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Primordial Prevention of Gestational Diabetes Mellitus: A Prospective Cohort

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Introduction

"Children and mothers never truly part; bound in the beating of each other's heart." - Charlotte Grey

Ancient Tamil wisdom advises against seeking the origins of a sage and a river's headwaters due to their mysteries. However, understanding the root causes of diabetes and non-communicable diseases (NCDs) is crucial for prevention and treatment. The rise in NCDs is driven by aging, genetics, urbanization, and lifestyle choices, with gestational diabetes being a significant factor. In the 1990s, David Barker's "fetal origins of adult disease (FOAD)" hypothesis suggested that adult disease susceptibility is programmed in the womb. Maternal hyperglycemia during pregnancy increases the fetus's risk of developing NCDs in adulthood. Women with gestational diabetes often develop diabetes within three to six years after delivery, perpetuating a cycle of obesity, insulin resistance, diabetes, and NCDs across generations. Breaking this cycle is now more crucial than ever. ¹

Impaired Glucose Tolerance (IGT) is a precursor to the worsening diabetes pandemic. Diabetes significantly contributes to morbidity, reduced quality of life, and premature death. It accounts for nearly 10% of global deaths among people aged 20 to 99 and is the fourteenth leading cause of Disability-Adjusted Life Years (DALYs) worldwide.²

The prevalence of diabetes is increasing worldwide due to factors like urbanization, nutrition, the elderly population, genetics, and lifestyle changes. An often-overlooked factor is gestational diabetes mellitus, which leads to glucose intolerance during pregnancy.³ Gestational diabetes mellitus (GDM), according to the World Health Organization, is characterized by carbohydrate intolerance leading to elevated blood sugar levels, with variable severity, first recognized during pregnancy. It is the very common metabolic disorder in pregnancy. Insulin resistance increases during pregnancy due to the development of carbohydrate intolerance.⁴

Adiponectin, which has antidiabetic and anti-inflammatory effects, is present in low levels in pregnant women with gestational diabetes mellitus (GDM). This decrease is associated with increased insulin resistance during pregnancy, playing a role in the onset of GDM. Insulin resistance, resulting from the β -cells' failure to secrete insulin properly, may also be affected by maternal adiposity.⁵ Recent research has revealed that fetal overgrowth associated with GDM starts early in pregnancy, underscoring the importance of detecting glucose intolerance sooner. Previous studies have examined whether first-trimester HbA1c levels can predict GDM, but these studies often focused on high-risk groups, considered a threshold of 5.7% HbA1c (indicative of prediabetes), or used first-trimester GDM diagnosis as the primary outcome measure.⁶

According to NIH researchers, performing a blood test as early as the 10th week of pregnancy could aid in identifying women who are at risk of developing gestational diabetes. This condition carries significant health risks for both mothers and infants, emphasizing the importance of early detection.⁷

Previous studies focused solely on predicting Gestational Diabetes Mellitus (GDM) from 24 weeks onward. Therefore, this study is designed to investigate GDM starting from as early as 8 weeks of pregnancy.



- 1. The rising prevalence of GDM is primarily driven by modifiable risk factors like obesity, poor diet, sedentary lifestyle, and pre-existing insulin resistance, which can be reduced through early interventions.
- 2. GDM has long-term effects on both the mother and offspring, influencing health outcomes across generations.
- 3. Primordial prevention of GDM, by addressing its root causes, is more cost-effective than managing its complications during and after pregnancy.
- 4. Preventing GDM can significantly improve maternal outcomes (such as reducing preeclampsia and cesarean deliveries) and neonatal outcomes (such as reducing macrosomia and NICU admissions).
- 5. Current preventive strategies have limitations; primordial prevention offers a proactive approach by modifying lifestyle and environmental factors before pregnancy to prevent GDM.
- 6. Primordial prevention of GDM promotes lifelong health and reduces the risk of other non-communicable diseases in women of reproductive age.

This study was broadly focused on antenatal care (ANC) mothers in rural areas, given the importance of this population. It explored various parameters, including demographic factors, postprandial blood sugar (PPBS) levels, and Oral Glucose Challenge Test (OGCT) at specific times. The primary aim was to identify early indicators of hyperglycaemia among these mothers.

Aims and Objectives

To determine early prediction of Hyperglycaemia in pregnancy and Treat with MNT

OBJECTIVES

- 1. To study socio-demographic profile of ANC mothers.
- 2. To assess the early prediction of gestational diabetes mellitus.

