Original Article

A sequential explanatory mixed method study of maternal and fetal outcome in gestational diabetes mellitus using Diabetes in Pregnancy Study Group India (DIPSI) test in Puducherry

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Abstract

Background: Gestational diabetes mellitus in pregnancy is associated with polyhydramnios, macrosomia, and shoulder dystocia, and it also increases maternal and perinatal mortality. **Methods:** This sequential explanatory mixed-method study was conducted for six months. All the pregnant women attending the outpatient department of the Obstetrics and Gynaecology Department at 24-28 weeks of gestation were subjected to universal screening with 75 gms of glucose and 2 hours of plasma glucose >140 mgs% is taken for diagnosis (according to DIPSI guidelines). After diagnosis, they were subjected to an HbA1c test. Women with HbA1c is >6.5% were excluded from the study. If pregnant women are screened negative by the DIPSI test, the test was repeated in the third trimester (32-34 weeks of gestation). Chi-square tests were used to find out the test of association for quantitative data and manual content analysis was performed for qualitative data. **Results:** DIPSI test was found to decrease the adverse maternal and neonatal outcome by early screening and management. The stakeholders' perspectives identified by key informant interview were improper knowledge and awareness about the testing and others were anxiety and fear associated with the testing procedure. **Conclusions:** As DIPSI test is an effective single step in screening and diagnostic test, hence all pregnant mothers should undergo this glucose challenge test in their antenatal visits.

Keywords: DIPSI, GDM, morbidity, mortality, pregnant women

Introduction

Gestational diabetes (GDM) is defined as glucose intolerance that begins or is first detected during pregnancy. This definition also helps to diagnose undetected existing diabetes. Hyperglycemia during pregnancy is associated with adverse maternal and prenatal outcomes.[1] Screening, diagnosis, and treatment of hyperglycemia during pregnancy are important to avoid side effects. There is no international consensus on the timing of the screening method and the optimal cut-off points for GDM diagnosis and intervention.[2,3] DIPSI and WHO recommend a fasting oral glucose tolerance test (OGTT) with 75 g of glucose and a cut-off of ≥140 mg/dL after 2 hours. The American Diabetes Association (ADA)/The International Association of the Diabetes and Pregnancy Study Groups (IADPSG)

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recommendations for screening women at risk for diabetes are as follows, in the first and subsequent trimesters at 24-28 weeks, the criteria for the diagnosis of gestational diabetes mellitus (GDM) are 75 g Oral Glucose Tolerance Test (OGTT) and fasting 5.1 mmol/l, 1 hour 10.0 mmol/l, 2 hours 8.5 mmol/l with the general glucose tolerance test.[4-8] Critics of these criteria argue that it leads to overdiagnosis of GDM and unnecessary interventions, but controversy continues. OGTT is a three-step process, which includes fasting value, 1 hour postprandial, 2 hour postprandial values and if any one value is abnormal patient is diagnosed as GDM. DIPSI is a single-step test which does not involve fasting hence GTT overestimate pregnant women as GDM which results more evaluation. American College of Obstetricians and Gynecologists (ACOG) still prefers a 2-step procedure, Glucose Challenge Test (GCT) with 50 g of fasting glucose if >7.8 mmol/L, followed by a 3-hour OGTT to confirm the diagnosis. The conclusion is based on the study of Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) because the degree of mild dysglycemia is associated with adverse events and a high prevalence of type 2 DM to reach an international consensus. It recommends the IADPSG criteria, although there is controversy. The IADPSG criteria are the only outcome-based criteria because it allows earlier diagnosis and treatment of GDM, thus reducing fetal and maternal complications associated with GDM. The advantage of this one-step method is ease of implementation, more patience, more accurate diagnosis and close to international consensus.[9-12] Based on the diversity and variability of the Indian population, the evaluation of international criteria may not be conclusive, thus more comparative studies of different diagnostic criteria in relation to negative pregnancy outcomes are needed. The reason for studying GDM in this population is its high prevalence. With this background, the objective of the study was to assess the factors associated with Gestational Diabetes Mellitus (GDM) among antenatal mothers using Diabetes in Pregnancy Study Group India (DIPSI) test and to explore their perspective among the stakeholders.

Material and Methods

Study area and setting: The study was conducted in the Department of Obstetrics and Gynecology-Outpatient Block (OBG-OPD) at Sri Manakula Vinayagar Medical College and Hospital. It is a tertiary care, ultramodern hospital with 932 bedded facilities and provides healthcare services to the people residing in Puducherry and Tamilnadu (Villupuram) regions.

