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A NOVEL APPROACH TO PREDICT GESTATIONAL DIABETES MELLITUS FOR EARLY AND ACCURATE PREVENTION

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ABSTRACT **Background-** Gestational Diabetes Mellitus (GDM) is rising in prevalence, posing risks to both maternal and fetal health, and contributing to fetal origin of adult diseases by affecting pancreatic development. Early predictive testing is essential to implement preventive measures. **Methods-** A prospective analytical comparative study was conducted on 296 pregnant women in Prayagraj, India. All underwent a 75g OGTT within 8 weeks of gestation, with ≥110 mg/dl postprandial blood sugar (PPBS) considered screen positive. Follow-up included DIPSI testing for GDM diagnosis. The impact of Medical Nutrition Therapy (MNT) in screen-positive cases was also assessed. **Results-** Out of all women screened within 8 weeks gestation, 73% were screen negative (PPBS ≤110 mg/dl) and 27% were screen positive (PPBS >110 mg/dl). Among screen positives, 12.8% received MNT and 14.8% did not. GDM developed in 16% of screen positives who received MNT, and 60.7% of those who did not receive MNT ($p<0.001$). The early screening test demonstrated 77.8% sensitivity and 81.1% specificity. Additionally, high BMI and positive family history emerged as independent GDM risk factors because GDM developed in 4.2% of screen negatives who had positive family history and high BMI. **Conclusion-** A PPBS level ≥110 mg/dl within 8 weeks of pregnancy can serve as an effective predictive test for GDM. Early intervention with MNT in screen-positive cases significantly reduced the risk of future GDM development. This highlights the value of early screening and primordial prevention strategies.

KEYWORDS : GDM, GDM Prediction Test, Primordial Prevention, Fetal Pancreatic Development

INTRODUCTION

Diabetes mellitus poses a substantial burden on global health and India is termed as the "diabetes capital of the world," having about 74 million individuals with diabetes, a figure that has doubled in two decades and proportionately GDM has also increased from 3-5% to 18-22% in last decade [1,2].

Maternal hyperglycemia during pregnancy is worrisome because it does not adversely affect the present pregnancy only, but also predispose the offspring to metabolic disorders in later life as hypothesized by David Barker as 'Fetal origin of adulthood diseases'. [3]

Presently, all GDM management guidelines in India focus on early detection by universal screening with DIPSI test at the very 1st antenatal visit. But till now there is no tool for prediction of GDM, like we have for PIH. Medical literature dictum says 'Primary prevention is better than Secondary prevention' and if we can have Primordial prevention, that is avoidance of emergence of risk factors, this would the best modality to curb any disease.

So far, there are no defined strategies to predict future development of GDM, however a study conducted by NIH in year 2018 stated that women with blood sugar levels >110 mg/dl (HbA1c > 5.3) at 10 weeks of gestation are more likely to develop GDM, the reason being that by 11th week, beta cells of fetal pancreas begin to produce insulin, so, disturbing fetal blood sugars at this gestation may alter fetal pancreatic development permanently. Utilizing this fact, if we perform postprandial blood glucose levels (PPBS) at around 8 weeks of gestation, there will be a grace period of 2 weeks to maintain the blood sugar levels at the critical window of 11-12 weeks below the cut off levels to maintain normal fetal pancreatic development.

This study aims to determine the early first-trimester cut off levels of blood sugars to accurately predict GDM development later on, so as to offer a valuable opportunity for primordial prevention by keeping blood sugar levels below the cut off to avoid emergence of new risk factors for future GDM development.

Materials and methods

Study Type- Prospective analytical Study

Study Duration- 1 year (Patients were enrolled in the first 4 months and were followed up subsequently in pregnancy)

Site of Study- Department of Obstetrics and Gynaecology, Swaroop Rani Hospital, Prayagraj

Primary Objectives-

- To determine the cutoff levels of Blood sugars in pregnant women within 8 weeks of pregnancy as a 'GDM prediction test' to predict future GDM development along with the sensitivity and specificity of the test.
- To demonstrate impact of MNT to prevent GDM in screen positives

Secondary Objectives- To establish association of Positive family history and High BMI as independent/dependent risk factor for GDM development.

