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Comparative study of capillary blood glucose estimation by glucometer and venous plasma glucose estimation in antenatal women undergoing screening for gestational diabetes

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Abstract

Background: Women with history of gestational diabetes mellitus are at increased risk of future diabetes, predominantly type 2 diabetes, as their children. Timely action taken now in screening of 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. This study was undertaken to find one step procedure as screening and diagnostic tool that is acceptable and feasible and to compare merits and demerits of capillary blood glucose over venous plasma glucose estimation by DIPSI for detection of gestational diabetes mellitus.

Methods: It was a Comparative analytical study. Conducted on 300 ANC consenting booked women aged between 25-35 years of any parity with live singleton pregnancy between the gestational age of 24-28 weeks and were not known to have other chronic illnesses. DIPSI performed by administering 75 gm glucose dissolved in 300 ml water and patient was asked to drink irrespective of fasting status. Venous blood drawn after 2 hours while CBS measured by glucometer.

Result: Sensitivity of CBS method in detecting gestational diabetes mellitus is 96.2% as compared to venous plasma glucose and specificity 94.5%.

Conclusion: Due to high sensitivity and specificity it is feasible to offer capillary blood sugar sampling by DIPSI test for screening and diagnosis of gestational diabetes mellitus in remote areas of India. Prevalence of gestational diabetes mellitus is 13.6% by CBS and 9% by venous plasma glucose.

Keywords: NIL.

INTRODUCTION

Women with history of gestational diabetes mellitus are at increased risk of future diabetes, predominantly type 2 diabetes, as their children.[1] Timely action taken now in screening in 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.[1] Diabetes in pregnancy study group India (DIPSI) diagnostic criterion of 2-h plasma glucose 140 mg/dl with 75 g oral glucose load was performed in the fasting/ non fasting state irrespective of last meal timing. This prospective study has been undertaken to ascertain the validity of DIPSI criterion by capillary blood glucose estimation by glucometer to diagnose gestational diabetes mellitus by a more easy, portable and cost-effective method rather than expensive, time

consuming and laboratory-based skill requiring method of venous sampling.

AIMS AND OBJECTIVES

To find out a one-step procedure which can serve both as screening and diagnostic tool at the same time and which is acceptable, economical and feasible to perform in the Indian context. To compare merits and demerits of capillary blood glucose estimation by glucometer over venous plasma glucose estimation by DIPSI test, for the detection of gestational diabetes mellitus.

MATERIALS AND METHODS

This study was done at a teaching hospital in Jaipur, India. 300 ANC consenting booked women aged between 25-35 years of any parity with live singleton pregnancy between the gestational age of 24-28 weeks were included in this study. Women with pregestational diabetes and other chronic renal, cardiac, hepatic or respiratory diseases and women taking glucose altering medication were excluded.

After taking approval of Institute review board and ethical committee, a detailed history of the patient was taken including family and past history of chronic diseases especially diabetes, obstetric history and socioeconomic status. Thorough general physical examination and obstetric examination was carried out. Patients underwent routine investigations during antenatal visits which were recorded. A standard proforma was used to tabulate the above data along with test results of the following procedure.

Patient was instructed to come irrespective of fasting and was asked to take a carbohydrate unrestricted diet (not less than 150 g per day) for 3 days before test was performed. 75 g of glucose was dissolved in 200-400 ml of water and asked to drink in 5 minutes.

2 ml of venous blood sample was collected in a fluoride vacutainer. The venous sample was then centrifuged at 2000 to 3000 rpm for seven minutes to separate the plasma. The plasma obtained was used to estimate the glucose concentration by Glucose Oxidase Peroxidase method using ERBA 360 auto analyzer. Simultaneously, capillary blood was collected by applying a small needle prick to the middle or ring finger under aseptic conditions. The glucometer used for the study used test strips which included Glucose dehydrogenase-PQQ (Acinetobactercalcoaceticus), mediators, buffers and stabilizers.

Categorical variables were summarized and analysed using Chi-square test. P-value < 0.05 taken as significant.

Interpretation of OGTT	2-hour venous blood sugar (mg/dl)
Normal	<140
Gestational diabetes mellitus	140-199
Overt diabetes	>200

RESULTS

As per Table-1, the mean age of the participants taken was 31.33±2.75 with the age range being 25-35 years.

The mean pre-pregnancy BMI of the participants was 21.12±2.64 with the maximum BMI being 30 and minimum BMI being 17.

