Original Article

Magnitude of Gestational Diabetes Mellitus, its Influencing Factors and Diagnostic Accuracy of Capillary Blood Testing for its Detection at a Tertiary Care Centre, Rajkot, Gujarat

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Abstract

Background: Gestational diabetes mellitus (GDM) occurs during pregnancy which affects mother, fetus, and outcome of pregnancy, hence early detection is necessary. The objective of this study was to ascertain the validity of glucometer over standard biochemical testing for detection of GDM and to estimate prevalence of GDM and its associated risk factors. **Materials and Methods:** A hospital-based study was conducted at Antenatal clinics of Obstetrics Department, tertiary care hospital, based on the "National Guidelines for Diagnosis and Management of GDM." Totally 357 pregnant women between 21 and 28 weeks of gestational age agreed were included in the study from January to March 2016. After obtaining written consent, one step procedure was offered to pregnant women by giving 75 g of anhydrous glucose dissolving in 200–250 ml of water. After 2 h, glucose level was estimated by capillary testing with glucometer and venous glucose by glucose oxidase test. **Results:** GDM was found in 20.4% pregnant women with capillary testing done by glucometer compare to 11.5% with venous blood testing. GDM 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%. **Conclusion:** Intermediate agreement between two methods indicates glucometer testing can be used to screen pregnant women at an early gestational age (21 weeks), at the community level by health-care workers.

Keywords: Gestational diabetes mellitus, glucometer, prevalence, validity, venous blood testing

Introduction

At present, diabetes mellitus (DM) is one of the most common noncommunicable diseases globally. It is a major public health problem in India with reported prevalence rate between 4.6%–14% in urban areas and 1.7%–13.2% in rural areas.[1] With increasing prevalence of diabetes, there seems to be an increase in the prevalence of gestational DM (GDM). The GDM is defined as impaired glucose intolerance with onset or first recognition during pregnancy.[2] Globally, one in 10 pregnancies is associated with diabetes, 90% of which are GDM. Undiagnosed or inadequately treated GDM can lead to significant maternal and fetal complications. Women with GDM and their offspring's are at increased risk of developing type 2 diabetes in later life.[2,3]

The prevalence of gestational diabetes has been reported from 3.8% to 17.9% in different parts of India.[4-6] It is difficult to predict any uniform prevalence levels of GDM in India, because of wide differences in living conditions, socioeconomic levels, and dietary habits.[3] Several professional bodies such as the American Diabetes Association (ADA), International Association of Diabetes and Pregnancy Study Group (IADPSG), and the Diabetes in Pregnancy Study Group of India (DIPSI) recommended that screening for GDM should be universal.[7] In India, where the prevalence of diabetes is

Access this article online

Quick Response Code:

Website: www.ijcm.org.in

DOI: 10.4103/ijcm.IJCM_283_18

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How to cite this article: Chudasama RK, Kadri AM, Ratnu A, Jain M, Kamariya CP. Magnitude of gestational diabetes mellitus, its influencing factors and diagnostic accuracy of capillary blood testing for its detection at a Tertiary Care Centre, Rajkot, Gujarat. Indian J Community Med 2019;44:142-6.

Received: 12-09-18, **Accepted:** 30-05-19

very high, the chances of detecting preexisting diabetes are quite high with screening.

Despite a high prevalence of GDM in Indian women, currently, screening of pregnant women for GDM is not being done universally as part of the essential antenatal package.[2] The test is sporadically being done at district hospitals and medical colleges in some states as per direction of individual. Even though GDM is a sizeable public health problem with serious adverse effects on mother and child, testing is still at a pilot level in Gujarat state also. State Ministry of Health and Family Welfare, Government of Gujarat, planned this study at Pandit Deendayal Upadhyay (PDU) Government Medical College and Civil Hospital, Rajkot. The objective of this study was to ascertain the validity of glucometer over standard biochemical testing for the detection of GDM and to estimate prevalence of GDM and its associated risk factors.