Inclusion Criteria- Pregnant women with singleton pregnancy within 8 weeks of gestation consenting to participate

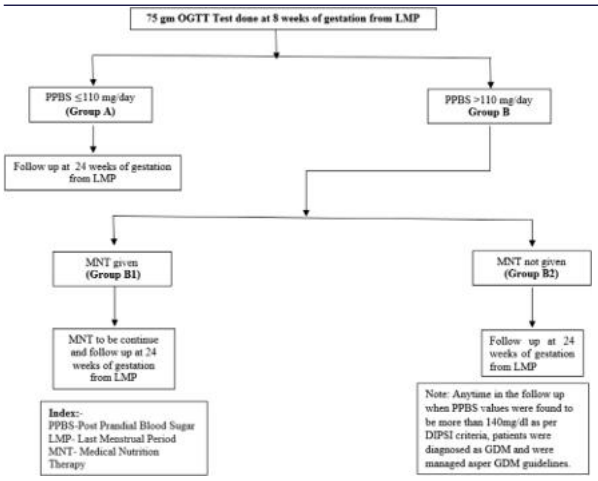
Exclusion Criteria-

- Known diabetic (Type 1 and Type 2)
- Known GDM (PPBS>140mg/dl)
- Any women on metformin for PCOS
- Women beyond 8 weeks of pregnancy
- Multiple Pregnancy
- Not consenting to participate

Sample Technique- Consecutive sampling Technique

We studied 296 pregnant women fulfilling inclusion criteria

Methodology- After approval from the Institutional Ethical Committee, patients were enrolled, history taking, examination and blood tests and further follow ups were done as per following schedule.



Study Tools:
Blood sugar assessment: as per DIPSI guideline at ≤8 weeks of gestation.
MNT: Advised for women with blood sugar >110 mg/dl.
BMI: measured by Quetelet index (body weight in kilograms divided by height squared in meters)

Data Management and Statistical Analysis: By Chi-square test for categorical data and the student's t-test for continuous variables. Statistical significance was set at a p-value < 0.05.

ROC curve was used to determine the cut off level for blood glucose levels to predict GDM.

Tables and Figures

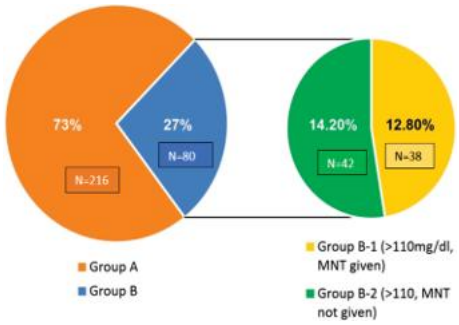


Figure 1. Population Distribution as Per Postprandial Blood Sugar Levels at ≤ 8 Weeks Gestation (N = 296)

Table 1. Sociodemographic Characteristics of the Participants (n=296)

Factors	Group A (%) (PPBS≤110 mg/dl) n= 216 (100%)	Group B (%) (PPBS>110mg/dl) n= 80(100%)		p-value
		Group B1 (%) (PPBS>110mg/dl, MNT given) n=38(100%)	Group B2 (%) (PPBS>110mg/dl, MNT not given) n=42 (100%)	
Age group				
20-24	88 (40.6%)	15 (40%)	21 (50%)	0.885
25-29	93 (43.4%)	15(40%)	15 (35.7%)	
30-34	30 (13.9%)	6 (16%)	4 (10.7%)	
>34	5 (2.1%)	2 (4%)	2 (3.6%)	
SES				
Upper	9 (4.2%)	3 (8%)	2 (3.6%)	0.186
Upper middle	62 (28.7%)	15 (40%)	22 (53.6%)	
Lower Middle	110 (51%)	15 (40%)	18 (42.9%)	
Upper lower	15 (7%)	3 (8%)	0 (0%)	
Lower	20 (9.1%)	2 (4%)	0 (0%)	
Residence				
Rural	109 (50.3%)	15 (40%)	15 (35.7%)	0.277
Urban	107 (49.7%)	23 (60%)	27 (64.3%)	
Gravida				
1	85 (39.2%)	19 (52%)	17 (39.3%)	0.102
2	85 (39.2%)	8 (20%)	8 (21.4%)	
>2	46 (21.7%)	11 (28%)	17 (3.93%)	

Table 2. Proportion of the Patients Who Developed GDM (N = 296)

