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Prevalence and predictors of Gestational Diabetes Mellitus in rural Assam: A cross-sectional study using mobile medical units

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Prevalence and predictors of Gestational Diabetes Mellitus in rural Assam: A cross-sectional study using mobile medical units

Subrata Chanda[1], Vishal Dogra[2], Najeeb Hazarika[1], Hardeep Bambrah[1], Ajit Kisanrao Sudke[3], Anupa Vig[3], Shailendra Kumar Hegde[4]

Corresponding Author: Vishal Dogra, Research and Analytics, Piramal Swasthya Management and Research Institute, Plot no. 120, 5th Floor, Srinagar Colony, Hyderabad, India; Email: vani1825@gmail.com; Tel: +9140-49451999

[1]Assam and North East State Office, Piramal Swasthya Management and Research Institute, Guwahati, India

[2]Research and Analytics, Piramal Swasthya Management and Research Institute, Hyderabad, India

[3]Clinical Domain, Piramal Swasthya Management, and Research Institute, Hyderabad, Telangana, India

[4]Department of Innovations, Piramal Swasthya Management and Research Institute, Hyderabad, India

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Key Words: Gestational Diabetes Mellitus, Assam, Mobile Medical Unit, OGTT

ABSTRACT

Objective To determine the prevalence and predictors of Gestational Diabetes Mellitus(GDM) in rural Assam, India using a network of Mobile Medical Units

Study Design A field-based cross-sectional study

Settings Rural areas of Assam state, India

Participants A total of 1410 pregnant women in gestational age of 24-28 weeks

Intervention Identification of pregnant women in 24-28 weeks of pregnancy from villages and administering them oral glucose tolerance test for Gestational Diabetes Mellitus confirmation.

Primary and secondary outcome measures Presence of gestational diabetes among pregnant women, risk factors, and predictors of Gestational Diabetes Mellitus.

Results A total of 1212 pregnant women underwent the oral glucose tolerance test. One hundred and ninety-eight women were ineligible due to existing chronic diseases or very high blood glucose level before the test. The overall GDM prevalence in Assam was 16.67% (95% CI 14.61-18.89%). Women aged 26-30 years (aOR 1.70; CI 1.14-2.52), who passed 10th class (aOR 1.58; CI 1.05-2.37), belonging to Muslim religion (aOR 1.52; 95% CI 1.05-2.21), and above poverty line (aOR 1.38; 95% CI 1.00-1.91) had significantly increased likelihood of developing GDM compared to respective baseline groups (p<0.05). Body mass index, gravida, and being non-anaemic were non-significant risk factors for GDM. Family history of diabetes (aOR 1.82; 95% CI 1.08-3.06), and smoking (aOR 1.61; 95% CI 1.10-2.35) were significant and independent predictors of GDM.

Conclusion The prevalence of gestational diabetes mellitus in rural Assam is high. The mobile medical units may play a significant role in the implementation of GDM screening, diagnosis, treatment to ensure better maternal and foetal health outcomes in rural Assam.

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Strengths and limitations of this study

1. The study used a representative sample of all eligible pregnant women in rural Assam

2. All eligible pregnant women underwent blood glucose estimation before initiating the oral glucose tolerance test

3. A standardised gold standard oral glucose tolerance test confirmed the presence of gestational diabetes mellitus among pregnant women

4. We could neither obtain a venous blood sample of pregnant women for glucose estimation nor test the blood glucose level early in pregnancy due to operational constraints

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BACKGROUND

Glucose intolerance or high blood sugar detected for the first time during pregnancy is known as Gestational Diabetes Mellitus (GDM).[1] Worldwide GDM is a significant public health problem.[2] GDM not only leads to adverse foetal health outcomes in the form of neonatal jaundice, stillbirths, macrosomia but also affects maternal health. [3] The GDM associated maternal complications include preeclampsia, the need for caesarean section, and respiratory distress.[4] Even GDM mother's risk of developing diabetes is up by 10% immediately after delivery. Evidence suggests that children born to GDM mothers are nearly four to eight times more likely to develop diabetes in later life compared to their siblings born to the same parent with no GDM.[5]

GDM affects about four million women in India. The prevalence of GDM in the Indian population is high compared to other Asian countries. At any point in time, The GDM prevalence ranges from 6 to 9% in rural and 12 to 21% in the urban areas.[6–8]

The Government of India guidelines mandates age-appropriate GDM screening of pregnant women at primary health centres during regular antenatal check-ups (ANC).[9] However, due to infrequent glucose and insulin supply, and the non-availability of healthcare staff at primary public health facilities in most of the Indian states, GDM screening is not a regular part of ANC visits, results of which rural pregnant women are not timely screened and in some cases, leads to misdiagnosis of GDM among suspected pregnant women.[10,11]

The public health facilities and their problems are no different in the north-eastern Indian state of Assam. Issues like hilly and challenging terrain, poor health infrastructure, and acute shortage of medical doctors at peripheral public health facilities contribute to inadequate or non-implementation of different government health schemes including GDM screening.[12,13] Therefore, reliable GDM data and estimations for rural Assam are inadequately studied. A few research studies, with a limited sample, documented GDM prevalence in scattered rural geography of Assam but all such estimates are from hospital-based studies and lack generalizability.

The state government of Assam runs a large Mobile Medical Unit (MMU) program to deliver basic primary health services to its rural population. The vast network of MMUs allows us not only to study the pattern of healthcare morbidities among program beneficiaries but provide a platform to routinely report and derive the population-based estimates on key health conditions.[14,15] Evidence also suggests that MMUs are useful in screening of diseases

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like tuberculosis, breast cancer, HIV, hepatitis.[16–18] Hence, we take the opportunity to leverage the MMU platform to reach and screen eligible pregnant women in rural Assam. We aim to determine the prevalence and associated risk factors of GDM in rural Assam.

METHODS

We did a cross-sectional study in rural Assam. We divided the state into five zones. Using multi-stage sampling, pregnant women in the gestational age of 24-28 weeks were identified. All eligible pregnant women were reached through MMUs in each zone and screened for GDM using the oral glucose tolerance test (OGTT) irrespective of fasting status.

Study Design

Cross-sectional study.

Setting and Participants

The north-eastern state of Assam has a population of 30.12 million with 993 females per 1000 males.[19] As per recent rural health statistics, Assam has a shortfall of 21 % of Sub-Centres (SCs), 1 % of Primary Health Centres (PHCs) and 28 % of Community Health Centres(CHCs) against the sanctioned numbers.[20] Access to 15% of sub-centres and 3.1% of PHCs is difficult due to the unavailability of roads. Nearly 16.8% SCs are beyond 3 kilometres radius of villages and 31.7% of PHCs are beyond 10 km radius of villages.[21] People in rural Assam depends heavily on public health services (82.7%). As of 2015-17, Assam has the highest Maternal Mortality Ratio (MMR) in the country at 229 deaths per 100 000 live birth compared to India's MMR of 122. The state reports high Infant Mortality Rate (44/1000 live births) compared to national averages (33/1000 live births). The incidence of non-communicable diseases is rising, especially diabetes and hypertension. As per National Family Health Survey-4, 5.2% women and 6.6% men have high blood sugar levels; 11.8 % women and 15.1% men have raised blood pressure.[22,23]

The MMU Program Description

The MMU program, known as "Sanjeevani," in Assam state, is a public-private partnership between the Government of Assam and Piramal Swasthya Management and Research Institute (PSMRI). The program scope is to provide promotive, preventive, curative and referral services to villagers at their doorstep for non-emergency primary health conditions

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such as seasonal illnesses and common diseases. The state government provides funds while PSMRI implements field services and run program operations.

Sanjeevani is a nurse-led MMU program, having a fleet of 78 MMUs, and covers nearly 3744 (14.4%) of all villages (26,000) across Assam state. Each MMU has a nurse, pharmacist, laboratory technician and a registration and measurement officer (RMO). Every MMU follows a fixed day service delivery schedule and visit a particular village once in a month for delivering health services.

