Dr. Kajal Krishna
PG Resident 3rd year, Department of OBG, Shri Aurobindo Institute of Medical Science and PG Institute, Indore, Madhya Pradesh, India

Dr. Neeta Natu
Prof. & HOD, Department of OBG, Shri Aurobindo Institute of Medical Science and PG Institute, Indore, Madhya Pradesh, India

Gestational diabetes: A clinical observational non-randomized study

Dr. Kajal Krishna and Dr. Neeta Natu

Abstract
Aim & Objective: The aim of the study is to see the effects of early screening for gestational diabetes mellitus on maternal and fetal outcome.

Pregnant women attending the ante natal clinic at a tertiary care hospital before 16 weeks, and follow up at 24 weeks to 28 weeks and 32 weeks to 34 weeks of pregnancy. Registration details of all the patients including their OPD number, name, age, sex were noted. Consent of each patient was taken.

It was observed that amongst the women with positive DIPSI at 24-28 weeks, 88% patients were managed on diet and exercise alone with a favorable outcome. Only 5 patients required insulin in order to control GDM (due to features of polyhydramnios and increased abdominal circumference of fetus as suggested on growth scan).

The present study shows that most of the cases (63%) can be managed with diet & exercises as first line of therapy. Treatment includes simple dietary modifications, walking after every meal for 15 minutes to insulin therapy. Counseling the patients regarding the need for frequent blood glucose monitoring and frequent antenatal visits helps to achieve good glycemic control. Based on our analysis we can interpret that DIPSI test can be an effective screening tool at 16-18 weeks of pregnancy in order to intervene early in GDM. Early diagnosis and good glycemic control reduces both maternal and fetal complications in GDM. Early diagnosis at 16-18weeks and with early interventions like strict Diabetic diet and exercise we were able to reach Full Term (37 weeks) in 89% patients of GDM.

Keywords: Gestational diabetes, diagnostic criteria, treatment, complications
Study Design: Observational study

Introduction
Gestational diabetes mellitus (GDM) is a common pregnancy complication, affecting about 7% of pregnancies in the United States, and its prevalence has been increasing [1, 2] GDM is associated with both perinatal and longer-term maternal and offspring risks, such as cesarean delivery [3, 4] fetal macrosomia [3, 5] development of type 2 diabetes in the mother [6] and obesity in the offspring [7]. Because of these risks and the potential implications of treatment [8, 9] GDM is an important, emerging area for clinical, epidemiologic, and basic research. Notably, between 2001 and 2010, MEDLINE included >3000 citations indexed as "gestational diabetes mellitus" compared with <1700 citations in the prior decade. In addition, the majority of clinical trials on GDM have been published in the last 10 years.

In 2008, we completed an Agency for Healthcare Research and Quality (AHRQ)-funded systematic review on specific aspects of management of GDM [10]. The review addressed 4 questions proposed by the American College of Obstetricians and Gynecologists (ACOG) because of their high clinical relevance:

1. What are the risks and benefits of an oral diabetes agent (e.g., glyburide), as compared with all types of insulin, for GDM?
2. What is the evidence that elective labor induction, cesarean delivery, or timing of induction is associated with benefits or harm to the mother and neonate?
3. What risk factors are associated with the development of type 2 diabetes after a pregnancy with GDM?
4. What are the performance characteristics of diagnostic tests for type 2 diabetes in women with prior GDM? [10]

We identified 11,400 unique citations, independently reviewed titles, abstracts, and full articles and included 45 articles, which included 9 randomized controlled trials (RCT) that applied to review questions I and II [10]. We graded the evidence as either insufficient or low strength for

Corresponding Author:
Dr. Neeta Natu
Prof. & HOD, Department of OBG, Shri Aurobindo Institute of Medical Science and PG Institute, Indore, Madhya Pradesh, India

addressing the 4 review questions, suggesting widespread deficiencies in the field and the need for higher-quality studies to address the gaps.[10] Although the review synthesized and graded the existing evidence, the next step of identifying and prioritizing research gaps was descriptive and not systematic, as few frameworks currently exist to inform this final process [11]. AHRQ recognized that relying on systematic reviews to identify and report research needs was not sufficient and, thus, has funded various pilot studies, including the one reported here, to develop standard methods.