Materials and Methods

The present study was conducted at antenatal outpatient department (OPD) at Obstetrics Department, PDU Government Medical College and Civil Hospital, Rajkot, Gujarat, India. As the screening for GDM is still not universal, the State Ministry of Health and Family Welfare directed to conduct this study at the above institute to know the GDM status. The study was conducted based on the "National Guidelines for Diagnosis and Management of GDM," Ministry of Health and Family Welfare, Government of India, December 2014.[2]

Study design and study population

A hospital-based study was conducted from January 2016 to March 2016. The study population comprised of pregnant women between 21 and 28 weeks of gestational age attending the OPD at obstetrics department during the study.

Sample size calculation

The sample size was estimated considering 16.55% prevalence of GDM reported previously.[8] The sample size of 375 was calculated by using Epi Info 7 software (version 7.2.2.2) – (Centres for Disease Control and Prevention, Atlanta, USA).[9] However, 357 eligible pregnant women were agreed to participate in the study.

Inclusion and exclusion criteria

Pregnant women between 21 and 28 weeks of gestational age were included who were attending antenatal clinic of PDU Civil Hospital, Rajkot. The national guideline recommendation includes women with 24–28 weeks of pregnancy, but in the present study as per the state ministry directives, women with 21–28 weeks of pregnancy were included. Pregnant women below 21 weeks and above 28 weeks of gestational age, and pregnant women who refused to participate in the study were excluded.

Sampling technique

All consecutive eligible women attending morning antenatal OPD daily during the study and agreed to participate in the study were selected.

Screening method and data collection

Team of two members was made including medical social workers. Pregnant women with the above inclusion criteria were invited to participate in the study. After obtaining written consent, one step procedure was offered to pregnant women by giving 75 g of anhydrous glucose dissolving in 200–250 ml of water. The intake of solution was completed within 5 min. After that, necessary sociodemographic information and anthropometric information was collected in predesigned pro forma. Modified Prasad's socioeconomic classification was used considering All India Consumer Price Index of April 2016 of Rajkot.[10] Social Class I was considered as upper, Classes II and III were considered as middle and Classes IV and V as lower for analysis. Body mass index (BMI) was calculated based on the World Health Organization (WHO) classification.[11] The study participants remained in separate premises provided for their rest. Two hours after the glucose load, the capillary blood sample was taken by pricking with lancet and blood glucose level was measured by glucometer on the spot.

The results of blood glucose level were recorded and also communicated to the pregnant women. At the same time, venous blood was also collected and sent to laboratory for 2 h postglucose load level estimation. The venous blood sample testing was done at laboratory of biochemistry department, PDU Government Medical College, Rajkot. In both the above-mentioned methods, glucose level of >140 mg/dL was taken as cutoff for the diagnosis of GDM. If required, pregnant women were referred to obstetrician/physician for further management. The data were entered and analyzed using Epi Info 7 software (version 7.2.2.2), CDC, Atlanta.[9] Data were expressed as frequencies, percentages, and appropriate statistical tests such as Chi-square test, standard error of proportion, Kappa test applied, sensitivity and specificity were measured. An ethical clearance was taken from the institutional ethical committee for conducting the study.

Results

A total of 357 pregnant women participated in the study [Table 1]. More than half (56.6%) women were from 21 to 25 years of age group [Table 1]. Majority of women were literates (85.7%), homemaker (95.2%), from joint family (65.5%), middle socioeconomic class (85.1%), and from urban area (72.6%). Two-third (66.7%) women married before 20 years of age, majority (86.3%) become pregnant by the age of 25 years. At least 3 antenatal visits were taken by 57.4% of participants. None has past history of GDM or currently diagnosed DM, hypertension. Only 3 (0.8%) participants reported family history of diabetes and hypertension each.

GDM estimation with capillary blood glucose done by glucometer was 20.4% (73/357), which was 11.5% (41/357) with venous blood testing [Table 2]. Majority of participants reported GDM with capillary testing (64.4%) and venous testing (73.2%) were below or up to 25 years of age. GDM reported with capillary method among pregnant women

were literates, homemakers, Hindus, living in nuclear family, belonging to middle class, residing in urban area, primigravidae, and obese. Participants with gestational age between 21 and 24 weeks were diagnosed GDM significantly with venous testing.

