Hussain T *et al.* (2020)**, in the study 2% were illiterate, 96% had studied up to college level as there is a difference between educational status of participants.

In my study, 30 (30%) of the participants resided in rural areas, whereas 70 (70%) participants lived in urban areas. A similar study conducted by **Hussain T *et al.* (2020)** total of 33% patients were from rural areas, 12% were from urban areas and 55% were residing in slums. About 56% of the pregnant women residing in slums were having diabetes.

In the present study, 38 (38%) participants were primigravida and 62 (62%) were multigravida. Findings agree with the study conducted by **Riaz M *et al.* (2018),** in the study (29.1%) women were primigravida, while (69.9%) were multigravida.

In my study, 14 (14%) participants had a history of LGA/macrosmia. In another study conducted by **Wahi P *et al.*, (2011),** 10% study subjects had macrosomia.

In my study, 17 (17%) participants had a history of polyhydromnios. In my study, 8 (8%) participants had a history of preterm labour. In another study conducted by **Wahi P *et al.* (2011),** 4.2% study subjects had preterm delivery. In my study, 19 (19%) participants had a history of spontaneous abortions.

In a study conducted by **Zargar AH *et al.* (2004)** reported that women with gestational diabetes mellitus had a history of abortions. In my study, 8 (8%) participants had a history of congenital malformations.

Findings agree with the study conducted by **Wahi P *et al.* (2011),** 6.45 % study subjects had congenital malformation, shoulder dystocia. In my study, family history of diabetes was reported by 69 (69%) participants while 31 (31%) participants did not have family history of diabetes.

In another study conducted by **Riaz M *et al.* (2018) and Hinkle SN *et al.* (2017)**, 18.8% had family history of diabetes. In my study according to WHO GTT criteria, there were 79 (79%) participants who were diagnosed as having Gestational Diabetes Mellitus (GDM).

In similar study conducted by **Mohan V *et al.* (2014)** out of 1031 pregnant females who underwent a 75gm OGTT in both fasting and non-fasting states ,83 women had GDM by WHO 1999 criteria and 23 women were diagnosed as GDM by DIPSI.

In another study conducted by **Saxena P *et al.* (2017)** out of 800 women 51 were diagnosed for GDM by WHO 1999 criteria and 63 by DIPSI. In my study there was statistically insignificant association between demographic variables, obstetrics history and GDM in this sample.

In my study there was a statistically significant association between GDm and the family history of diabetes (P=0.017). Those having a family history of Diabetes mellitus were significantly more likely to have GDM. In my study women diagnosed as GDM by the DIPSI method were 74 and diagnosed as GDM by WHO method were 79. Sensitivity (TP/TP+FN) of DIPSI in this study was found to be 93.7%. Specificity (TN/TN+FP) of DIPSI in this study was found to be 90.5%. Positive Predictive Value (TP/TP+FP) of DIPSI in this study was

found to be 97.4%. Negative Predictive Value (TN/TN+FN) of DIPSI in this study was found to be 79.2%. Diagnostic Accuracy of DIPSI (TP+TN/TP+TN+FP+FN) in this study was found to be 93%.

In similar study conducted by **Shrestha B and Pokhrel L (2020)**, reported 25 (5.88%) cases were diagnosed GDM, 5 (1.18) only by WHO 2018, 6 (1.41%) were diagnosed only by DIPSI, and 14 (3.29%) by both methods. DIPSI was found to be 73.68% sensitive and specificity was 98.52%. The agreement between the WHO 2018 and DIPSI criteria ranged from 60% to 80% (Kappa value = 0.68).

In another study conducted by **Mounika E & Loke C (2018)**, compared the 75gm glucose load in non-fasting state DIPSI criteria for GDM in pregnant women with Oral Glucose Tolerance Tests (OGTT). The plasma glucose value ≥140 mg/dl two hours after glucose load in 45 (7.5%) patients. When compared to IADPSG and WHO criteria, the sensitivity values were 72.4 and 63.3% respectively and the specificity was 96.9 and 96.3% respectively.