MATERIAL AND METHODS

1. Study design:

Hospital based prospective Cohort study

2. Study setting:

Tertiary care Centre.

3. Ethical considerations:

Ethical committee approval was obtained from the Institutional ethical committee prior to the start of the study.

4. Study duration:

The present study was carried out over a period of 2 years from October 2022 to September 2024.

5. Study population:

All ANC mothers visiting tertiary care Centre.

Inclusion criteria:

ANC mothers at 8 weeks to 10 weeks



Exclusion criteria:

ANC mothers are not willing to participate and are not willing to give consent for study.

6. Sample Size:

Total population (N): 30,000

Prevalence (P): 0.07 (7%) Confidence level: 95%

Z value (Z): 1.96

Margin of error (D): Not directly specified, but let's assume a commonly used margin of error of 5% (0.05)

Using the simplified formula for calculating the sample size n for a proportion:

 $n=Z2\times P(1-P)/D2$

Where:

Z=1.96 (Z-score for 95% confidence)

P=0.07

1-P=0.93

D=0.05

 $n=1.96^2\times0.07\times(1-0.07)/0.05^2$

 $n=3.8416\times0.07\times0.93/0.0025$

 $n=3.8416\times0.0651/0.0025$

n=0.2501/0.0025

n=101

Final sample size was taken 135 ANC mothers, attending weekly ANC check-ups. It took 3 months to gather the sample size, and participants were included from the 8th week of pregnancy onwards.

7. Conduct of the Study:

Permission was obtained from the Head of the Department of Obstetrics and Gynecology to conduct ANC examinations, including measurements of height, weight, BMI, blood pressure (BP), postprandial blood sugar (PPBS), and oral glucose tolerance test (OGTT). The ANC mothers were screened for Gestational Diabetes Mellitus (GDM) starting from the 8th week of gestation.

8. Consent of study participants:

Those who were willing to participate in the study, their written informed consents were taken and enrolled in the study.

9. Data collection:

Prior to enrollment in the study, pregnant women attending obgy opd were provided with detailed information about the study objectives, procedures, potential risks, and benefits. Written informed consent was obtained from each participant before their inclusion in the study. Participants were assured of the confidentiality of their information and were informed of their right to withdraw from the study at any time without any impact on their ANC services. Participants who declined to provide consent for participation in the study were excluded. Only those who willingly consented to be part of the study were included in the cohort.

After enrolling in the study, participants will have their postprandial blood sugar (PPBS) levels checked at the 8th and 12th weeks. Participants with PPBS levels above 110 mg/dL will receive dietary education, while those with levels below 110 mg/dL will not receive dietary education. Subsequently, both groups will undergo an Oral Glucose Tolerance Test (OGTT) at the 16th, 24th, and 32nd weeks. Additionally, PPBS levels will be measured postpartum for all participants.

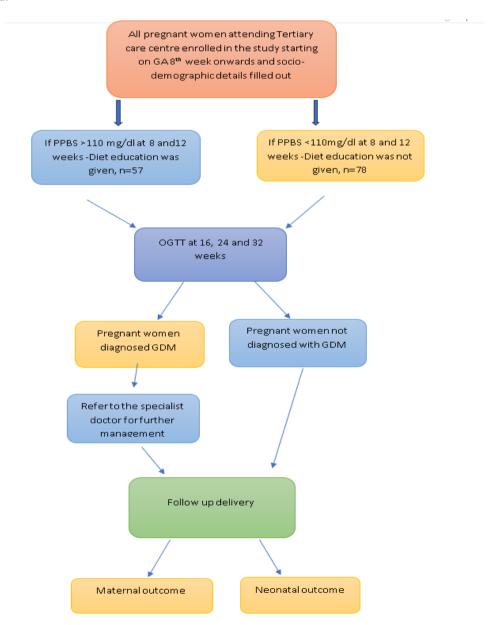
Sociodemographic Inquiry: During the initial visit, participants were asked to provide sociodemographic details such as age, educational level, occupation and socioeconomic status. This information was crucial for understanding the demographic characteristics of the study population and identifying any potential sociodemographic factors associated with gestational diabetes mellitus (GDM) risk.**Blood Sugar Level (BSL) Assessment**: between 8th and 10th week of gestation visit, participants underwent a PPBS (post prandial blood sugar) assessment to screen for gestational diabetes mellitus (GDM).