The primary objective of this study was to identify clinically important research questions for the management GDM using a process that involved stakeholder input and the 2008 systematic review's findings as a starting point. The secondary objectives were to prioritize outcomes to measure in future trials and to highlight feasibility and study design challenges related to the identified research questions. Ultimately, the goal was to guide future research endeavors on GDM management.

Materials and Methods

This study, observational non-randomized clinical study to evaluate the Effect of early screening for GDM on maternal and fetal outcome. The study was conducted in the Department of Obstetrics and Gynecology at a Multi-specialty Tertiary Care Centre Sri Aurobindo Medical College Indore (M.P.) June 2018 to May 2019. Our study plane of 101 pregnant women attending the ante natal clinic at a tertiary care hospital. The findings were tabulated and analyzed.

Inclusion criteria

- Pregnant women attending the ante natal clinic at a tertiary care hospital before 16 weeks of gestation.
- Irrespective of maternal age and gravidity and the presence or absence of clinical or historic risk factors of Gestation Diabetes Mellitus.
- All the women willing to provide voluntary written consent for participation in the study.

Exclusion criteria

1. Patients who are known case of Diabetes in preconceptional period (Pregestational Diabetes) and are on oral hypoglycemic drugs or insulin.
2. Patients who register in OPD in late pregnancy i.e. beyond 24 weeks of conception

Methodology

Pregnant women attending the ante natal clinic at a tertiary care hospital before 16 weeks, and follow up at 24 weeks to 28 weeks and 32 weeks to 34 weeks of pregnancy. Registration details of all the patients including their OPD number, name, age, sex were noted. Consent of each patient was taken. A thorough history of each patient was taken regarding education of the attendant, past ocular history, Family history, previous Gynae surgery or IVF treatment, history drug allergy, systemic surgery, history of number of child. After enrolling into the study and taking informed valid consent for the same, history was taken, general physical examination, systemic examination and per abdomen examination conducted we evaluated the patient at presentation complete history and physical examination-Details of family history of diabetes, history of previous pregnancies were obtained. Blood pressure was recorded using mercury sphygmomanometer, which was calibrated periodically. The body mass index (BMI) of the subjects was calculated from the pre-pregnancy weight and expressed in kg/m². Complete blood cell count with differential and platelet counts, Urine examination. USG-Dating scan, NT scan, detailed Anamoly scan, and serial growth scan. Glucose challenge test (DIPSI test) was done at 16-18 weeks, 24-28 weeks and at 32-34 weeks for all antenatal patients.

Statistical Analysis & Plan: Numeric data will be summarized by descriptive statistics using n, mean, and standard deviation, median, minimum and maximum. Categorical data has been summarized using frequency counts and percentages. Significance is assessed at 5% level of significance. We have assumed that the data is independently normally distributed and no test to check the normality has been performed. Chi square/Fisher's exact test has been used to check the statistical significance between two or more categorical variables. Moreover, to check whether there is any effect of Age, Family history, BMI and Parity on occurrence of GDM or not, Logistic regression model was used.

Results and observations

A observational non-randomized clinical study was carried out to determine the effect of early screening for GDM on maternal and fetal outcome carried out on 101 pregnant women between 16 to 20 weeks, 24 to 28 weeks and 32 to 34 weeks for the screening and diagnosing GDM in pregnancy for the period of 1 year according to the selection criteria listed in materials and methods and the results were analyzed.