In my study DIPSI showed high positive correlation (r = 0.658, P<0.001) with WHO criteria of blood sugar after 1 hour and high positive correlation (r = 0.742, P<0.001) with blood sugar after 2 hours. The area under ROC = 0.943.

Findings agree with the study conducted by **Saxena P *et al.* (2017)**. Authors reported the diagnostic accuracy of 98.25%. The area under the ROC curve related to DIPSI was 0.988 ($p < 0.001$) (95% confidence interval: 0.960-1.000).

In similar study conducted by **Mohan V *et al.* (2014)** The DIPSI non-fasting OGTT 2-h VPG cut point value of 140 mg/dl (7.8 mmol/l) relates to very low sensitivity as compared to the criteria of WHO (1999) (specificity 97.7 %, sensitivity 27.7 %) and IADPSG criteria (specificity 97.8 %, sensitivity 22.6 %).

In my study women diagnosed as GDM by HbA1c method were 45 and diagnosed as GDM by WHO method were 79. Sensitivity (TP/TP+FN) of HbA1c in this study was found to be 56.9%, Specificity (TN/TN+FP) of HbA1c in this study was found to be 100%, Positive Predictive Value (TP/TP+FP) of HbA1c in this study was found to be 100%, Negative Predictive Value (TN/TN+FN) of HbA1c in this study was found to be 38.2%.

The findings agree with the study conducted by Saxena *et al.* (2017) reported that the sensitivity of HbA1c to that of WHO GTT was 47.06%, and specificity 97.86%.

In another study conducted by **Renz PB *et al.* (2015)** reported 6.5% women presented HbA1c ≥48 mmol/mol. This cut-off point presented 100% specificity but very low sensitivity (7%). Based on ROC curve, and considering OGTT as the reference criterion, HbA1c ≥40 mmol/mol (5.8%) showed adequate specificity in diagnosing GDM (94.9%) but low sensitivity (26.4%). HbA1c values of 31 mmol/mol (5.0%) presented adequate sensitivity (89.7%) but low specificity (32.6%) to detect GDM. For women with HbA1c ≥40 mmol/mol (5.8%), the positive and negative likelihood ratios were 5.14 (95%CI 2.49–10.63) and 0.78 (0.68–0.88), respectively.

In similar study conducted by **Rajput R *et al.* (2012)** reported that the mean HbA(1c) value in women having GDM was higher (5.73 ± 0.34% compared to 5.34 ± 0.35%) than women without GDM. An HbA(1c) cut-off value ≥5.95% had sensitivity 28.6% and specificity 97.2% in diagnosing GDM while an HbA(1c) cut-off value ≥ 5.45% had sensitivity - 85.7% and specificity - 61.1% in diagnosing GDM.

In present study the diagnostic Accuracy (TP+TN/TP+TN+FP+FN) of HbA1c in this study was found to be 66%. HbA1c showed a moderate positive correlation (r = 0.456, P=<0.001) with WHO criteria of blood sugar after 1 hour, and a high positive correlation (r = 0.614, P<0.001) with WHO criteria of blood sugar after 2 hours. The area Under ROC = 0.809.

Findings are correlated with the study conducted by **Rajput R *et al.* (2012)** reported area under ROC curve of HbA(1c) to detect GDM was 0.805. In another study conducted by **Renz PB *et al.* (2015)** reported that based on ROC curve, and considering OGTT as the reference criterion, HbA1c ≥40 mmol/mol (5.8%) showed adequate specificity in diagnosing GDM (94.9%) but low sensitivity (26.4%).

In another study conducted by **Saxena P *et al.* (2017)** reported the diagnostic accuracy 94.63% as thehe ROC curve between WHO GTT and HbA1c covered an area of 0.805 ($p < 0.01$) (95% confidence interval: 0.731-0.879).

CONCLUSIONS

The gestational diabetes mellitus is usually asymptomatic and is, most commonly diagnosed by routine screening during pregnancy. In order to diagnose gestational diabetes mellitus, the diagnostic accuracy of nonfasting DIPSI and HbA1c with fasting WHO criteria was examined. It was found that DIPSI showed better agreement with gold standard WHO criteria in diagnosing the cases of gestational diabetes mellitus compared to HbA1c.

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