10. Health education on prevention of GDM:

The dietary advice emphasizes promoting better health and managing conditions such as gestational diabetes by consuming smaller, more frequent meals and ensuring adequate fluid intake through water, juices, and soups while limiting caffeine and artificial sweeteners. A balanced diet rich in essential nutrients is also crucial during pregnancy, including vegetables (such as carrots, spinach, and tomatoes), fruits (like mangoes and bananas), dairy products (such as low-fat yogurt and milk), grains high in iron and folic acid, and protein sources like eggs, beans, nuts, and certain types of fish to support maternal health and fetal development.

- 11. Oral Glucose Tolerance Test (OGTT): Starting from the 16th or 24th or 32 weeks of gestation, participants underwent an oral glucose tolerance test (OGTT) during subsequent visits to tertiary care center. OGTT is a diagnostic test used to confirm the presence of gestational diabetes mellitus (GDM) by assessing the body's ability to metabolize glucose effectively. Participants consumed 75gm of glucose solution, and blood samples were taken after 2 hours to measure glucose levels.
- **12. Postnatal Data Collection:** Following delivery, postprandial blood glucose (PPBS) testing was conducted, and data on delivery outcomes, including the baby's weight and any complications experienced during pregnancy and childbirth, were documented.





13. Instruments used for data collection:

The instruments used in this study included a glucometer, a blood pressure apparatus, and a weighing machine, all of which were regularly standardized throughout the data collection period.

14. Cut off point:

The Diabetes in Pregnancy Study Group India (DIPSI) recommends a non-fasting Oral Glucose Tolerance Test (OGTT) with 75 grams of glucose, using a cut-off of \geq 140 mg/dL after 2 hours as a single-step procedure, irrespective of the last meal. Pregnant women attending the antenatal OPD were given 75 grams of anhydrous glucose dissolved in 250-300 mL of water, and plasma glucose was estimated after 2 hours. A 2-hour plasma glucose level of \geq 140 mg/dL is considered diagnostic of gestational diabetes mellitus (GDM). If the level is between 120 mg/dL to less than 140 mg/dL, it is considered as gestational glucose intolerance (GGI).

15. Procedure of Measurement of Oral Glucose Tolerance Test: -

At the antenatal clinic, after a pregnant woman had undergone a preliminary clinical examination, she was given a 75g oral glucose load, regardless of the time of her last meal.

If a 75g glucose packet was not available, 5 level teaspoons (not heaped) of glucose were removed from a 100g packet, which was commonly available.

A venous blood sample was then collected two hours later to measure plasma glucose. Gestational Diabetes Mellitus (GDM) was diagnosed if the 2-hour plasma glucose level was \geq 140 mg/dl.

All pregnant women attending the ANC were evaluated for eligibility. Trained research assistants collected data using an interviewer-administered questionnaire. Capillary blood samples were taken from the anterolateral aspect of the pulp of the middle finger on the non-dominant hand for non-fasting blood glucose level testing and OGTT. The first blood drop was wiped away with a sterile dry piece of cotton, and the subsequent blood drops were collected onto the glucose strip inserted into a glucometer.

16. Height, Weight & BMI Recording:

- A. Height was measured in cm by drawing metric scale on walls.
- B. Weight recording of every subject was done with the help of standardized weighing machine. The machine was standardized from time to time with the help of standard weight. Before taking weight zero was adjusted properly.
- C. Body mass index was calculated by formula Body Mass Index = Weight (Kg)/ Height (M)².

Data compilation:

Collected data was entered into Microsoft-Excel 2021 worksheets and coded appropriately.

17. Data analysis: Data was analysed using Microsoft Excel 2021, Open EPI-Info Version 3.01 updated on 2013/04/06. Descriptive statistics (percentage, mean) were used to describe the data appropriately. Appropriate statistical test used as per type of data. The significant association was considered when p-value was less than 0.05.

18. Operational definitions

Diabetes mellitus: Diabetes mellitus is a chronic metabolic disorder due to either insulin deficiency (relative or absolute) or due to peripheral tissue resistance (decreased sensitivity) to the action of insulin.⁸

GDM: GDM is defined as carbohydrate intolerance of variable severity with onset or first recognition during the present pregnancy and according to DIPSI (Diabetes in Pregnancy study group of India): recommends 1-step procedure with 75 gm oral glucose without regard to the time of the last meal. A venous plasma glucose value at 2-hour more than 140 mg/dL is diagnosed GDM.⁸

EGGI: Early Gestational Glucose Intolerance



Gestational hypertension (GHTN): A sustained rise of blood pressure to 140/90 mm Hg or more on at least two occasions 4 or more hours apart beyond the 20th week of pregnancy or within the first 48 hours of delivery in a previously normotensive woman is called gestational hypertension⁸

