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Original Article

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Primary Maternal Neonatal Outcome with MNT Metformin in Early Gestational Glucose Intolerance (EGGI)

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Abstract

To explore the roles of Medical Nutritional Therapy (MNT) and Metformin in managing early gestational glucose intolerance (EGGI) with the potential to prevent the development of gestational diabetes mellitus (GDM) and reduce primary neonatal outcomes. ***Objectives:*** This important study examines the effectiveness of Medical Nutrition Therapy (MNT) and Metformin in managing early gestational glucose intolerance during the 8th to 10th week of pregnancy, specifically for postprandial blood glucose (PPBG) levels over or equal to 110 mg/dL. ***Materials and Methods:*** A prospective cohort study at the Upper India Sugar Exchange Maternity Hospital in Kanpur involved 231 pregnant women between the 8th and 10th weeks of gestation, all with a postprandial blood glucose (PPBG) level of 110 mg/dL or higher. Participants were randomly assigned to two groups: one received Medical Nutrition Therapy (MNT) combined with Metformin, while the other received MNT alone. ***Results:*** The results reveal that mean postprandial blood glucose (PPBG) levels were significantly lower in the Metformin + MNT group compared to the MNT group at key time weeks: 126.77 ± 6.55 vs. 134.1 ± 10.74 at 12 weeks, 122.95 ± 8.47 vs. 126.65 ± 13.2 at 16 weeks, 117.80 ± 4.91 vs. 124.76 ± 11.03 at 24 weeks, and 113.92 ± 8.94 vs. 127.71 ± 17.65 at 32 weeks, with all P-values ≤ 0.001. Additionally, the incidence of primary composite adverse neonatal outcomes was significantly higher in the MNT group (35 cases, 32.41%) than in the Metformin + MNT group (21 cases, 17.07%), with a P-value ≤ 0.0001. ***Conclusion:*** Recognizing and addressing Early Gestational Glucose Impairment (EGGI) as soon as possible, with the support of Medical Nutrition Therapy (MNT) and Metformin, can truly make a difference. This approach not only helps in preventing the progression to Gestational Diabetes Mellitus (GDM) and improving blood sugar control, but it can also lead to significantly better Neonatal outcomes. By taking this proactive step, we can provide a nurturing foundation for better Maternal fetal health, helping to set the stage for Diabetes Prevention.

Keywords: ***Metformin, gestational diabetes mellitus (GDM), PPBG Post prandial blood glucose, MNT Medical Nutrition Therapy, OGCT Oral Glucose Tolerance Test, Oral Glucose challenge Test, DIPSI diabetes in pregnancy study group India.***

Introduction

Approximately 14% of pregnancies worldwide are affected by gestational diabetes mellitus (GDM), a common and serious complication characterized by elevated blood sugar levels during pregnancy that typically resolve after childbirth. Recognizing the far-reaching implications of GDM is essential, as it poses significant long-term health risks for both mothers and their children. Currently, 23.0 million live births (19.7%) to women will experience some form of hyperglycemia in pregnancy around 13.4% of pregnancies globally. Both mothers and their infants are at an increased risk of developing type 2 diabetes and other health issues later in life. Therefore, it is vital to implement effective strategies to manage and address gestational diabetes. By doing so, we can help safeguard the health of mothers and their children. Notably, in South Asia, 1 in 3 live births are affected by hyperglycaemia in pregnancy; prevalence of GDM is especially concerning at 28%, as highlighted in the recently published IDF Atlas 11th edition 2025 (Picture 1). This underscores the need for targeted interventions and awareness to improve maternal and child health outcomes in the region [1,2].

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Picture 1 Diabetes & Gestational Diabetes in South East Asia 2024 Credit (IDF Atlas 11th Edition 2025)

In India, a significant number of pregnant women approximately 70% attend check-ups during the first trimester as per latest NFHS-5 data, 2019-2020, making this an ideal time for early screening. By conducting screenings as early as 8 to 10 weeks of pregnancy (around 2 months of amenorrhea), healthcare providers have the opportunity to diagnose early gestational dysglycemia when blood glucose levels are ≥110 mg/dl. Early identification of dysglycemia is essential, as it can prevent prolonged exposure of both the mother and fetus to mild to moderate elevated blood glucose levels, unlike late-onset gestational diabetes mellitus (GDM), which typically arises between 24 and 28 weeks of gestation or eGDM below 20 weeks.

The TOBOGM study has shown that early screening and treatment, ideally before 20 weeks of gestation, can lead to positive health outcomes. In line with WHO guidelines, diagnosing gestational diabetes between 24 and 28 weeks involves a 75 g 2-hour oral glucose tolerance test, utilizing a threshold of 153 mg/dl for diagnosis. Furthermore, the DIPSI Indian criteria present an effective cutoff of ≥140 mg/dl which is well Justified in India or south east Asia Who are at high risk.

Addressing diabetes as a growing public health concern requires the implementation of innovative and evidence-based strategies for effective blood glucose management. By maintaining mild to moderate hyperglycemia during pregnancy through accessible and safe interventions like Metformin and tailored medical nutrition therapy, we can significantly enhance outcomes. Initiating these measures in the first trimester has the potential to be transformative in the prevention and control of Type 2 diabetes, benefiting both mothers and their children alike.

Asian genotypes are likely to have elevated post-meal blood glucose levels compared to Caucasians, who have elevated fasting blood glucose [3].