In Table-2, amongst the 27 patients who tested positive for DIPSI by venous plasma glucose method, 2 patients recorded a glucose level of >200mg/dl which indicates that these patients are undiagnosed overt diabetics and need to be managed accordingly.

As we interpret from Table-3, out of 300 patients who underwent screening for gestational diabetes, 27 patients tested positive (venous plasma glucose >140 mg/dl) by the DIPSI criteria. Amongst these, 26 patients also recorded capillary blood glucose levels of >140 mg/dl and one patient recorded CBS of <140 mg/dl. This shows very high true positives and low false negatives leading to high sensitivity.

Out of 300 patients undergoing screening, 273 patients tested negative for DIPSI out of which 258 patients also tested negative by the capillary method and 15 patients tested positive. This shows very high number of true negatives and less number of false positives leading to high specificity.

In Table-4, we summarize the Sensitivity (96.2%), Specificity (94.5%), Positive predictive value (63.4%) and Negative predictive value (99.6%).

After all calculations, Chi-square value of 164.084 and p-value of <0.001 was obtained which is statistically significant.

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DISCUSSION

The present study is a comparative analytical study of cross-sectional type conducted at tertiary centre in Jaipur, India. This study involved screening of 300 antenatal patients registered with us. Patients were screened between 24-28 weeks gestational age.

Insulin resistance causing hyperglycemia increases in third trimester. Early testing may miss some patients who become glucose intolerant later. Third trimester screening limits our time for conducting metabolic interventions. Hence, this gestational age has been chosen.

Amongst ethnic groups in South Asian countries, Indian population has highest frequency of gestational diabetes mellitus rounding off to 16% prevalence. Hence, the aim of this study is conducting a one-step procedure which can justify as screening as well as diagnostic tool at the same time taking into consideration its acceptability, cost and feasibility in the Indian scenario.

Various types of tests are available to determine glucose levels. One of them performed in laboratories is the GOD-POD (glucose oxidase peroxidase method) which is done using plasma and has a turnover time of 30-40 minutes. Advantages of venous plasma glucose estimation method is that it is the standard method of screening for gestational diabetes mellitus approved by ADA and WHO. The results reflect actual glucose values in the body. But its high cost, non-portability and time-consuming nature makes it less feasible for using it as a screening method in a large Indian population considering the high prevalence of the disease in the country.

On the other hand, capillary blood glucose method of sugar estimation is portable, affordable and the test results are obtained instantly. It also requires less laboratory expertise.

The results of this study show that capillary blood glucose estimation method has good sensitivity and specificity for it to replace the conventional venous blood glucose estimation method in large populations without obtaining grossly incorrect results.

The comparative study conducted by Jadhav DS et al, where out of 1000 women screened by OGTT using capillary blood sample, 80 women were found to have gestational diabetes mellitus. Prevalence of gestational diabetes mellitus was 8% by capillary blood sugar method and 7.5% by venous plasma glucose method whereas in our study prevalence of gestational diabetes mellitus by capillary blood sugar method is 13.6% and by venous plasma glucose method is 9%.[1]

A longitudinal study conducted by Sonali Deshpande et al included 700 antenatal patients out of which 70 were diagnosed as having abnormal glucose challenge test. Sensitivity of capillary glucometer method was 100% and specificity was 99.68% when compared to venous laboratory method. This was in accordance with the results of our study with sensitivity of 96.2% and specificity of 94.5% for capillary method of estimation.[2]

In a comparative study evaluated by Nazli Hussain et al capillary blood glucose value at 2-h plasma glucose level of ≥140 mg/dl had a sensitivity of 94.87% and specificity of 79.10% with area under receiver operative curve (ROC) 86%.[3]

SAbo-Elkheir EMM conducted a study on The Accuracy of Capillary Whole Blood Glucose Versus Venous Plasma Glucose in the Diagnosis of Gestational Diabetes Mellitus in Egyptian Women.