GDM	Group A (PPBS≤110 mg/dl) N=216 (100%) No. (%)	Group B1 (PPBS>110mg/dl, MNT given) N=38(100%) No. (%)	Group B2 (PPBS>110mg/dl, MNT not given) N=42(100%) No. (%)	p- value
Yes	9 (4.2%)	7 (16%)	25 (60.7%)	<0.001*
No	207 (95.8%)	31 (84%)	17 (39.3%)	
Total (N=296)	216 (100%)	38 (100%)	42(100%)	

Table 3. BMI and Family History in Patients Who Developed GDM (N=296)

Parameters							p-value
	Group A (PPBS ≤ 110 mg/dl) N= 216		Group B1 (PPBS>110 mg/dl, MNT given) N = 38		Group B2 (PPBS>110mg/dl, MNT not given) N = 42		
	Developed GDM n=9 (100%)	Didn't develop GDM n=207 (100%)	Developed GDM n=7	Didn't develop GDM n= 31	Developed GDM n=25	Didn't develop GDM n=17	
Family history present	6 (66.7%)	14 (6.6%)	5 (71.4%)	7 (23.8%)	13 (52.9%)	5 (27.3%)	<0.001*
Family history not present	3 (33.3%)	193 (93.4%)	2 (28.5%)	24 (76.2%)	12 (47.1%)	12 (72.7%)	
p value	0.001		0.081		0.253		
BMI							
<18.5	0 (0%)	18 (8.8%)	0 (0%)	3 (9.5%)	0 (0%)	0 (0%)	<0.001*
18.5-22.9	5 (55.5%)	140 (67.9%)	4 (57.1%)	13 (42.9%)	7 (29.4%)	11 (63.6%)	
23-24.9	2 (22.2%)	49 (23.4%)	2 (28.5%)	9 (28.6%)	15 (58.8%)	6 (36.4%)	
25 and above	2 (22.2%)	0 (0%)	1 (14.2%)	6 (19 %)	3 (11.8%)	0 (0%)	
p value	0.001		0.920		0.150		

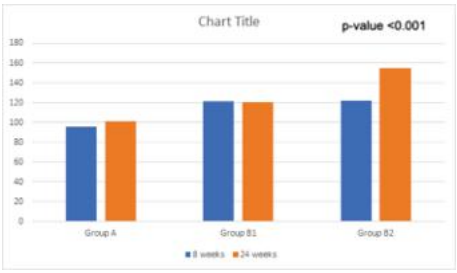


Figure 2. Mean PPBS Values Over Time in Study Groups (N=296)

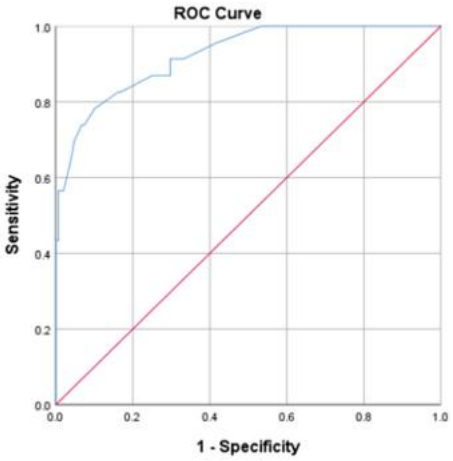


Figure 3. ROC Curve Determining Cut Off of PPBS at ≤ 8 Weeks For the Prediction of GDM Development Along with Sensitivity and Specificity. (N=258)

[Note- B1 study group was excluded to nullify bias of implementing MNT to avoid GDM development])

RESULTS

In Figure 1, amongst 296 participants, 73% had PPBS levels ≤110 mg/dl (Group A), while 27% had levels >110 mg/dl (Group B) out of which only 12.8% patients received MNT (Group B1).

In Table 1, Most of the patients in study groups were aged 25–29 years (43.4% in Group A, 40% in Group B1 and 35.7% in Group B2) and belonged predominantly to lower-middle-class in Group A (51%), while upper-middle-class in Group B1 and B2 (40% and 53.6%, respectively). Urban participants were more prevalent in Groups B1 (60%) and B2 (64.3%), while Group A had a nearly equal rural-urban distribution. The majority of study participants were primigravida in all the groups. No statistical significant difference was noted in any of the sociodemographic variable in all the groups.

In Table 2, occurrence of GDM was significantly higher ($p<0.001$) in Group B2 (60.7%) compared to Group B1 (16%), with only 4.2% in Group A.