The program, for its operations, operates in five distinct zones of the state. Table 1 summarises the details of each zone and the numbers of MMUs. For study purpose, we refer to each zone as a cluster.

Table 1: Zone and District wise distributions of MMUs in rural Assam

Zones	Name of the districts	Districts (#)	MMUs (#)
North	Sonitpur, Dhemaji, Lakhimpur, Darrang, Nagaon	5	15
South	Cachar, Karimganj, Hailakandi, NC Hills	4	17
East	Tinsukia, Dibrugarh, Jorhat, Karbi angling, Golaghat, Sivsagar	6	17
West	Bongaigaon, Kokrajhar, Dhubri, Barpeta, Chirang, Goalpara	6	17
Central	Kamrup, Udalguri, Baksa, Nalbari, Morigaon	5	12

Study Duration

Data were collected between July 2019 and September 2019.

Outcome Variable

The presence or absence of GDM among pregnant women confirmed through OGTT is the primary study outcome.

Independent variables

Sociodemographic variables (age, religion, education, economic status), body mass index (BMI), blood pressure (systolic and diastolic), gravida status (primi and multigravida), haemoglobin levels (for anaemia status), family history of diabetes, miscarriage history, alcohol, and tobacco use. The measurements of height, weight, and blood pressure were taken through the standardized and calibrated equipment as per the WHO STEPS manual.[24]

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Sample Size

We calculated a minimum sample of 150 for each cluster considering the expected proportion of GDM 7%, absolute precision 5%, design defect 1.5, and a 95% confidence interval.

We randomly selected 50% of the MMUs from each cluster. An MMU, on average, covers 48 villages (service delivery points) every month. From each cluster, we randomly selected 30 villages, using a probability proportional to size method. Next, we line listed all pregnant women in the gestational age of 24-28 weeks in the selected villages. However, to extend the benefit of GDM screening, all eligible women in 24-28 weeks of pregnancy were included in the study in the sampled villages. The random selection of MMUs, and villages was done through a random numbers table. Figure 1 depicts the sampling methodology

Inclusion and Exclusion Criteria

All pregnant women in the gestational age of 24 – 28 weeks were included. Pregnant women with known history of diabetes mellitus or GDM and other chronic illnesses such as cancer, hypertension, asthma, epilepsy, arthritis were excluded from the study. Pregnant women with blood random glucose level >200 mg/dl before initiating OGTT were also excluded.

GDM Screening-The Oral Glucose Tolerance Test(OGTT)

The study followed Diabetes In Pregnancy Study group India (DIPSI) guidelines endorsed by the Government of India for the diagnosis of GDM (2018), irrespective of the fasting status. A blood sugar level of 140 mg/dL (7.8 mmol/L) or higher at 2 hours after ingestion of 75gm glucose indicates GDM.[9,25]

All diagnosed positive cases were referred to the Primary Health Centre(PHC) Medical Officer (MO) to start the treatment immediately.

Data Collection

The first step involved line listing of all 24-28 weeks gestation pregnant women in the selected villages. We used government provided "Mother and Child Protection Card" issued to every pregnant mother to ascertain the last date of menstrual period and eligibility. In the next step, we identified a PHC nearest to at least two selected villages. Eligible pregnant women from these villages were then mobilised by a village health worker (Accredited Social Health Activist-ASHA) to a pre-identified PHC. At PHC, two MMUs were on standby.

Paramedical staff from one MMU helped PHC doctor in administering the OGTT and recording the results along with capturing other information using a data tool **(Annexure 1).** The other MMU was used to transport all identified pregnant women to and from their homes.

We incentivised ASHAs @$0.70 (INR 50) per pregnant woman for mobilising a pregnant woman to respective health facilities. The presence of a MO helped in managing any emergency and initiating immediate treatment for GDM positive cases.

Data were collected from July-Sept 2019 using a survey tool.

Data Analysis

Primary data were entered into excel and imported into STATA (version 15.1) for further analysis.[25] Categorical data were presented as percentages (%) and Pearson's Chi-square test was used to evaluate the difference in proportions. Logistic regression method established the independent associations between the outcome and the predictor variable giving odds ratios, 95% confidence intervals and p-values.

Patient and public involvement

No patient or public members were involved in the design and execution of this study.

Ethical Considerations

Piramal Swasthya Management and Research Institute's institutional research ethics committee approved the study (letter no. PSMRI/2019/11 dated 11th May 2019). In addition, we took administrative approval from the Government of Assam for smooth field operations. Research participants were told the purpose of the study and provided written informed consent.

RESULTS

A total of 1410 women were eligible for the study of which 198 pregnant were suffering from chronic illnesses including diabetes or blood glucose level >200 mg/dl before initiating OGTT, hence were excluded. We report the analysis of eligible 1212 pregnant women who underwent the OGTT.

The mean age of the study sample was 23.7 years (SD ± 4.20) years. More than two-thirds (70%) women were in 15-25 years age group. More than half (55%) were Hindu, educated up

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to primary level (50%), and belonging to below poverty line (74%). Nearly one third (32%) had abnormal BMI and very few were hypertensive (3%). More than half (51%) were already having three or more children. A large proportion of women were anaemic (83%). A few women reported a family history of diabetes (6%) or abortion (7%) in their previous pregnancy. A few pregnant women were smokers (2%) (Table 2).

Table 2: Basic characteristics of Pregnant Women according to GDM status in Rural Assam (2019)

Variable	GDM (-) N= 1010 (%)	GDM (+) N=202 (%)	Total N=1212 (%)
Age (Mean±SD)	23.5 (4.04)	24.4 (4.6)	23.7 (4.2)
Age Categories			
15-20 Years	291 (29)	51 (25)	342 (28)
21-25 Years	437 (43)	71 (35)	508 (42)
26-30 Years	235 (23)	63 (31)	298 (25)
>30 Years	47 (5)	17 (8)	64 (5)
Religion			
Hindu	566 (56)	102 (51)	668 (55)
Muslim	433 (43)	99 (49)	532 (44)
Christian	11 (1)	1 (1)	12 (1)
Education			
Illiterate	71 (7)	10 (5)	81 (7)
Primary School	516 (51)	93 (46)	609 (50)
10th Pass	234 (23)	53 (26)	287 (24)
12th Pass	136 (14)	31 (15)	167 (14)
Graduate and above	53 (5)	15 (7)	68 (6)
Economic Status			
Above Poverty Line	247 (24)	68 (34)	315 (26)
Below Poverty Line	763 (76)	134 (66)	897 (74)
Body Mass Index			
Normal	700 (69)	125 (62)	825 (68)
Underweight	194 (19)	43 (21)	237 (20)
Overweight/Obese	116 (12)	34 (17)	150 (12)
Blood Pressure levels			
Normal	681 (67)	138 (68)	819 (68)
Prehypertension	300 (30)	54 (27)	354 (29)
Hypertension	29 (3)	10 (5)	39 (3)
Gravida Status			
Primigravida	499 (49)	97 (48)	596 (49)
Multigravida	511 (51)	105 (52)	616 (51)
Anaemia (Y)	846 (84)	156(77)	1,002 (83)
Diabetes Family History (Y)	51 (5)	24 (12)	75 (6)
Miscarriage History (Y)	70 (7)	19 (9)	89 (7)
Current Smoker (Y)	21 (2)	8 (4)	29 (2)

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Table 3: Prevalence of GDM (Zone wise) in rural Assam, (2019)

Zone	N	GDM Prevalence (%)	95% CI	P-value
North	218	18.4	13.7-24.1	
South	253	15.0	11.1-20.0	
Central	282	20.6	16.2-25.7	0.18
East	194	12.9	8.8-18.4	
West	265	15.5	11.6-20.3	
Total	**1212**	**16.7**		

North (Sonitpur, Dhemaji, Lakhimpur, Darrang, Nagaon), South (Cachar, Karimganj, Hailakandi, N C Hills), Central (Kamrup, Udalguri, Baksa, Nalbari, Morigaon), East (Tinsukia, Dibrugarh, Jorhat, Karbi angling, Golaghat), West (Bongaigaon, Kokrajhar, Dhubri, Barpeta, Chirang, Goalpara)

The GDM prevalence in rural Assam is 16.7% (range 12.9-20.6%). The central zone has a higher GDM prevalence (20.6%) compared to the other four zones (North-18.4%; South-15.0%; East-12.9%; West-15.5%). (Table 3).