Table 1: Age group wise distribution of cases

GE Group	GDM	Without GDM	Total	Percentage
16-25 YRS	1	7	8	8%
26-35 YRS	15	68	83	83%
36-45 YRS	3	7	10	10%

The study group has the highest percentage of pregnant women from the age group of 26-35. It was observed that amongst the women included in the study, in this age group 15 women had GDM whereas in the age group of 16-25 years, 1 out of the 8 patients have GDM. Hence it can be concluded that as the age increased, the risk for developing GDM increased.

Table 2: Correlation of PCOD with GDM

History of PCOD	GDM	Without GDM	Total	Percentage
PRESENT	08	13	21	20.7%
NO HISTORY	11	69	80	79.3%
Total	19	82	101	100%

It was observed that women with positive history of PCOD were significantly associated with increased risk of GDM as out of total 19 GDM patients, 8 had a positive history of PCOD. The results show a statistically significant association between Presence of PCOD and occurrence of GDM (*p*-value<0.001) using Fisher's exact test

Table 3: DIPSI at 16-18 weeks of gestation.

DIPSI	Number of Patients	Percentage
< 140mg/dl	23	22.3%
> 140mg/dl	78	77.2%
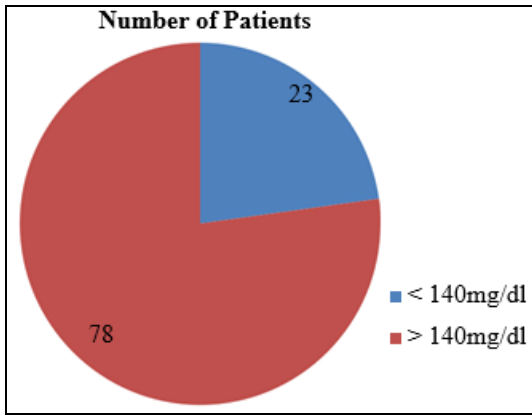
Graph 1: It was observed that amongst 101 women subjected to DIPSI test at 16-18 weeks, 22.3% were found to have impaired glucose tolerance (i. e Blood Sugar >140mg/dl)

Table 4: Rate of detection of GDM at 16-18 weeks as compared to 24-28 weeks & 32-34 weeks by 75gm GCT

DIPSI Test	16-18 Weeks	24	-28 Weeks	32-34 Weeks
< 140mg/dl	78 (77.2%)	82	(81.2%)	84 (83.2%)
> 140mg/dl	23 (22.3%)	19	(18.8%)	17 (16.8%)
Total	101		101	101

The rate of detection of GDM by the 75g GCT during 16-18 weeks gestation was 23 and at 24-28 weeks was 19. The decrease in detection of blood glucose level by DIPSI test reflects those cases which were managed by lifestyle modification alone. At 32-34 weeks, the case detection rate was 17 which was still comparatively less than the 23 detected at 16-18 weeks and also included two new cases of abnormal GCT which were earlier observed to be normal. It is also to be noted, that there were 2 cases in whom the GCT was not performed at 32-34 weeks as these two were already on insulin therapy for glucose control.

Hence, the number of cases found to be positive by the 75g GCT were more or less the same during the three intervals of gestation. Based on our analysis we can interpret that DIPSI test can be an effective screening tool at 16-18 weeks gestation (early screening) which will help to intervene early and thereby improve the maternal and fetal outcome by simple lifestyle modifications.

Table 5: Intervention after 1ST DIPSI test AT 16-18 weeks (Blood Sugar>140mg/dl)

Interventions at 16-20 WKS	Repeat DIPSI test AT 24-28 weeks*		Total
	<140mg/dl	> 140mg/dl	
Diabetic diet and 15 min walk after every meal	82	19	101
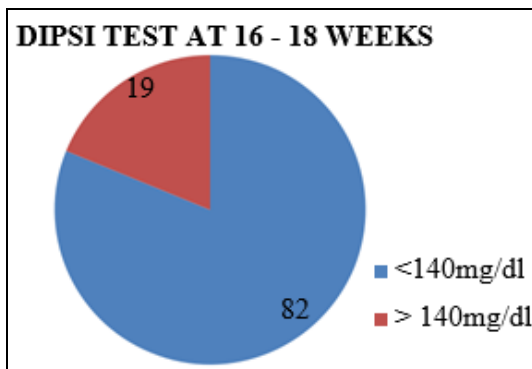
Graph 2: It was observed that early intervention with diet modification and exercise (15 min. walk after every meal) significantly improves the course of disease

Table 6: Intervention after 2nd DIPSI test at 24-28 weeks.