In Table 3, association of high BMI and positive family history in Group A was highly significant for GDM development in group A ($p>0.001$).Whereas, this association was not significant in groups B1 and B2. ($p = 0.150 – 0.920$). Across all the groups, majority of participants who developed GDM had BMI categories of 23.0-24.9 (46.3%) and ≥25 (14.6%) and positive family histories (58.5%).The overall association between positive family history, high BMI with GDM development was highly significant ($p < 0.001$) in all the study groups.

In figure 2, mean PPBS levels varied significantly across all the groups at stated gestational ages. At 8 weeks, group A had significantly lower levels (95.3mg/dl) as compared to Group B1(120.9 mg/dl) and Group B2(122.2mg/dl), having comparable distributions. At 24 weeks, the mean PPBS was 101.mg/dl in Group A,120.5 mg/dl in Group B1 and 154.4 mg/dl in Group B2.Group A exhibited the lowest mean PPBS levels followed by Group B1 and Group B2. The p-value of <0.001 highlights a highly significant difference in PPBS values in different study groups .

Figure 3, establishes PPBS cut off of 110 mg/dl at 8 weeks of gestation with 77.8% sensitivity and 81.1% specificity for future GDM development. (AUC 0.882, $p<0.001$).

DISCUSSION

Gestational Diabetes mellitus is detrimental for both mother as well as foetus and needs a predictive test to find out high risk women likely to develop GDM so as to implement preventive measures in screen positives to avoid actual onset of GDM by implementing primordial prevention. The study aimed at assessing the feasibility of using first-trimester PPBS with relevant cut off value to predict future GDM development in that particular pregnancy and also to see whether the early implementation of Medical Nutrition Therapy (MNT) for women with blood sugar more than cut off blood sugar levels could prevent the onset of GDM later in pregnancy.

Distribution of Age, habitats, socioeconomic strata and gravidity amongst study groups were all comparable with no significant statistical difference avoiding them to be confounding factors for GDM development.

The relationship between family history and BMI with GDM developments in different study groups categorically showed significant association with GDM development even screen negative Group A, establishing them as an independent risk factors for GDM development irrespective of blood sugar levels in early 1st trimester. This is in line with various studies like Zhang et al. and Wei et al and Bao et al., which also showed higher prevalence of GDM in overweight and obese women. [4,5,6]. This association calls for modifying the modifiable by weight management strategies, including diet and exercise, to prevent GDM in such patients.

Depending upon the development of GDM in various study groups, the ROC curve determined the mean PPBS level of 110 mg/dl at ≤8 weeks as a predictor of GDM with 77.8% sensitivity and 81.1% specificity. As documented, any screening test must have approximately 80% sensitivity to qualify the criteria to be useful screening tool [7], 77.8 % sensitivity of screening test in our study can be very well used as a predictive modality for future GDM development in that particular pregnancy.

Success to achieve strategies for prediction of GDM in otherwise non high risk women will definitely help us and patients too to adopt preventive measures thus avoiding GDM development and related adverse pregnancy outcomes. Rising incidences and prevalences of GDM definitely calls for newer discoveries in the field to significantly impact the occurrence of GDM because GDM not only leads to psychosocial adversities to the patient and family, but it affects the generations.

Advocacy of continued life style modification strategies even after delivery will further reduce the overall prevalence of Type II Diabetes in the population and thus serve the purpose of NHM missions to curtail the non communicable disease like, Diabetes, Hypertension and metabolic syndrome in India. Various studies like Yeral et al., Bhattacharya et al. and Simmons et al have reported lifestyle modifications effectively prevent Diabetes and 39% decrease in GDM have been documented in theses studies through combined lifestyle interventions, highlighting the synergistic effects of diet and exercise. [8,9,10]. Lower incidence of GDM in group B2 of our study, who adopted MNT, again emphasizes the protective effect of MNT against GDM. Work of Seshiah et al and Rani et al have shown early intervention significantly reduces GDM prevalence[11,12].

CONCLUSION

Some obstetric complications like PIH, FGR, PTL have predictive markers which help us in preventing their onset, but Gestational Diabetes mellitus do not have any predictive test. Prediction of high risk women likely to develop GDM will definitely help us to focusing on primordial prevention. This will not only enable us to prevent GDM in that particular pregnancy but also future development of Type II diabetes in that woman by continuing life style modifications. This will also help us in saving the generations from metabolic syndromes by maintaining euglycemia in the mothers for optimized pancreatic developments of the offsprings.

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Declarations

Conflict of Interest

None

Ethical Issue

Study was approved by Institutional Ethical Committee.

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