Study design: A sequential explanatory mixed-method study design was used (QUAN followed by qual). In which QUAN (major component) was performed using cross-sectional study and qual (minor component) was performed through key informant interview (KII).

Study duration: All the pregnant women attending OBG OPD and the stakeholders were interviewed for the period of 6 months.

Sample size and sampling

QUAN: Using open epi software sample size was calculated to be 100. On considering the prevalence of GDM in rural population as 9.9% with 95% confidence interval, 80% power, and 6% absolute precision from the study performed by Purandare *et al.*[3] Consecutive sampling techniques were used for recruiting the study participants.

qual: Since there is no sample size calculation available for qualitative study, the interview was performed among the stakeholders till the point of saturation, meaning no new information was generated further. Purposive sampling technique was used for selecting the stakeholders for KII.

Study participants

QUAN: All pregnant women (primigravida and multigravida) aged 18-40 years attending the Obstetrics and Gynaecology Department, which includes both singleton and multiple gestation were included in the study. Antenatal women with preexisting diabetes mellitus, hepatic, renal disease and patients taking drugs, which alters glucose metabolism were excluded.

qual: Stakeholders (obstetricians, medical officers, staff nurses, ANM and ASHAs) providing services and antenatal mothers were included for KII. Those who are not vocal enough, and not willing to participate in the interview will be excluded.

Data collection procedure

Phase 1: QUANTITATIVE data collection: After obtaining clearance from the Research and Institutional Ethical Committee (IEC no: 0423:2014), the data collection was performed by the principal investigator using pre-tested semi-structured questionnaire. All the pregnant women who fulfil the inclusion criteria were explained about DIPSI test. Informed written consent was obtained from all the study participants. Their demographic variables, menstrual history, marital history, obstetric history, past medical history and family history were collected. General physical examination and pre-pregnancy BMI were recorded in the proforma. Irrespective of their last meal, 75 gm glucose was given orally after dissolving in approximately 300 ml water, and blood sugar was measured after 2 hours of ingestion. The intake of the solution has to be completed within 5-10 minutes. A plasma standardized glucometer was used to evaluate blood sugar after 2 hours of the oral glucose load. If vomiting occurs within 30 minutes of oral glucose intake, the test was repeated the next day. If vomiting occurs after 30 minutes, the test was continued. The threshold blood sugar level of ≥140 mg/dl was taken as cut-off for diagnosis of GDM (according to DIPSI guidelines). After diagnosis, they were subjected to HbA1c test. Women with HbA1c is >6.5% were excluded from the study. If pregnant women are screen negative by DIPSI test, the test was repeated in the third trimester (32-34 weeks of gestation). Pregnant women who were diagnosed as GDM by DIPSI test were counselled regarding Medical Nutritional Therapy (MNT)

and regular self-monitoring of the blood sugar at home for the requirement of good maternal and perinatal outcomes. Venous plasma glucose was checked two weeks after MNT, if PPBS is > 120 mg%, an oral hypoglycemic agent or insulin was started in consultation with a physician or endocrinologist. Adherence to these interventions were ensured and measured during the regular follow-up visits. Maternal and fetal outcomes were analyzed by grouping the patients as follows, patients treated with medical nutritional therapy (MNT), patients treated with MNT and oral hypoglycemic agent and patients treated with MNT and insulin. Privacy and Confidentiality were maintained throughout the study. Other ethical principles such as anonymity, beneficence, etc., were also adhered.

Phase 2: qualitative data collection: After obtaining written informed consent, KII was conducted by a female principal investigator trained in QRM among the stakeholders at their convenient place and time to maintain privacy and confidentiality. Probing questions were asked as and when required by the interviewer to address the in-depth information and explore the reasons for GDM and antenatal mothers' perspective in their native language among the stakeholders. Interviews were conducted until the point of saturation, meaning no new information was generated further (n = 9). At the end of all interviews, debriefing and member checking with stakeholders were performed to improve the validity of the study. Field notes were taken at the time of the interview, and all the interviews were audio recorded. Each interview lasts between 35 and 45 minutes. The respondents' anonymity and other ethical principles were maintained.