We found an increased likelihood of GDM with increasing age. Pregnant women (aged 26-30 years) were 1.7 times [adjusted odds ratio (aOR); 95% Confidence Interval (CI)] (aOR 1.7; 95% CI 1.14-2.52) more likely to have GDM compared to younger women (15-20 years) (p=0.01). Women who passed 10th class (aOR 1.58; CI 1.05-2.37), belonging to Muslim religion (aOR 1.52; 95% CI 1.05-2.21), and above poverty line (aOR 1.38; 95% CI 1.00-1.91) had significantly increased likelihood of developing GDM compared to respective baseline groups (p<0.05). Gravida status, BMI, and being non-anaemic were non-significant risk factors for GDM. Family history of diabetes (aOR 1.82; 95% CI 1.08-3.06), and smoking (aOR 1.61; 95% CI 1.10-2.35) were significant and independent predictors of GDM (Table 4).

Table 4: Crude and adjusted Odds Ratios (with Confidence Intervals) of GDM in relation to other predictor variables

Variable	Unadjusted		Adjusted	
	Odds Ratio (95% CI)	P-value	Odds Ratio (95% CI)	P-value
Age				
15-20 years	1.00		1.00	
21-25 years	0.93 (0.63-1.37)	0.70	1.00 (0.54-1.84)	0.99
*26-30 years	1.53 (1.02-2.30)	0.04	1.70 (1.14-2.52)	0.01
> 30 years	2.06 (1.10-3.87)	0.02	2.33 (0.78-6.95)	0.13
Education				
Illiterate	1.00		1.00	

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Primary School	1.28 (0.64-2.57)	0.49	1.28 (0.52-3.16)	0.58
*10th Pass	1.61(0.78-3.32)	0.20	1.58(1.05-2.37)	0.03
12th Pass	1.62(0.75-3.49)	0.22	1.41 (0.94-2.11)	0.10
Graduate and above	2 (0.84-4.82)	0.12	1.47 (0.62-3.48)	0.38
Religion				
Hindu	1.00		1.00	
*Muslim	1.27 (0.94-1.72)	0.12	1.52 (1.05-2.21)	0.03
Christian	0.5 (0.06-3.95)	0.52	0.70 (0.14-3.45)	0.66
Economic status				
Below Poverty Line (BPL)	1.00		1.00	
*Above Poverty Line (APL)	1.56 (1.13-2.17)	0.01	1.38 (1.00-1.91)	0.05
Body Mass Index				
Normal	1.00		1.00	
Underweight	1.24 (0.85-1.82)	0.27	1.35 (0.93-1.96)	0.11
Overweight/Obese	1.64 (1.07-2.51)	0.02	1.38 (0.90-2.10)	0.13
Gravida				
Multigravida	1.00		1.00	
Primigravida	0.95 (0.70-1.28)	0.72	1.27 (0.84-1.92)	0.25
Haemoglobin Status				
Anaemic	1.00		1.00	
Non-Anaemic	1.52 (1.05-2.20)	0.03	1.46 (0.94-2.26)	0.09
Diabetes in Family				
No	1.00		1.00	
*Yes	2.53 (1.52-4.22)	0.00	1.82 (1.08-3.06)	0.02
Miscarriage History				
No	1.00		1.00	
Yes	1.4 (0.82-2.37)	0.22	1.53 (0.93-2.52)	0.09
Smoking Status				
Non-smokers	1.00		1.00	
*Current Smokers	1.94 (0.85-4.45)	0.13	1.61 (1.10-2.35)	0.01

Estimates were calculated using logistic regression with a robust cluster estimator of the variance in stata 15.1. The clustered standard error estimated with clustering at the zone level. * Significant variable in multivariate logistic regression

DISCUSSION

Using a network of mobile medical units in rural Assam, we derived not only the first-hand estimates of GDM prevalence and its relationship with sociodemographic and other risk but

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also assessed the feasibility of GDM screening in the community settings. In our study, the basic characteristics of GDM mothers and non-GDM mothers did not vary significantly (not shown in results) except for age, BMI, economic status and family history of diabetes.

The study sample consists of pregnant young, literate, Hindu and Muslim females which correspond to the latest population statistics of the state.[26] We found GDM prevalence of 16.7% in rural Assam (range- 12.9 to 20.6%). Education (10th pass), age (26 to 30 years), religion (Muslim), socio-economic status (above the poverty line), tobacco use (currently smokers) and past history (family history of diabetes) were the significant primary predictors of GDM in rural Assam. The GDM prevalence estimates, as found in our study, in rural Assam, are high compared to international and national evidence. For example, studies from Bangladesh, Egypt, and Ethiopia reported prevalence rates of 9.7%, 8.0%, and 7.7% respectively.[27–29] Likewise, GDM prevalence ranges from 6 to 9% in rural India and remain high for rural Assam.[7,8,30–33] It is imperative to state that majorities of the Indian evidence come from studies done in North and South India. Studies from northeast India are scarce and primarily done under hospital settings. Evidence from these studies reports a low prevalence of GDM in the northeast region (Assam 3%, Manipur 0–1%,) compared to other states (Jammu and Kashmir 3.8–11%; Maharashtra 0.5–9.5%; Andhra Pradesh 17.20–21.81%; and Uttar Pradesh 13.38–41.87%). Similarly, studies from rural and urban India found a considerable variation in GDM prevalence in rural (0.5-13.9%) and urban areas (0.56-41.9%) respectively.[8,34,35]

Geographically, the central zone districts had the highest GDM prevalence among all study zones. The geographical differences in prevalence in different regions are due to differences in the demographic and socioeconomic status of pregnant women in these regions.[31] Studies show that the likelihood of GDM among pregnant women increases with increasing maternal age, and BMI. Particularly mothers aged 25 years or more have increased risk of GDM and the likelihood of GDM rises after 25 years of age. In our study, we found a similar trend finding a non-significant positive relationship between the two. Evidence around the world suggests maternal age and BMI as significant predictors for GDM.[36-37] However, in our study, pregnant women aged 26-30 years only had a significantly increased likelihood of GDM, while BMI had no significant association. Family history of diabetes and current smoking status were significant predictors of GDM and findings were similar as reported in other studies.[29,38-39] However, unlike other studies, our study did not find any significant association between GDM and hypertension.[37,38]

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Among GDM confirmed cases, a high fraction (34%) were from APL category compared to non-GDM APL women (24%). This result is inconsistent with other studies where low socioeconomic status emerges as a significant risk factor for the development of type 2 diabetes mellitus.[40,41] This may also be due to the fact our study sample is from rural areas where monthly disposable income is less than the national or state averages.[42] Socioeconomic status and education had no significant effect on developing GDM which is in line with other studies finding no independent association between GDM, education and socioeconomic status.[40, 43] A higher proportion of pregnant women in our study were anaemic (83%). The rates of anaemia were disproportionately higher compared to state averages (45.7%) and as reported in a local study (72%) conducted in a rural block of Dibrugarh district of Assam state.[22,41] This could be explained to poor dietary habits and local food culture among pregnant women.[42] Further, we found an inverse relationship between anaemia and GDM adjusted for other variables and this finding aligns to as reported in other studies examining the association of GDM and anaemia.[41]