The capillary blood glucose cut point of 140 mg/dl provides the optimal sensitivity and specificity of 90.91% and 96.63%, respectively.[4]

Sofia Nevander et al completed a study of Comparison of Venous and Capillary Sampling in Oral Glucose Testing for the Diagnosis of Gestational Diabetes Mellitus: A Diagnostic Accuracy Cross-Sectional Study Using Accu-Chek Inform II in Sweden in 2020. The results of this study concluded a sensitivity of 85.0% and specificity of 95.0%. [5]

Vijayam Balaji et al held a study of Comparison of venous plasma glucose and capillary whole blood glucose in the diagnosis of gestational diabetes mellitus: a community-based study. The capillary blood glucose value at a 2-h plasma glucose level of ≥140 mg/dl had a sensitivity of 80.2% and specificity of 98.5% with false-positive and false-negative rates of 1.5% and 19.8%, respectively. The area under the receiver operator characteristic curve of capillary blood glucose was 0.991.[6]

Rajesh K Chudasama conducted a study on Magnitude of gestational diabetes mellitus, its influencing factors

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and diagnostic accuracy of capillary blood testing for its detection at a Tertiary Care Centre, Rajkot, Gujarat. gestational diabetes mellitus was found in 20.4% pregnant women with capillary testing done by glucometer compare to 11.5% with venous blood testing. gestational diabetes mellitus was found higher among literates, homemakers, Hindus, people living in nuclear family, belongs to middle class, residing in urban area, primigravidae, obese and with gestational age between 21 and 24 weeks. Intermediate agreement (Kappa = 0.42) was found between two methods with sensitivity of 70.7%, specificity of 86.1%, positive predictive value 39.7%, and negative predictive value 95.8%.[7]

Nasreen Akther et al study to Determine the Diagnostic Accuracy of (Dipsi Criteria) Non-Fasting Oral Glucose Tolerance Test for Diagnosing Gestational Diabetes Mellitus in Mirpur Azad Jamu Kashmir concluded that There is no significant difference between plasma and capillary blood glucose. Sensitivity is 85.42% and specificity is 86.84% with positive predictive value of 67.21%. Diagnostic accuracy is 81.5%.[8]

NazliHussain et al conducted a comparative study in Pakistan where mean maternal age was 25.8 ± 5.2 years whereas in our Indian study 31.33 ± 2.75 years was the mean maternal age of being diagnosed with gestational diabetes mellitus.[3]

In a study conducted by Sofia Nevander et al in Sweden mean BMI of all antenatal women taken in the cross sectional study of OGTT for gestational diabetes mellitus diagnosis was 32.3 ± 5.1 kg/m² where in our study mean BMI is 21.12 ± 2.64.This might be because majority of the women who visited for an OGTT in European countries did so due to BMI ≥30 kg/m^2 or a family history of diabetes type 2.[5]

Ebtehal Mohsen Mahmoud Abu-Elkheir et al found that the positive predictive value was 76.92%, and negative predictive value was 98.85% which is in accordance with the values of our study.[4]

CONCLUSION

It is appropriate and feasible to offer capillary blood sugar sampling by DIPSI test for screening and diagnosis of gestational diabetes mellitus in remote areas of India where there is scarcity of medical equipments and laboratory expertise. The prevalence of gestational diabetes mellitus in this study is 13.6% by capillary blood sugar sampling and 9% by venous plasma glucose sampling according to DIPSI test.

Compliance: With ethical standards

Conflict of interest: The authors declare that they have no conflict of interest.

Ethical Statement: The study has been approved by Human and Animal Rights. This study does not involve any research work involving animals and was performed on booked antenatal patients.

Informed Consent: Informed consent has been obtained from all participating subjects prior to study.

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Table 1 : Distribution of age and pre-pregnancy BMI amongst the participants of this study

	Mean	Median	Minimum	Maximum
Age	31.33±2.75	30	25	35
Pre-pregnancy BMI	21.12±2.64	22	17	30

Table 2 : Distribution of participants into Gestational and Overt diabetics

	Venous plasma glucose levels	(mg/dl)	Total
	140-200 (Gestational diabetes)	>200 (Overt diabetes)	
Number of participants	25	2	27

Table 3 : Summary of statistical results of estimating blood sugar levels by capillary sampling using DIPSI criteria

Sensitivity	96.2%
Specificity	94.5%
Positive predictive value	63.4%
Negative predictive value	99.6%

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Table 4 : Comparison of gestational diabetes mellitus as per capillary blood sugar and venous plasma glucose sampling by DIPSI test

Test results		Venous plasma glucose levels (mg/dl)		Total patients
		≥140	<140	
Capillary blood sugar levels (mg/dl)	≥140	26	15	41
	<140	1	258	259
Total patients		27	273	300

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