Interventions at 24-28wks	Number of Patients
Diet, Exercise and Home glucose Monitoring	21
Insulin	5
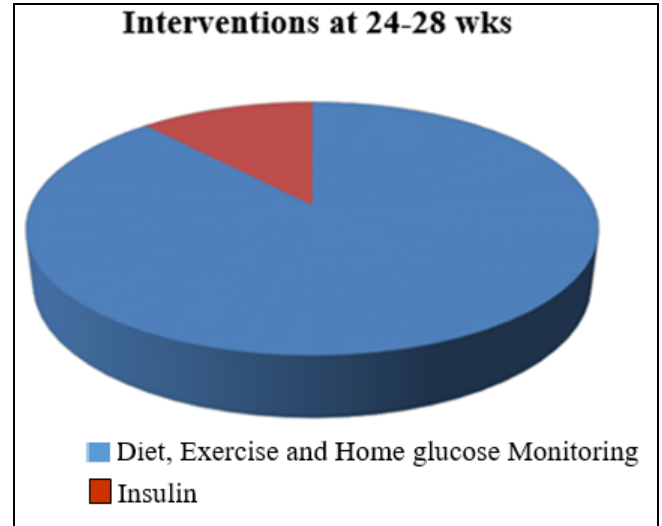
Graph 3: It was observed that amongst the women with positive DIPSI at 24-28 weeks, 88% patients were managed on diet and exercise alone with a favorable outcome. Only 5 patients required insulin in order to control GDM (due to features of polyhydramnios and increased abdominal circumference of fetus as suggested on growth scan)

Discussion

The concept of Gestational Diabetes Mellitus (GDM) goes back to at least 1946. The importance of GDM is that two generations-the woman herself and her children are at risk of developing diabetes in the future. Increasing the maternal carbohydrate intolerance in pregnant women is associated with graded increase in adverse maternal and fetal outcomes. Ethnically, Indian women have a high prevalence of diabetes. They have an eleven-fold increase in developing Gestational Diabetes compared to Caucasian women.

Gestational diabetes mellitus (GDM) is associated with an increased risk of maternal and perinatal short- and long-term complications [12]. Screening and diagnosis of GDM is traditionally delayed until the late second or early third trimester of pregnancy with the rationale that the diabetogenic effects of pregnancy increase with gestation, and therefore, delayed testing would maximize the detection rate [13].

Universal screening during pregnancy has become important in our country. For this we need a simple, reliable and cost effective procedure. Despite more than 30years of research there is no consensus regarding the optimal approach to the screening of Gestational Diabetes. Hence, a prospective study of 101 pregnant women between 16-34weeks of gestation was done to find out several risk factors that play a role in the development of GDM, role of DIPSI procedure (which is attributed to be both a screening and a diagnostic tool) in pregnancy for early detection and the effect of early intervention with Diet and Lifestyle modifications on maternal and fetal outcome.

"Gestational diabetes mellitus is a Carbohydrate intolerance of variable severity with the onset or first recognition during the present pregnancy". GDM is associated with important prenatal & long term health risks & many of the risks increase in relation to the severity of maternal hyperglycemia.