Our study is an attempt to define GDM prevalence estimates in rural Assam. This was possible because of three factors (1) unique presence and positioning of an extensive network of MMUs in rural Assam reaching to far-flung remote areas (2) government ownership and support for carrying field data collection. Auxiliary Nurse Midwives and ASHAs helped identification and mobilization of pregnant women from the villages to respective MMU screening points located at public health facilities (3) presence of government MOs during screening helped in prompt treatment of GDM positive women and counselling support. Despite a large study, we faced certain definite challenges. First, due to resource constraints, we could not obtain a venous blood sample of pregnant women for glucose estimation. Secondly, maternal blood glucose estimation during the initial phase of pregnancy could not be assessed. This could have reinforced our findings. However, we tested maternal blood glucose before initiating OGTT. Additionally, we could not ascertain the reasons for the association of above poverty line pregnant women with GDM due to unavailability of data. Further research is needed on this. However, despite its limitations, our study used a representative sample of all eligible pregnant women in rural Assam. A standardised gold standard oral glucose tolerance test confirmed the presence of GDM among pregnant women. In summary, MMUs are increasingly becoming an essential component in resource-constrained health systems. Such a unique model of healthcare service delivery not only reach the difficult and underserved areas but has the potential to screen communicable and

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non-communicable conditions and linking beneficiaries with the local healthcare for timely and prompt health interventions.[43]

CONCLUSIONS

Our study gives first-hand estimates of GDM prevalence in rural Assam. A high prevalence of GDM in rural Assam warrants immediate government attention to safeguard the maternal and child health in the state. MMUs could be an option to initiate GDM screening in rural areas with appropriate compliance to guidelines and sufficient resource allocation.

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Declaration of interests

We declare no competing interests

Data availability statement

Data can be requested from the principal investigator citing a reasonable request.

Contributors

SC, VD and SH conceptualised the study. NH and HB supervised the field operations and data collection. SC cleaned the field data and wrote the first draft paper. VD performed the statistical analysis, interpreted the results and wrote the final manuscript. SH, AS, AV supervised the data transcription, and reviewed and edited the manuscript. All authors approved the final version of the manuscript.

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ORCID Ids of Authors

Subrata Chanda https://orcid.org/0000-0003-3427-4731
Vishal Dogra https://orcid.org/0000-0001-9725-5699
Najeeb Hazarika https://orcid.org/0000-0001-6778-6325
Hardeep Bambhrah https://orcid.org/0000-0002-9209-9743
Ajit Sudke https://orcid.org/0000-0001-7068-8478
Anupa Vig https://orcid.org/0000-0003-3074-3844
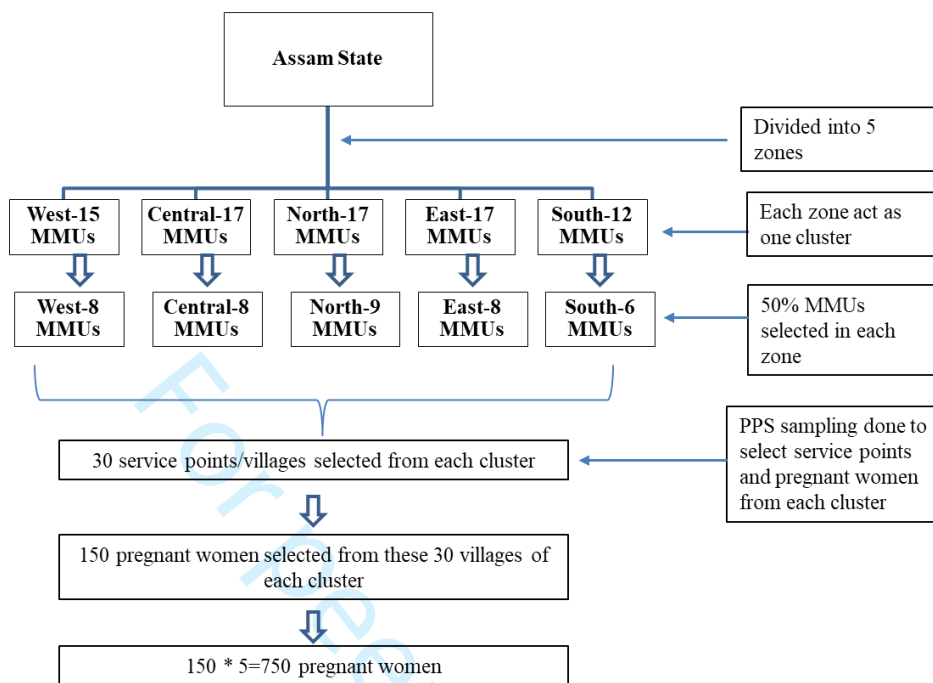Shailendra Hegde https://orcid.org/0000-0002-8756-9085

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Fig 1: Sampling Methodology

Assam State

Divided into 5 zones

| West-15 MMUs | Central-17 MMUs | North-17 MMUs | East-17 MMUs | South-12 MMUs |

Each zone act as one cluster

| West-8 MMUs | Central-8 MMUs | North-9 MMUs | East-8 MMUs | South-6 MMUs |

50% MMUs selected in each zone

30 service points/villages selected from each cluster

PPS sampling done to select service points and pregnant women from each cluster

150 pregnant women selected from these 30 villages of each cluster

150 * 5=750 pregnant women

Annexure 1

Survey Questionnaire for GDM

Sl No.	GDM Survey Tool	
1	**Name of Pregnant woman**	
2	**Name of Husband**	
3	**Age (in Yrs)**	[ ]
4	**District**	[ ]
5	**Block**	[ ]
6	**Village**	[ ]
7	**Religion**	[1] Hindu [2] Muslim [3] Christian [4] Others
8	**Education (Highest qualification)**	[ ]
9	**Do you consume alcohol?**	[Yes/No]
10	**Do you chew or smoke tobacco?**	[Yes/No]
11	**Number of ANCs done**	[Number]
12	**Whom do you contact during your illness?**	[HF/doctor/Quack]
13	**Are you consulting any doctor for your regular checkup?**	[Yes/No]
14	**if yes, is the doctor a specialist (O & G)?**	
15	**where do you want to have delivery?**	[Home/Hospital]
16	**Gestation (completed weeks of pregnancy)**	[ ]
17	**Last Menstrual Period (LMP)**	[DD-MM-YY]
18	**Expected Date of Delivery(EDD)**	[DD-MM-YY]
19	**MCTS ID**	[ID number]
20	**Gravida**	[No. of times pregnant]
21	**Parity No.**	[Primi/multipara]
22	**No. of children**	[Number]
23	**Order of pregnancy**	[Number]
24	**Have you had a stillborn or previous spontaneous miscarriage?**	[Yes/No/Don't Know]
25	**Blood Pressure**	[Systolic/Diastolic in mm Hg]
26	**Height (in metres)**	[ ]
27	**Weight (in Kg)**	[ ]
28	**BMI (Kg/m2)**	[ ]
29	**Waist Circumference (in Inches)**	[ ]
30	**Are you suffering from diabetes(pre-existing)?**	[Yes/No/Don't Know]

31	**Do you have family history of type 2 diabetes (parents/brothers/sisters)**	[Yes/No/Don't Know]
32	**Have you had diabetes in previous pregnancy?**	[Yes/No/Don't Know]
33	**Have you had high blood pressure in previous pregnancy?**	[Yes/No/Don't Know]
34	**Blood sugar level (before OGTT) in mg/dl**	[ ]
35	**Taken 75 gm of glucose**	[Yes/No]
36	**Blood sugar at 2 hr after taking 75 grams glucose (in mg/dl)**	[ ]
37	**Suspected Gestational diabetes mellitus**	[Yes/No]

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STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any pre-specified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	7
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	8

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	8
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-9
		(b) Indicate number of participants with missing data for each variable of interest	NA
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	NA
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA
		Cross-sectional study—Report numbers of outcome events or summary measures	9
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	10-11
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	11-12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13
Generalisability	21	Discuss the generalisability (external validity) of the study results	13-14
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Prevalence and predictors of Gestational Diabetes Mellitus in rural Assam: A cross-sectional study using mobile medical units

Subrata Chanda[1], Vishal Dogra[2], Najeeb Hazarika[1], Hardeep Bambrah[1], Ajit Kisanrao Sudke[3], Anupa Vig[3], Shailendra Kumar Hegde[4]