Data analysis

QUAN: Collected data were entered in epi info software version 7.2 and analyzed using SPSS (Statistical Package for the Social Sciences) software version 24.0. Categorical variables were expressed as percentages and frequencies. Continuous variables were expressed as mean and standard deviation. Chi-square tests were used to find out the test of association. STROBES checklists were used for validation of the study findings.

qual: On the same day as the interview, transcripts were prepared verbatim from the audio-visual recordings in English. Manual content analysis of the transcripts was performed by the PI in consultation with the co-PI to ensure the credibility of the findings. Specific sentences with distinct and meaningful response characteristics were coded. Similar sentences were grouped together with descriptive codes. Common codes were grouped into different categories. Later, similar categories were merged to form board themes. Any discrepancy arising between the investigators was solved by mutual consensus for qualitative data. The qualitative study findings were reported using "consolidated criteria for reporting qualitative research" guidelines. Statements in *italics* indicate direct quotes verbatim from the respondents and represent the description shared by the respondents. A Good Reporting of a Mixed-Methods Study (GRAMMS) checklist was used for reporting the study findings.

Results

From the socio-demographic details of the study participants age of the patient, area of residence, type of family, educational status and socio-economic status of the patient were calculated. [Table 1] Among the study participants, majority 55% were in the age group of 25-29, 22% were in 21-24 years, 15% were in 30-34 years, 5% in 35-40 years and remaining 3% were from 18-20 years of age. Most of them, 56% were from urban and 44% of the antenatal women were from rural areas. 57% of the mothers were residing in the joint type of family and 43% were from nuclear family. Half of the antenatal women 48% were completed their undergraduate course, 32% were educated from 8-12th standard, 18% completed their postgraduation and 2% were educated less than 8th standard. Most of them 50% were from the lower class, 44% were from the middle class and 6% of the mothers were from the upper class. Among the antenatal women, 90% had no family history of diabetes and 90% had positive history. 54% were multigravida and 46% were primi.

In our study, majority of the multiparous women had GDM and 10% of the patients had positive family history of diabetes. Normal BMI values were found among 73% of women. Most of them had GCT values in the range of 141-150 mg/dl. The majority of GDM mothers had features of hypothyroidism and 15% had associated features of pre-eclampsia. In our study majority (80%)

Table 1: Socio-demographic details of the antenatal mothers (*n*=100)

Variables	No of subjects in % (*n*=100)
Age of the patient	
18-20	3
21-24	22
25-29	55
30-34	15
35-40	5
Residence	
Rural	44
Urban	56
Family type	
Nuclear	43
Joint	57
Education	
<8th standard	2
8th-12th standard	32
Undergraduate	48
Postgraduate	18
Socio economic status	
Lower	50
Middle class	44
Upper class	6
Family history of Diabetes	
Yes	10
No	90
Parity	
Primi	46
Multi	54

of the women required medical nutritional therapy, 16% required insulin and 4% required an oral hypoglycemic agent (metformin). The majority of them had term vaginal delivery without any maternal and newborn complications. Most of the babies had birth weight in the range of 2.5-3 Kg and had a good APGAR score. Most of the women who were diagnosed as GDM did not develop complications during pregnancy. Pregnancy-induced hypertension and its complications were found to be higher, followed by hypothyroidism and polyhydramnios. There was a significant correlation between gestational age and age of the mother, birth weight and gestational age of the mother, APGAR score and Birth weight of the baby.

[Table 2] shows values of GCT and BMI of the antenatal mothers, 73% had BMI of 18.5-24.9 and 27% had BMI of 25-29.9. 41% of the participants had GCT value ranging from 141-150 mg, 33% had value of 151-160 mg, 12% had 171-180 mg, 6% of them had 161-170 mg, 5% had value <140 mg, 2% had 191-200 mg and 1% had value of 190-200 mg.

[Table 3] shows the associated factors for GDM, majority 97% of them had term delivery and 53% had vaginal mode, 34% had emergency c-sections, 10% had elective section and remaining 3% had pre-term vaginal delivery. No complications were found among the 77% of the newborns and 21% had respiratory distress. 56% of the babies had APGAR score of 7-8, 38% had score of 8-10 and 5% had score of 6-7. 43% of them were born with 2.5-2.9 kg body weight, 34% had weight of 3-3.4, 13% had 3.5-4 kg and 10% were below 2.5 kg.

Among all the variables, gestational age had correlation with maternal age, birth weight had correlation with gestational age and APGAR score and birth weight. [Table 4] All were found to be significant; *P* value is less than 0.05 [Table 5].