Conclusion

This study was done on study the effect of early screening for Gestational Diabetes Mellitus on Maternal and Fetal outcome by DIPSI (Diabetes in Pregnancy study group) method. Patients were in the age group 20-38 yrs. highest incidence of GDM was seen at around 26-35 years. It was observed that women with positive family history of diabetes were significantly associated with increased risk of GDM. 80% patients with impaired glucose tolerance had family history of Diabetes (Mother/Father). 42% patients with BMI > 30 had impaired glucose tolerance. Most common associated risk factor with GDM were Previous LSCS (16%), prematurity (10.5%) and polyhydramnios (10.5%) followed by breech, IUGR and PROM. Risk factors in previous pregnancies which are associated with increased incidence of GDM like H/o smoking, previous history of still birth, H/o GDM in previous pregnancy were present in 36% patients of GDM and was also present in 18% of patients with normal glucose tolerance.

The present study shows that most of the cases (63%) can be managed with diet & exercises as first line of therapy. Treatment includes simple dietary modifications, walking after every meal for 15 minutes to insulin therapy. Counseling the patients regarding the need for frequent blood glucose monitoring and frequent antenatal visits helps to achieve good glycemic control. Basedon our analysis we can interpret that DIPSI test can be an effective screening tool at 16-18 weeks of pregnancy in order to intervene early in GDM. Early diagnosis and good glycemic control reduces both maternal and fetal complications in GDM. Early diagnosis at 16 - 18weeks and with early interventions like strict Diabetic diet and exercise we were able to reach Full Term (37 weeks) in 89% patients of GDM.

References

1. Ferrara A, Kahn HS, Quesenberry CP, Riley C, Hedderson MM. An increase in the incidence of gestational diabetes mellitus: Northern California, 1991–2000. Obstet Gynecol. 2004; 103:526-533.
2. Dabelea D, Snell-Bergeon JK, Hartsfield CL *et al*. Increasing prevalence of gestational diabetes mellitus (GDM) over time and by birth cohort: Kaiser Permanente of Colorado GDM screening program. Diabetes Care. 2005; 28:579-584.
3. Xiong X, Saunders LD, Wang FL, Demianczuk NN. Gestational diabetes mellitus: Prevalence, risk factors, maternal and infant outcomes. Int J Gynaecol Obstet. 2001; 75:221-228.
4. Casey BM, Lucas MJ, Mcintire DD, Leveno KJ. Pregnancy outcomes in women with gestational diabetes compared with the general obstetric population. Obstet Gynecol. 1997; 90:869-873.
5. Pettitt DJ, Knowler WC, Baird HR, Bennett PH. Gestational diabetes: Infant and maternal complications of pregnancy in relation to third-trimester glucose tolerance in the Pima Indians. Diabetes Care. 1980; 3:458-464.
6. Kim C, Newton KM, Knopp RH. Gestational diabetes and the incidence of type 2 diabetes: A systematic review. Diabetes Care. 2002; 25:1862-1868.
7. Gillman MW, Rifas-Shiman S, Berkey CS, Field AE, Colditz GA. Maternal gestational diabetes, birth weight, and adolescent obesity. Pediatrics. 2003; 111:e221-226.
8. Crowther CA, Hiller JE, Moss JR *et al*. Effect of treatment of gestational diabetes mellitus on pregnancy outcomes. N Engl J Med. 2005; 352:2477-2486.
9. HAPO Study Cooperative Research Group. The Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Study. Int J Gynaecol Obstet. 2002; 78:69-77.
10. Nicholson WK, Wilson LM, Witkop CT *et al*. Therapeutic management, delivery, and postpartum risk assessment and screening in gestational diabetes. Evid Rep Technol Assess. 2008; 162:1-96.
11. Robinson KA, Saldanha IJ, McKoy NA. Development of a framework to identify research gaps from systematic reviews. J Clin Epidemiol. 2011; 64:1325-1330.
12. Adams Kristina M, Li Hongzhe, Nelson Roger L, Ogburn Paul L, Danilenko-Dixon Diana R. Sequele of unrecognized gestational diabetes. Am J ObstetGynecol 1998; 178(6):1321-26.
13. Green J, PawsonI, Schumacher L. Glucose tolerance in pregnancy: ethnic variation &influence of body habitus. Am J Obstet Gynecol. 1990; 163:86-92.