Corresponding Author: Vishal Dogra, Research and Analytics, Piramal Swasthya Management and Research Institute, Plot no. 120, 5th Floor, Srinagar Colony, Hyderabad, India; Email: vani1825@gmail.com; Tel: +9140-49451999

[1]Assam and North East State Office, Piramal Swasthya Management and Research Institute, Guwahati, India

[2]Research and Analytics, Piramal Swasthya Management and Research Institute, Hyderabad, India

[3]Clinical Domain, Piramal Swasthya Management, and Research Institute, Hyderabad, Telangana, India

[4]Department of Innovations, Piramal Swasthya Management and Research Institute, Hyderabad, India

Word count (Excluding title page, abstract, references, figures and tables)- **3140**

Key Words: Gestational Diabetes Mellitus, Assam, Mobile Medical Unit, OGTT

ABSTRACT

Objective To determine the prevalence and predictors of gestational diabetes mellitus (GDM) in rural Assam, India using a network of Mobile Medical Units

Study Design A field-based cross-sectional study

Settings Rural areas of Assam state, India

Participants A total of 1410 pregnant women in gestational age of 24-28 weeks

Intervention Identification of pregnant women in 24-28 weeks of pregnancy from villages and administering them Government of India recommended oral glucose tolerance test for Gestational Diabetes Mellitus confirmation.

Primary and secondary outcome measures Presence of gestational diabetes among pregnant women, risk factors, and predictors of Gestational Diabetes Mellitus.

Results A total of 1212 pregnant women underwent the oral glucose tolerance test. One hundred and ninety-eight women were ineligible due to existing chronic diseases or very high blood glucose level before the test. The overall GDM prevalence in Assam was 16.67% (95% CI 14.61-18.89%). Women aged 26-30 years (aOR 1.70; CI 1.14-2.52), who passed 10th class (aOR 1.58; CI 1.05-2.37), belonging to Muslim religion (aOR 1.52; 95% CI 1.05-2.21), and above poverty line (aOR 1.38; 95% CI 1.00-1.91) had significantly increased likelihood of developing GDM compared to respective baseline groups (p<0.05). Body mass index, gravida, and being non-anaemic were non-significant risk factors for GDM. Family history of diabetes (aOR 1.82; 95% CI 1.08-3.06), and smoking (aOR 1.61; 95% CI 1.10-2.35) were significant and independent predictors of GDM.

Conclusion The prevalence of gestational diabetes mellitus in rural Assam is high. The mobile medical units may play a significant role in the implementation of GDM screening, diagnosis, treatment to ensure better maternal and foetal health outcomes in rural Assam.

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Strengths and limitations of this study

1. The study used a representative sample of all eligible pregnant women in rural Assam
2. All eligible pregnant women underwent blood glucose estimation before initiating the oral glucose tolerance test
3. A standardised gold standard oral glucose tolerance test confirmed the presence of gestational diabetes mellitus among pregnant women
4. We could neither obtain a venous blood sample of pregnant women for glucose estimation nor test the blood glucose level early in pregnancy due to operational constraints

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BACKGROUND

Glucose intolerance or high blood sugar detected for the first time during pregnancy is known as Gestational Diabetes Mellitus (GDM).[1] Worldwide GDM is a significant public health problem.[2] GDM not only leads to adverse foetal health outcomes in the form of neonatal jaundice, stillbirths, macrosomia but also affects maternal health.[3] The GDM leads to maternal complications such as preeclampsia, the need for caesarean section, and respiratory distress.[4] Even GDM mother's risk of developing diabetes is up by 10% immediately after delivery. Evidence suggests that children born to GDM mothers are nearly four to eight times more likely to develop diabetes in later life compared to their siblings born to the same parent with no GDM.[5]

GDM affects about four million women in India. The prevalence of GDM in the Indian population is high compared to other Asian countries. At any point in time, The GDM prevalence ranges from 6 to 9% in rural and 12 to 21% in the urban areas.[6 7 8]

The Government of India guidelines mandates age-appropriate GDM screening of pregnant women at primary health centres during regular antenatal check-ups (ANC).[9] However, due to infrequent glucose and insulin supply, and the non-availability of healthcare staff at primary public health facilities in most of the Indian states, GDM screening is not a regular part of ANC visits, results of which rural pregnant women are not timely screened and in some cases, leads to misdiagnosis of GDM among suspected pregnant women.[10 11]

The public health facilities and their problems are no different in the north-eastern Indian state of Assam. Issues like hilly and challenging terrain, poor health infrastructure, and acute shortage of medical doctors at peripheral public health facilities contribute to inadequate or non-implementation of different government health schemes including GDM screening.[12 13] Therefore, reliable GDM data and estimations for rural Assam are inadequately studied. A few research studies, with a limited sample, documented GDM prevalence in scattered rural geography of Assam but all such estimates are from hospital-based studies and lack generalizability.

The state government of Assam runs a large Mobile Medical Unit (MMU) program to deliver basic primary health services to its rural population. The vast network of MMUs allows us not only to study the pattern of healthcare morbidities among program beneficiaries but provide a platform to routinely report and derive the population-based estimates on key health conditions.[14 15] Evidence also suggests that MMUs are useful in screening of diseases

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like tuberculosis, breast cancer, HIV, hepatitis.[16] [17] [18] Hence, we take the opportunity to leverage the MMU platform to reach and screen eligible pregnant women in rural Assam. We aim to determine the prevalence and associated risk factors of GDM in rural Assam.

METHODS

We did a cross-sectional study in rural Assam. We divided the state into five zones. Using multi-stage sampling, pregnant women in the gestational age of 24-28 weeks were identified. All eligible pregnant women were reached through MMUs in each zone and screened for GDM using the oral glucose tolerance test (OGTT) irrespective of fasting status.

Study Design

Cross-sectional study.

Setting and Participants

The north-eastern state of Assam has a population of 30.12 million with 993 females per 1000 males.[19] As per recent rural health statistics, Assam has a shortfall of 21 % of Sub-Centres (SCs), 1 % of Primary Health Centres (PHCs) and 28 % of Community Health Centres(CHCs) against the sanctioned numbers. Access to 15% of sub-centres and 3.1% of PHCs is difficult due to the unavailability of roads. Nearly 16.8% SCs are beyond 3 kilometres radius of villages and 31.7% of PHCs are beyond 10 km radius of villages.[20] People in rural Assam depends heavily on public health services (82.7%). As of 2015-17, Assam has the highest Maternal Mortality Ratio (MMR) in the country at 229 deaths per 100 000 live birth compared to India's MMR of 122. The state reports high Infant Mortality Rate (44/1000 live births) compared to national averages (33/1000 live births). The incidence of non-communicable diseases is rising, especially diabetes and hypertension. As per National Family Health Survey-4, 5.2% women and 6.6% men have high blood sugar levels; 11.8 % women and 15.1% men have raised blood pressure.[21] [22]

The MMU Program Description

The MMU program, known as "Sanjeevani," in Assam state, is a public-private partnership between the Government of Assam and Piramal Swasthya Management and Research Institute (PSMRI). The program scope is to provide promotive, preventive, curative and referral services to villagers at their doorstep for non-emergency primary health conditions

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such as seasonal illnesses and common diseases. The state government provides funds while PSMRI implements field services and run program operations.

Sanjeevani is a nurse-led MMU program, having a fleet of 78 MMUs, and covers nearly 3744 (14.4%) of all villages (26,000) across Assam state. Each MMU has a nurse, pharmacist, laboratory technician and a registration and measurement officer (RMO). Every MMU follows a fixed day service delivery schedule and visit a particular village once in a month for delivering health services.

The program, for its operations, operates in five distinct zones of the state. Table 1 summarises the details of each zone and the numbers of MMUs. For study purpose, we refer to each zone as a cluster.