From the transcript, three broad themes were obtained, namely, individual, family-level and community-level reasons. The five categories that emerged from interviews were mentioned in [Table 6]. 1. general awareness and practical issues; 2. family-related issues; 3. economic issues; 4. cultural issues; and 5. health care-associated issues. The following reasons were identified from the stakeholders: The major reasons were improper knowledge and awareness about the testing; others were: anxiety and fear associated with the testing procedure, time constraints, socio-cultural myths, lack of support from husband and other family members, transportation difficulties and engaging in daily routine activities at home.

Table 2: Details of BMI and GCT values

Variables	No of subjects in % (*n*=100)
BMI	
<18.5	0
18.5-24.9	73
25-29.9	27
30-34.9	0
GCT values in mg	
140	5
141-150	41
151-160	33
161-170	6
171-180	12
181-190	1
190-200	2

Table 3: Variables showing outcomes of GDM

Variables	No of subjects in % (*n*=100)
Time of delivery	
Pre term	3
Term	97
Mode of delivery	
Term vaginal delivery	53
Pre term vaginal delivery	3
Emergency cesarean section	34
Elective cesarean section	10
Complications associated	
Polyhydramnios	2
Severe pre-eclampsia	5
Non- severe pre -eclampsia	3
Gestational hypertension	7
Hypothyroidism	8
Asymptomatic	75
Neonatal complications	
Respiratory distress	21
Hypoglycemia	0
Hyperbilirubinemia	0
Intra uterine death	2
No complication	77
Birth weight in Kg	
<2	5
2-2.49	5
2.5-2.99	43
3-3.49	34
3.5-4	13
APGAR score	
<4	0
5-6	1
6-7	5
7-8	56
8-10	38

Discussion

In our study, majority of the women were in 25-29 years of age, were from joint type of family and low socio-economic class. Family history of diabetes was found in 10% of the antenatal mothers and only 27% of the women had BMI in the pre obese range. Majority of the women did not have associated risk factors. 97% of the women had term delivery in which majority had vaginal delivery. 21% of the newborns had respiratory distress, whereas 77% of the newborns did not have any complications after birth. Majority of the newborns had good APGAR score. 12% of the multiparous women and 10% of the primigravida had GDM-associated complications

Table 4: Correlation of variables

	Age	Parity	BMI	DIPSI value	Gestational age	Birth weight	APGAR
Age	1						
Parity	0.141	1					
BMI	-0.017	-0.064	1				
DIPSI value	0.144	-0.045	0.107	1			
Gestational age	-0.353*	-0.052	-0.003	-0.142	1		
Birth weight	-0.056	-0.094	-0.019	-0.062	0.398*	1	
APGAR	0.045	-0.018	0.061	0.007	0.133	0.383*	1

*0.001

Table 5: Significant correlations of variables

Variable-1	Variable-2	Correlation coefficient (*r*)	*P*
Gestational age	Age	-0.353	0.000
Birth weight	Gestational age	0.398	0.000
APGAR	Birth weight	0.383	0.000

in which majority had pregnancy-induced hypertension. There was significant correlation between gestational age of the patient and age of the mother, Birth weight and gestational age of the mother, APGAR score and Birth weight of the baby.

Indian women are more prone to develop GDM during pregnancy, hence the need for universal screening is mandatory. For universal screening, the WHO recommended 75 grams of OGTT as a one-step screening and diagnostic procedure.[1] On 14th march 2007, the Government of India, recommended universal Screening at 24-28 weeks of pregnancy with 75 grams oral glucose tolerance test. Venous blood glucose sample of 140 mg% or more is suggestive of GDM. The step procedure is less time-consuming, economical and feasible. The two-step procedure of screening with 50-gram OGCT is not practical as the pregnant women have to visit the clinic twice and 3 or 4 blood samples are drawn, which is distressing to the patient. DIPSI procedure is cost-effective, without compromising the clinical equipoise and can be continued to diagnose GDM in our country.[12]

Raghav M *et al.*[13] conducted a prospective cohort study and found the prevalence of GDM in DIPSI was 5.1%, according to WHO 2013 criteria 10.5%. Of the 550 women, 492 had a normal DIPSI and a normal WHO 2013 test. Of these 492, 116 (23.6%) women had adverse effects on the fetus. 58 of 550 women had a normal DIPSI but an abnormal WHO 2013 test. Thirty-seven of 58 women (63.8%) had adverse effects on the fetus. They found a statistically significant association between adverse tides and GDM using the WHO 2013 test (the standard DIPSI test). In our study we also find the correlation factor associated with GDM. Another cross-sectional study by Riaz M *et al.*[14] in Pakistan, of the 11,430 participants in the study, the mean gestational age was 27.12 ± 6.84 weeks, and 18.8% and 23.1% had a positive family history of diabetes and hypertension. A previous history of GDM was present in only 6.8% of participants. Approximately 1,349 (11.8%) pregnant women were diagnosed with gestational diabetes, of which 6.2%, 39.9% and 51.1% were diagnosed in the 1st, 2nd and 3rd trimesters, respectively. 25.6% of women had no known risk factors for GDM. In our study, 10% had positive family history.