Pregnancy- induced hypertension (PIH): is defined as the hypertension that develops as a direct result of the gravid state. It includes—(i) gestational hypertension, (ii) preeclampsia and (iii) eclampsia.⁸

Pre-eclampsia: Preeclampsia is a multisystem disorder of unknown aetiology characterized by development of hypertension to the extent of 140/90 mm Hg or more with proteinuria after the 20th week in a previously normotensive and nonproteinuric woman⁸

Primigravida: A primigravida is one who is pregnant for the first time.⁸

Multigravida: A multigravida is one who has previously been pregnant. She may have aborted or have delivered a viable baby.⁸

Primipara: a primipara is one who has delivered one viable child. Parity is not increased even if the fetuses are many (twins, triplets)⁸

Multipara: Multipara is one who has completed two or more pregnancies to the stage of viability or more.⁸

Preterm delivery: A baby born before 37 completed weeks of gestation calculating from the first day of last menstrual period is arbitrarily defined as preterm baby⁸

Term delivery: the birth of a baby that occurs between 37 and 42 weeks of gestation.8

Low birth weight (LBW): Low birth weight is defined as a birth weight of less than 2,500 grams (5 pounds, 8 ounces) regardless of gestational age⁸

Macrosomia: Fetal macrosomia (40–50%) with birth weight > 3.45 kg ⁸

Large for Gestational Age (LGA): Large for gestational age is defined as a new born whose birth weight is above the 90th percentile for their gestational age⁸

Hyperbilirubinemia: When the bilirubin (unconjugated) level rises more than the arbitrary cut-off point of 12 mg/dL, in a term infant the condition is called "hyperbilirubinemia of the newborn".⁸

Hypoglycaemia: All new-borns should have their blood glucose levels checked within 2 hours of birth to prevent complications related to hypoglycaemia, defined as a blood glucose level of less than 35 mg/dL.⁸

Phototherapy: It is best when used in moderate cases where the bilirubin level rises above 12 mg%. Skin colour is not a reliable guide to assess the response and hence periodic bilirubin estimation should be done. Phototherapy is discontinued when serum bilirubin level is <13mg/dl in term and <11mg/dl in pre-term neonates. Phototherapy should be started early, exposing the maximum surface area and shielding the eyes. It may be continuous or interrupted for breastfeeding.⁸

Abortion: Abortion is the expulsion or extraction from its mother of an embryo or fetus weighing 500 g or less when it is not capable of independent survival (WHO). This 500 g of fetal development is attained approximately at 22 weeks (154 days) of gestation. ⁸

Still birth: A stillbirth is the birth of a new born after 28th completed week (weighing 1000 g or more) when the baby does not breathe or show any sign of life after delivery.⁸

PROM (pre-term rupture of membranes): Spontaneous rupture of the membranes any time beyond 28th week of pregnancy but before the onset of labour is called prelabour rupture of the membranes (PROM).⁸

 $\textbf{CPD} \text{ (cephalopelvic disproportion):} \text{ The disparity in the relation between the head and the pelvis is called cephalopelvic disproportion.}^{8}$

Fetal distress: Even in a normal labour, the baby experiences stress due to factors such as: (1) uterine contractions that temporarily reduce uteroplacental circulation, and (2) head compression that affects the function of vital centres in the brain. While a healthy



fetus can generally tolerate the stress of labour within physiological limits, a compromised fetus or a pathological state of labour can lead to sudden fetal distress.⁸

MSL (meconium stained liquor): The meconium stained liquor may be aspirated by the fetus-in-utero or during first breath.8

Respiratory Distress Syndrome (RDS): is a condition commonly seen in premature new-borns, characterized by difficulty in breathing due to immature and underdeveloped lungs.⁸

Normal Vaginal Delivery (**NVD**), also known as spontaneous vaginal delivery, refers to the natural process of childbirth where a baby is delivered through the birth canal (vagina) without the need for surgical intervention, such as a caesarean section.⁸

LSCS (**Lower Segment Caesarean Section**): In this operation, the extraction of the baby is done through an incision made in the lower segment through a trans peritoneal approach.⁸

Gestational glucose intolerance: Gestational Glucose Intolerance (GGI) is defined as a plasma glucose level of 120 to 139 mg/dL after 2 hours of an Oral Glucose Tolerance Test (OGTT). ⁹

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Informed Consent

Written Consent taken from Patients

Conflict of Interest Statement

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