Table 1: Zone and District wise distributions of MMUs in rural Assam

Zones	Name of the districts	Districts (#)	MMUs (#)
North	Sonitpur, Dhemaji, Lakhimpur, Darrang, Nagaon	5	15
South	Cachar, Karimganj, Hailakandi, NC Hills	4	17
East	Tinsukia, Dibrugarh, Jorhat, Karbi angling, Golaghat, Sivsagar	6	17
West	Bongaigaon, Kokrajhar, Dhubri, Barpeta, Chirang, Goalpara	6	17
Central	Kamrup, Udalguri, Baksa, Nalbari, Morigaon	5	12

Study Duration

Data were collected between July 2019 and September 2019.

Outcome Variable

The presence or absence of GDM among pregnant women confirmed through OGTT is the primary study outcome.

Independent variables

Sociodemographic variables (age, religion, education, economic status), body mass index (BMI), blood pressure (systolic and diastolic), gravida status (primi and multigravida), haemoglobin levels (for anaemia status), family history of diabetes, miscarriage history, alcohol, and tobacco use. The measurements of height, weight, and blood pressure were taken through the standardised and calibrated equipment as per the WHO STEPS manual.[23]

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Sample Size

We calculated a minimum sample of 150 for each cluster considering the expected proportion of GDM 7%, absolute precision 5%, design defect 1.5, and a 95% confidence interval.

We randomly selected 50% of the MMUs from each cluster. An MMU, on average, covers 48 villages (service delivery points) every month. From each cluster, we randomly selected 30 villages, using a probability proportional to size method. Next, we line listed all pregnant women in the gestational age of 24-28 weeks in the selected villages. However, to extend the benefit of GDM screening, all eligible women in 24-28 weeks of pregnancy were included in the study in the sampled villages. The random selection of MMUs, and villages was done through a random numbers table. Figure 1 depicts the sampling methodology

Inclusion and Exclusion Criteria

All pregnant women in the gestational age of 24 – 28 weeks were included. Pregnant women with known history of diabetes mellitus or GDM and other chronic illnesses such as cancer, hypertension, asthma, epilepsy, arthritis were excluded from the study. Pregnant women with blood random glucose level >200 mg/dl before initiating OGTT were also excluded.

GDM Screening-The Oral Glucose Tolerance Test

The study followed Ministry of Health and Family Welfare (MoHFW), Government of India's "Technical and Operational Guidelines for Diagnosis and Management of GDM", which are more relevant for Indian population. These guidelines took into consideration the recommendations of the county's subject experts available national and international evidences including the Diabetes in Pregnancy Study Group in India (DIPSI) and World Health Organization's (1999) GDM diagnostic criteria.[9 24 25]

As per MoHFW guidelines, irrespective of the fasting status, all eligible women were asked to drink 75 grams of anhydrous glucose dissolved in 300 ml of water over five to ten minutes period. After two hours of glucose ingestion, we measured blood glucose levels using plasma calibrated glucometers. A blood sugar level equal to 140 mg/dL or higher indicates GDM.[9]

All diagnosed positive cases were referred to the Primary Health Centre (PHC) Medical Officer (MO) to start the treatment immediately.

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Data Collection

The first step involved line listing of all 24-28 weeks gestation pregnant women in the selected villages. We used government provided "Mother and Child Protection Card" issued to every pregnant mother to ascertain the last date of menstrual period and eligibility. In the next step, we identified a PHC nearest to at least two selected villages. Eligible pregnant women from these villages were then mobilised by a village health worker (Accredited Social Health Activist-ASHA) to a pre-identified PHC. At PHC, two MMUs were on standby. Paramedical staff from one MMU helped PHC doctor in administering the OGTT and recording the results along with capturing other information using a data tool **(Annexure 1).** The other MMU was used to transport all identified pregnant women to and from their homes.

We incentivised ASHAs @$0.70 (INR 50) per pregnant woman for mobilising a pregnant woman to respective health facilities. The presence of a MO helped in managing any emergency and initiating immediate treatment for GDM positive cases.

Data were collected from July-Sept 2019 using a survey tool.

Data Analysis

Primary data were entered into excel and imported into STATA (version 15.1) for further analysis.[26] Categorical data were presented as percentages (%) and Pearson's Chi-square test was used to evaluate the difference in proportions. Logistic regression method established the independent associations between the outcome and the predictor variables giving odds ratios, 95% confidence intervals and p-values.

Patient and public involvement

No patient or public members were involved in the design and execution of this study.

Ethical Considerations

Piramal Swasthya Management and Research Institute's institutional research ethics committee approved the study (letter no. PSMRI/2019/11 dated 11th May 2019). In addition, we took administrative approval from the Government of Assam for smooth field operations. Research participants were told the purpose of the study and provided written informed consent.

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RESULTS

A total of 1410 women were eligible for the study of which 198 pregnant were suffering from chronic illnesses including diabetes or blood glucose level >200 mg/dl before initiating OGTT, hence were excluded. We report the analysis of eligible 1212 pregnant women who underwent the OGTT.

The mean age of the study sample was 23.7 years (SD ± 4.20) years. More than two-thirds (70%) women were in 15-25 years age group. More than half (55%) were Hindu, educated up to primary level (50%), and belonging to below poverty line (74%). Nearly one third (32%) had abnormal BMI, and very few were hypertensive (3%). More than half (51%) were already having three or more children. A large proportion of women were anaemic (83%). A few women reported a family history of diabetes (6%) or abortion (7%) in their previous pregnancy. A few pregnant women were smokers (2%) (Table 2).

Table 2: Basic characteristics of Pregnant Women according to GDM status in Rural Assam (2019)

Variable	GDM (-) N= 1010 (%)	GDM (+) N=202 (%)	Total N=1212 (%)
Age (Mean±SD)	23.5 (4.04)	24.4 (4.6)	23.7 (4.2)
Age Categories			
15-20 Years	291 (29)	51 (25)	342 (28)
21-25 Years	437 (43)	71 (35)	508 (42)
26-30 Years	235 (23)	63 (31)	298 (25)
>30 Years	47 (5)	17 (8)	64 (5)
Religion			
Hindu	566 (56)	102 (51)	668 (55)
Muslim	433 (43)	99 (49)	532 (44)
Christian	11 (1)	1 (1)	12 (1)
Education			
Illiterate	71 (7)	10 (5)	81 (7)
Primary School	516 (51)	93 (46)	609 (50)
10th Pass	234 (23)	53 (26)	287 (24)
12th Pass	136 (14)	31 (15)	167 (14)
Graduate and above	53 (5)	15 (7)	68 (6)
Economic Status			
Above Poverty Line	247 (24)	68 (34)	315 (26)
Below Poverty Line	763 (76)	134 (66)	897 (74)
Body Mass Index			
Normal	700 (69)	125 (62)	825 (68)
Underweight	194 (19)	43 (21)	237 (20)
Overweight/Obese	116 (12)	34 (17)	150 (12)

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Blood Pressure levels			
Normal	681 (67)	138 (68)	819 (68)
Prehypertension	300 (30)	54 (27)	354 (29)
Hypertension	29 (3)	10 (5)	39 (3)
Gravida Status			
Primigravida	499 (49)	97 (48)	596 (49)
Multigravida	511 (51)	105 (52)	616 (51)
Anaemia (Y)	846 (84)	156(77)	1,002 (83)
Diabetes Family History (Y)	51 (5)	24 (12)	75 (6)
Miscarriage History (Y)	70 (7)	19 (9)	89 (7)
Current Smoker (Y)	21 (2)	8 (4)	29 (2)

Table 3: Prevalence of GDM (Zone wise) in rural Assam, (2019)

Zone	N	GDM Prevalence (%)	95% CI	P-value
North	218	18.4	13.7-24.1	
South	253	15.0	11.1-20.0	
Central	282	20.6	16.2-25.7	0.18
East	194	12.9	8.8-18.4	
West	265	15.5	11.6-20.3	
Total	**1212**	**16.7**		

North (Sonitpur, Dhemaji, Lakhimpur, Darrang, Nagaon), South (Cachar, Karimganj, Hailakandi, N C Hills), Central (Kamrup, Udalguri, Baksa, Nalbari, Morigaon), East (Tinsukia, Dibrugarh, Jorhat, Karbi angling, Golaghat), West (Bongaigaon, Kokrajhar, Dhubri, Barpeta, Chirang, Goalpara)

The GDM prevalence in rural Assam is 16.7% (range 12.9-20.6%). The central zone has a higher GDM prevalence (20.6%) compared to the other four zones (North-18.4%; South-15.0%; East-12.9%; West-15.5%). (Table 3).