Obesity as an important risk factor for GDM is supported by several studies that identify overweight or obesity in early pregnancy as a risk factor for GDM. Obesity was a risk factor for GDM in studies conducted in Karachi, Peshawar and Bahawalpur, which showed that overweight and obese women are prone to GDM. Lifestyle changes over the years. increased the effect of obesity. Women have an increased tendency to increase visceral or central fat, a known risk factor for insulin resistance and cardiovascular disease. Education levels are low, leading to a lack of health awareness and acceptance. Unhealthy lifestyle that eventually leads to increased obesity. The family history of type 2 diabetes is a known risk factor, associated with the development of GDM, as reported in several studies. A study conducted at Baqai Medical University and in various other places reported that more than half of patients with a family history of diabetes.[15-18] In this study, the majority of GDM patients had a history of past GDM. Strength of the study is mixed-method study design was used. The stakeholder's perspective were obtained through KII. It helps in addressing the listed reasons in the future. Limitation is temporality cannot be found since it is cross-sectional study design. The result cannot be generalizable because it is a single-centric study.

Conclusion and Recommendation

As DIPSI test is an effective single step in screening and diagnostic test, hence all pregnant mothers should undergo this glucose challenge test in their antenatal visits. The timely action in screening all pregnant women for glucose intolerance achieving euglycemia and ensuring adequate nutrition may prevent all probabilities, the vicious cycle of transmitting glucose intolerance from one generation to another and also maternal and fetal complications. Community-level awareness of healthy food consumption and physical activity to maintain a normal body weight will help control the increasing trend of GDM among pregnant women. Screening with OGTT and early detection of GDM in all pregnant women and regular follow-up were also recommended to prevent various maternal and neonatal complications.

Ethical approval

The study was approved by the Institutional Ethics Committee (SMVMCH).

Table 6: Manual content analysis of the KII (*n*=9)

Themes	Categories	Codes
Community level	General awareness and practical issues	• Inadequate knowledge about the GDM screening test Obstetrician stated that, "*antenatal women were not aware about the screening test which is making them not to come forward for testing, in spite of giving sensitization, most of them especially from rural area are not willing for testing'. Henceforth, community level awareness generation can be initiated to overcome this inadequacy.*" • Lack of transportation. Staff nurse stated that, "*Most of the patients are from rural area, they do not have adequate transport facility during the daytime itself, this is making the antenatal mother not to spent more time in the hospital for testing purpose.*"
Family level	Family issues	• Lack of support from husband and other family members "*Dependent on husband and other family members for transportation". They are in working professionals, hence they will not allow them to do testing, thinking that it is time consuming.*" • Not giving importance to their health "*Since they are responsible person in running the family, most of them are not taking care of their own health.*" • Engaged in family functions and local festivals "*Few of them will have family functions and local festivals at their village, which makes them not to come to hospital for testing at the specific weeks.*"
	Economic issues	• Lack of money for testing due to financial crisis "*Antenatal women from low socio-economic status will not afford money for doing the test.*" • Daily wages. ANM stated that "*Antenatal mothers from low socio-economic status will be going to work as daily wages, the one-day money will be helpful for them to run their family, so they are not willing to spent more time for testing in the hospital.*"
Individual level	Daily chores	• Engaged in day-to-day activities at home. Medical officer stated that, "*Since most of the antenatal mothers are homemakers they were engaged in their daily activities like cooking, taking care of their children, washing clothes and utensils, etc. It leads to time constraint to do testing for them.*"
	Sociocultural issues	• Social belief and misconception like "*after doing this test i will get sugar, if i drink the sugar water my baby will born with sugar, etc.*"
	Health care associated issues	• Fear about the testing procedure • Fear and worried about false reporting of the test results

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Conflicts of interest

There are no conflicts of interest.

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