The agreement between the two methods of capillary and venous blood testing was found 0.42 indicating the intermediate agreement, i.e., glucometer testing can also be used to detect GDM though simultaneously the blood glucose level testing will be helpful to confirm the diagnosis of GDM [Table 3].

Table 1: Baseline characteristics and prevalence of gestational diabetes mellitus of pregnant women

Characteristics	GDM tested total (*n*=357), *n* (%)	GDM positive, total (*n*=73), *n* (%)
Age group (years)		
<20	49 (13.7)	11 (15.1)
21-25	202 (56.6)	36 (49.3)
26-30	88 (24.6)	22 (30.1)
>31	18 (5.1)	4 (5.5)
Education of participants		
Illiterate	51 (14.3)	5 (6.8)
Literate	306 (85.7)	68 (93.2)
Parity		
0	309 (86.6)	62 (84.9)
1	29 (8.1)	10 (13.7)
>2	19 (5.3)	1 (1.4)
Duration of pregnancy in weeks		
21-24	229 (64.1)	49 (67.1)
25-28	128 (35.9)	24 (32.9)
Number of ANC visits taken		
<2	152 (42.6)	34 (46.6)
3 or more	205 (57.4)	39 (53.4)

GDM: Gestational diabetes mellitus, ANC: Ante natal care

Sensitivity of 70.7% and specificity of 86.1% was found in the present study with capillary blood glucose testing for GDM among study participants. The above findings indicate that the glucometer can be used as the first step at both clinic level and in the community for a screening of GDM.

Discussion

DM is a growing epidemic in India, and GDM is not an exception. Several factors influence the capillary blood glucose measurements performed by different methods.[12] Various studies reported different rate of GDM prevalence ranging from 3.8% in Kashmir,[4] 6.6% in Rajasthan,[13] 6.94% in Jammu,[14] 7.1% in Haryana,[3] 9.5% in Western India,[7] 18.9% in Tamil Nadu,[6] to as high as 35% in Punjab[15] and 41% in Lucknow.[16] These studies used different criteria to diagnose the GDM such as ADA, IADPSG, DIPSI, and some others. The present study reported prevalence of GDM as 20.4% with capillary blood testing done by glucometer and confirmed as 11.5% with venous blood testing done by glucose oxidase test.

More than two-thirds (70.3%) of young pregnant women below 25 years age reported GDM,[3,6] in contrast to other studies who reported GDM with increasing age.[1,3,13,14] Higher education increases risk of GDM,[3] but the present study reported majority (75%) of pregnant women were educated up to secondary level. Homemakers are more prone to develop GDM in this study, as reported in several other studies from India.[17,18] Likewise, a study from Thiruvananthapuram, Kerala, India,[18] GDM reported among pregnant women with Hindu religion and staying in nuclear family.

The present study reported a significant number of participants with GDM were from middle socioeconomic class. In contrast, a study from Haryana and Kashmir reported that GDM was more common among women of upper socioeconomic status.[3,4] The Civil Hospital at Rajkot attracts more number of pregnant women from rural areas of Rajkot district to

Table 2: Factors associated with gestational diabetes mellitus among pregnant women

Characteristics	Total (*n*=357)	GDM	
		Capillary testing (*n*=73), *n* (%)	Venous testing (*n*=41), *n* (%)
Age group (years)			
<25	251	47 (64.4)	30 (73.2)
>25	106	26 (35.6)*	11 (26.8)*
Gravidae			
Primigravidae	309	62 (84.9)*	37 (90.2)*
Multigravidae	48	11 (15.1)	4 (9.8)
Duration of pregnancy (weeks)			
21-24	229	49 (67.1)*	33 (80.5)*
25-28	128	24 (32.9)	8 (19.5)
BMI			
<18.5 (underweight)	30	5 (6.8)	3 (7.3)
18.5-24.99 (normal)	221	43 (58.9)	23 (56.1)
25-29.99 (overweight)	79	15 (20.6)	7 (17.1)
>30 (obese)	27	10 (13.7)*	8 (19.5)*