We found an increased likelihood of GDM with increasing age. Pregnant women (aged 26-30 years) were 1.7 times [adjusted odds ratio (aOR); 95% Confidence Interval (CI)] (aOR 1.7; 95% CI 1.14-2.52) more likely to have GDM compared to younger women (15-20 years) (p=0.01). Women who passed 10th class (aOR 1.58; CI 1.05-2.37), belonging to Muslim religion (aOR 1.52; 95% CI 1.05-2.21), and above poverty line (aOR 1.38; 95% CI 1.00-1.91) had significantly increased likelihood of developing GDM compared to respective baseline groups (p<0.05). Gravida status, BMI, and being non-anaemic were non-significant risk factors for GDM. Family history of diabetes (aOR 1.82; 95% CI 1.08-3.06), and smoking (aOR 1.61; 95% CI 1.10-2.35) were significant and independent predictors of GDM (Table 4).

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Table 4: Crude and adjusted Odds Ratios (with Confidence Intervals) of GDM in relation to other predictor variables

Variable	Unadjusted		Adjusted	
	Odds Ratio (95% CI)	P-value	Odds Ratio (95% CI)	P- value
Age				
15-20 years	1.00		1.00	
21-25 years	0.93 (0.63-1.37)	0.70	1.00 (0.54-1.84)	0.99
*26-30 years	1.53 (1.02-2.30)	0.04	1.70 (1.14-2.52)	0.01
> 30 years	2.06 (1.10-3.87)	0.02	2.33 (0.78-6.95)	0.13
Education				
Illiterate	1.00		1.00	
Primary School	1.28 (0.64-2.57)	0.49	1.28 (0.52-3.16)	0.58
*10th Pass	1.61(0.78-3.32)	0.20	1.58(1.05-2.37)	0.03
12th Pass	1.62(0.75-3.49)	0.22	1.41 (0.94-2.11)	0.10
Graduate and above	2 (0.84-4.82)	0.12	1.47 (0.62-3.48)	0.38
Religion				
Hindu	1.00		1.00	
*Muslim	1.27 (0.94-1.72)	0.12	1.52 (1.05-2.21)	0.03
Christian	0.5 (0.06-3.95)	0.52	0.70 (0.14-3.45)	0.66
Economic status				
Below Poverty Line (BPL)	1.00		1.00	
*Above Poverty Line (APL)	1.56 (1.13-2.17)	0.01	1.38 (1.00-1.91)	0.05
Body Mass Index				
Normal	1.00		1.00	
Underweight	1.24 (0.85-1.82)	0.27	1.35 (0.93-1.96)	0.11
Overweight/Obese	1.64 (1.07-2.51)	0.02	1.38 (0.90-2.10)	0.13
Gravida				
Multigravida	1.00		1.00	
Primigravida	0.95 (0.70-1.28)	0.72	1.27 (0.84-1.92)	0.25
Haemoglobin Status				
Anaemic	1.00		1.00	
Non-Anaemic	1.52 (1.05-2.20)	0.03	1.46 (0.94-2.26)	0.09
Diabetes in Family				
No	1.00		1.00	
*Yes	2.53 (1.52-4.22)	0.00	1.82 (1.08-3.06)	0.02
Miscarriage History				
No	1.00		1.00	
Yes	1.4 (0.82-2.37)	0.22	1.53 (0.93-2.52)	0.09

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Smoking Status

Non-smokers	1.00		1.00	
*Current Smokers	1.94 (0.85-4.45)	0.13	1.61 (1.10-2.35)	0.01

Estimates were calculated using logistic regression with a robust cluster estimator of the variance in stata 15.1. The clustered standard error estimated with clustering at the zone level. *****Significant variable in multivariate logistic regression

DISCUSSION

Using a network of mobile medical units in rural Assam, we derived not only the first-hand estimates of GDM prevalence and its relationship with sociodemographic and other risk but also assessed the feasibility of GDM screening in the community settings. In our study, the basic characteristics of GDM mothers and non-GDM mothers did not vary significantly (not shown in results) except for age, BMI, economic status and family history of diabetes.

The study sample consists of pregnant young, literate, Hindu and Muslim females which correspond to the latest population statistics of the state.[27] We found GDM prevalence of 16.7% in rural Assam (range- 12.9 to 20.6%). Education (10th pass), age (26 to 30 years), religion (Muslim), socio-economic status (above the poverty line), tobacco use (currently smokers) and past history (family history of diabetes) were the significant primary predictors of GDM in rural Assam. The GDM prevalence estimates, as found in our study, in rural Assam, are high compared to international and national evidence. For example, studies from Bangladesh, Egypt, and Ethiopia reported prevalence rates of 9.7%, 8.0%, and 7.7% respectively.[28 29 30] Likewise, GDM prevalence ranges from 6 to 9% in rural India and remains high for rural Assam.[7 8 31 32 33 34] It is imperative to state that majorities of the Indian evidence come from studies done in North and South India. Studies from northeast India are scarce and primarily done under hospital settings. Evidence from these studies reports a low prevalence of GDM in the northeast region (Assam 3%, Manipur 0–1%,) compared to other states (Jammu and Kashmir 3.8–11%; Maharashtra 0.5–9.5%; Andhra Pradesh 17.20–21.81%; and Uttar Pradesh 13.38–41.87%). Similarly, studies from rural and urban India found a considerable variation in GDM prevalence in rural (0.5-13.9%) and urban areas (0.56-41.9%) respectively.[8 35 36]

Geographically, the central zone districts had the highest GDM prevalence among all study zones. The geographical differences in prevalence in different regions are due to differences in the demographic and socio-economic status of pregnant women in these regions.[32] Studies show that the likelihood of GDM among pregnant women increases with increasing maternal

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age, and BMI. Particularly mothers aged 25 years or more have increased risk of GDM and the likelihood of GDM rises after 25 years of age. In our study, we found a similar trend finding a non-significant positive relationship between the two. Evidence around the world suggests maternal age and BMI as significant predictors for GDM.[37][38] However, in our study, pregnant women aged 26-30 years only had a significantly increased likelihood of GDM, while BMI had no significant association. The increased risk of GDM in Muslim women (compared to Hindu women) could be due to differential social and behavioural culture, and or belief and health practices that were not investigated in this study. Family history of diabetes and current smoking status were significant predictors of GDM and findings were similar as reported in other studies.[30][39][40] However, unlike other studies, our study did not find any significant association between GDM and hypertension.[38][39]

Among GDM confirmed cases, a high fraction (34%) were from APL category compared to non-GDM APL women (24%). This result is inconsistent with other studies where low socio-economic status emerges as a significant risk factor for the development of type 2 diabetes mellitus.[40][41] This may also be due to the fact our study sample is from rural areas where monthly disposable income is less than the national or state averages.[27] Socio-economic status and education had no significant effect on developing GDM which is in line with other studies finding no independent association between GDM, education and socio-economic status.[16][41] A higher proportion of pregnant women in our study were anaemic (83%). The rates of anaemia were disproportionately higher compared to state averages (45.7%) and as reported in a local study (72%) conducted in a rural block of Dibrugarh district of Assam state.[41][42] This could be explained to poor dietary habits and local food culture among pregnant women.[43] Further, we found an inverse relationship between anaemia and GDM adjusted for other variables and this finding aligns to as reported in other studies examining the association of GDM and anaemia.[40]

Our study is an attempt to define GDM prevalence estimates in rural Assam. This was possible because of three factors (1) unique presence and positioning of an extensive network of MMUs in rural Assam reaching to far-flung remote areas (2) government ownership and support for carrying field data collection. Auxiliary Nurse Midwives and ASHAs helped identification and mobilisation of pregnant women from the villages to respective MMU screening points located at public health facilities (3) presence of government MOs during screening helped in prompt treatment of GDM positive women and counselling support. Despite a large study, we faced certain definite challenges. First, due to resource constraints,

we could not obtain a venous blood sample of pregnant women for glucose estimation. Secondly, maternal blood glucose estimation during the initial phase of pregnancy could not be assessed. This could have reinforced our findings. However, we tested maternal blood glucose before initiating OGTT. Additionally, we could not ascertain the reasons for the association of above poverty line pregnant women with GDM due to unavailability of data. Further research is needed on this. However, despite its limitations, our study used a representative sample of all eligible pregnant women in rural Assam. A standardised gold standard oral glucose tolerance test confirmed the presence of GDM among pregnant women. In summary, MMUs are increasingly becoming an essential component in resource-constrained health systems. Such a unique model of healthcare service delivery not only reach the difficult and underserved areas but has the potential to screen communicable and non-communicable conditions and linking beneficiaries with the local healthcare for timely and prompt health interventions.[16]

CONCLUSIONS

Our study gives first-hand estimates of GDM prevalence in rural Assam. A high prevalence of GDM in rural Assam warrants immediate government attention to safeguard the maternal and child health in the state. MMUs could be an option to initiate GDM screening in rural areas with appropriate compliance to guidelines and sufficient resource allocation.

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Declaration of interests

We declare no competing interests

Data availability statement

Data can be requested from the principal investigator citing a reasonable request.

Contributors

SC, VD and SH conceptualised the study. NH and HB supervised the field operations and data collection. SC cleaned the field data and wrote the first draft paper. VD performed the statistical analysis, interpreted the results and wrote the final manuscript. SH, AS, AV supervised the data transcription, and reviewed and edited the manuscript. All authors approved the final version of the manuscript.

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ORCID Ids of Authors

Subrata Chanda https://orcid.org/0000-0003-3427-4731
Vishal Dogra https://orcid.org/0000-0001-9725-5699
Najeeb Hazarika https://orcid.org/0000-0001-6778-6325
Hardeep Bambhrah https://orcid.org/0000-0002-9209-9743
Ajit Sudke https://orcid.org/0000-0001-7068-8478
Anupa Vig https://orcid.org/0000-0003-3074-3844
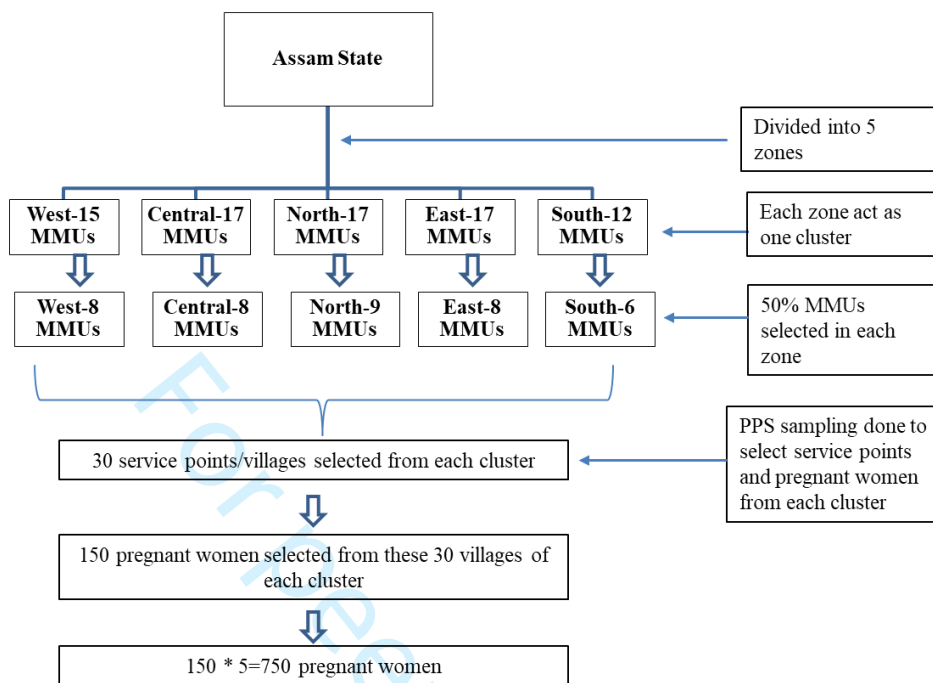Shailendra Hegde https://orcid.org/0000-0002-8756-9085

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Fig 1: Sampling Methodology

Assam State

Divided into 5 zones

| West-15 MMUs | Central-17 MMUs | North-17 MMUs | East-17 MMUs | South-12 MMUs |

Each zone act as one cluster

| West-8 MMUs | Central-8 MMUs | North-9 MMUs | East-8 MMUs | South-6 MMUs |

50% MMUs selected in each zone

30 service points/villages selected from each cluster

PPS sampling done to select service points and pregnant women from each cluster

150 pregnant women selected from these 30 villages of each cluster

150 * 5=750 pregnant women

Annexure 1

Survey Questionnaire for GDM

Sl No.	GDM Survey Tool	
1	**Name of Pregnant woman**	
2	**Name of Husband**	
3	**Age (in Yrs)**	[ ]
4	**District**	[ ]
5	**Block**	[ ]
6	**Village**	[ ]
7	**Religion**	[1] Hindu [2] Muslim [3] Christian [4] Others
8	**Education (Highest qualification)**	[ ]
9	**Do you consume alcohol?**	[Yes/No]
10	**Do you chew or smoke tobacco?**	[Yes/No]
11	**Number of ANCs done**	[Number]
12	**Whom do you contact during your illness?**	[HF/doctor/Quack]
13	**Are you consulting any doctor for your regular checkup?**	[Yes/No]
14	**if yes, is the doctor a specialist (O & G)?**	
15	**where do you want to have delivery?**	[Home/Hospital]
16	**Gestation (completed weeks of pregnancy)**	[ ]
17	**Last Menstrual Period (LMP)**	[DD-MM-YY]
18	**Expected Date of Delivery(EDD)**	[DD-MM-YY]
19	**MCTS ID**	[ID number]
20	**Gravida**	[No. of times pregnant]
21	**Parity No.**	[Primi/multipara]
22	**No. of children**	[Number]
23	**Order of pregnancy**	[Number]
24	**Have you had a stillborn or previous spontaneous miscarriage?**	[Yes/No/Don't Know]
25	**Blood Pressure**	[Systolic/Diastolic in mm Hg]
26	**Height (in metres)**	[ ]
27	**Weight (in Kg)**	[ ]
28	**BMI (Kg/m2)**	[ ]
29	**Waist Circumference (in Inches)**	[ ]
30	**Are you suffering from diabetes(pre-existing)?**	[Yes/No/Don't Know]

31	**Do you have family history of type 2 diabetes (parents/brothers/sisters)**	[Yes/No/Don't Know]
32	**Have you had diabetes in previous pregnancy?**	[Yes/No/Don't Know]
33	**Have you had high blood pressure in previous pregnancy?**	[Yes/No/Don't Know]
34	**Blood sugar level (before OGTT) in mg/dl**	[ ]
35	**Taken 75 gm of glucose**	[Yes/No]
36	**Blood sugar at 2 hr after taking 75 grams glucose (in mg/dl)**	[ ]
37	**Suspected Gestational diabetes mellitus**	[Yes/No]

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any pre-specified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-6
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	7
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	8

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	8
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-9
		(b) Indicate number of participants with missing data for each variable of interest	NA
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	NA
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA
		Cross-sectional study—Report numbers of outcome events or summary measures	9
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	10-11
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	11-12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13
Generalisability	21	Discuss the generalisability (external validity) of the study results	13-14
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.