*P<0.001. BMI: Body mass index, GDM: Gestational diabetes mellitus

Table 3: Sensitivity and specificity of capillary blood testing for detection of gestational diabetes mellitus compared to the gold standard, i.e., venous blood testing

Capillary blood testing	Venous blood testing		
	Positive	Negative	Total, *n* (%)
Positive	29	44	73 (20.4)
Negative	12	272	284 (79.6)
Total	41 (11.5)	316 (88.5)	357*

κ - 0.42 (intermediate agreement), 95% CI: 0.32-0.52, considering two glucose testing methods (value >0.75 presents excellent agreement beyond chance; <0.40 presents poor agreement; between 0.40-0.75 presents intermediate to good agreement). *Sensitivity=29/41×100=70.7%, Specificity=272/316×100=86.1%, positive predictive value=29/73×100=39.7%, negative predictive value=272/284×100=95.8%. CI: Confidence interval

utilize antenatal services. GDM was reported in 24.4% such pregnant women diagnosed by venous blood glucose from rural area, higher than study conducted in rural areas of Wardha (12.7%).[19] GDM reported more among primigravidae compare to previous studies.[3,17,18] Increasing parity increases risk of GDM, [5,14,17] but this study did not report such finding similar to previous studies.[3,20]

Several studies from different parts of India have reported association between occurrences of GDM and obesity/high BMI.[13,15,18] Similarly, obesity reported as a risk factor for GDM in the present study also. This may be due to increased demands on maternal metabolism during pregnancy from excess weight, resulting in imbalances in hormonal carbohydrate regulation mechanisms, and insulin sensitivity.[13] No study participant was reported with preexisting DM, past history of GDM during previous pregnancy or with hypertension. However, various studies have reported association of GDM with family history of diabetes and hypertension.[17,18]

The rationale for selecting the pregnant women of 21–24 weeks was implementation of the screening of GDM in community at subcenter and primary health center level which will help in early detection of GDM and its management. Considering the objective of screening by glucometer at community level, it was planned to start GDM testing from gestational age of 21 weeks. Two-third women from 21 to 24 weeks' gestational age reported GDM with glucometer testing and also with venous blood testing. A study from Maharashtra reported that prevalence rate will not change if diagnosis done before or after 24 weeks of gestational age.[6] They also recommend early detection will help in early management of GDM, especially for rural areas, with limited support.

One of the objectives of the present study was to ascertain the validity of glucometer with capillary glucose testing method with venous blood testing method. Intermediate agreement (Kappa = 0.42)[21] was observed between these two methods in the present study. Hence, the glucometer testing method can be used at community level to screen for GDM first, followed by venous blood testing if found positive with glucometer testing. Several studies have tested sensitivity and specificity using different diagnostic methods such as DIPSI, WHO, and IADPSG criteria.[22-24] Sensitivity for capillary testing by glucometer found 70.7% and specificity 86.1% when compared with venous blood testing. The study reported positive predictive value of 39.7% and negative predictive value of 95.8% with above comparison. Similar study from Tamil Nadu reported sensitivity of 62.3% and specificity of 80.7% using IADPSG criteria.[25]

The present study has some limitations including (i) it tested only national guideline of GDM, (ii) selection bias as it is only hospital based study, (iii) limited sample size, (iv) conducted at one institute only, (v) outcome not measured, (vi) follow-up was not done.

Conclusion

Various risk factors such as living in urban area, nuclear family, middle socioeconomic class, primigravidae, and obesity identified for GDM occurrence. Intermediate agreement between two methods indicates glucometer testing can be used to screen pregnant women at an early gestational age (21 weeks), at community level by health-care workers.

Financial support and sponsorship

This study was supported by the Ministry of Health and Family Welfare, Government of Gujarat.

Conflicts of interest

There are no conflicts of interest.

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