Recently, many centers in India have adopted a Postprandial Blood Glucose (PPBG) threshold of≥110 mg/dL in the 8-10 weeks of gestation for the early management of dysglycemia, resulting in better blood glucose control and neonatal outcomes. However, further outcome studies are needed to corroborate these findings in a large-scale study [4].

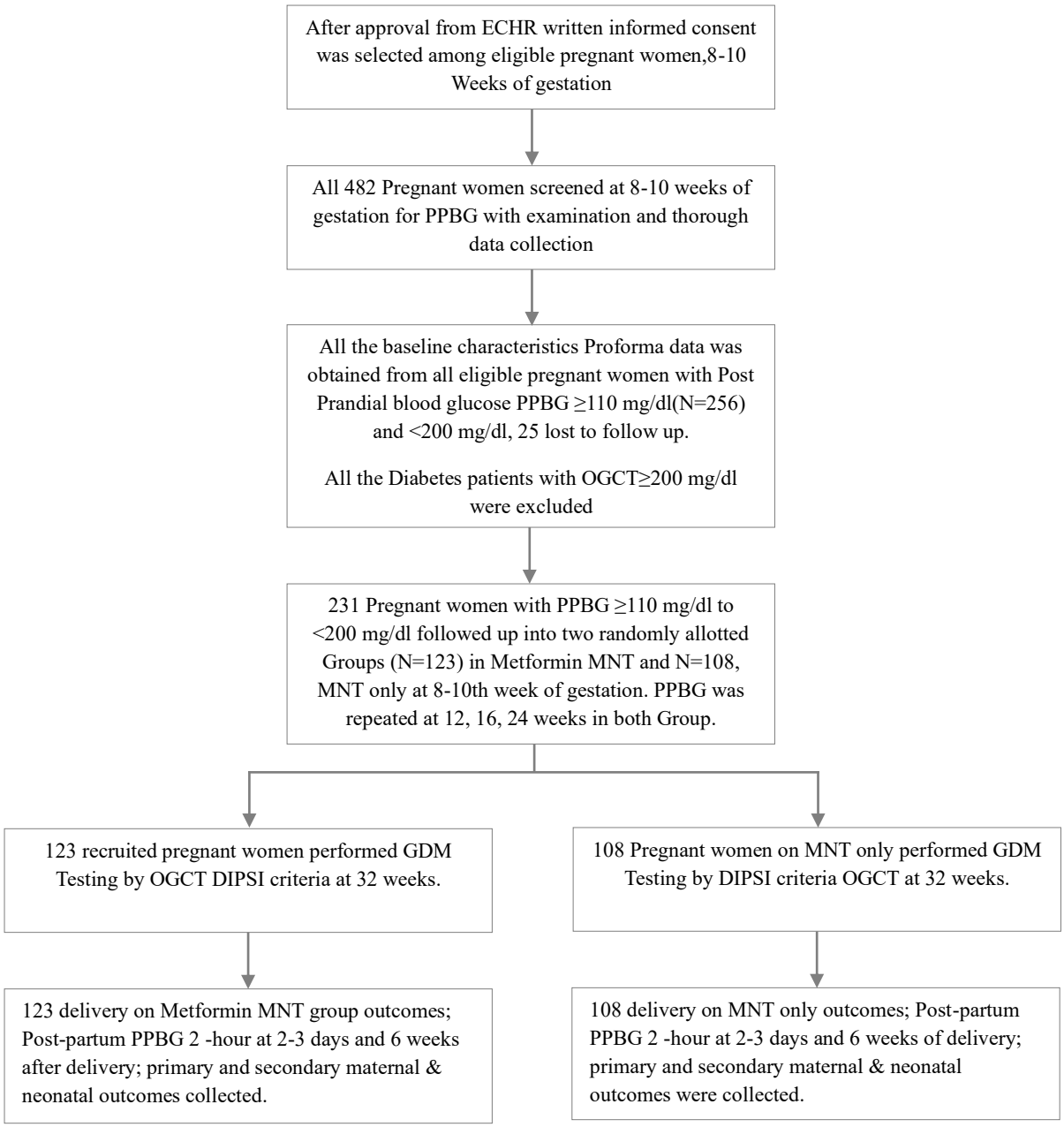
Metformin safety, Efficacy in GDM

Metformin is increasingly recognized for its safe and effective use during pregnancy, particularly in managing blood glucose levels in gestational diabetes. According to several studies, it appears to offer improved maternal-fetal outcomes when compared to insulin [5-7]. The recent findings from the Clue study further support the efficacy of Metformin. The European Working Group (EWG) has positively evaluated its use from conception to delivery, finding no adverse effects associated with its administration [8]. Additionally, Metformin has been associated with lower rates of large-for-gestational-age infants and reduced birth weights. A meta-analysis encompassing 13 studies utilizing a random effects model has indicated that Metformin intervention may reduce the risk of gestational diabetes mellitus (GDM) by approximately 34%, suggesting its potential effectiveness in this context [9]. While data on more recent long-acting insulins-such as glulisine basal, insulin degludec, and glargine 300-in pregnant women with gestational diabetes remains limited, observational studies have generally reported no adverse events related to their use [10]. The trend of utilizing oral medications for gestational diabetes is on the rise in many regions worldwide, attributed to their affordability, safety, accessibility, and convenience. A variety of insulins, including regular human premixed insulin, neutral protamine, short-acting insulin analogs, and long-acting analogs, continue to be employed as first-line treatments or in conjunction with Metformin. Insulin has long been regarded as the standard treatment for gestational diabetes, encompassing options such as regular human insulin, neutral protamine Hagedorn, and various short-acting and long-acting insulin analogs. Furthermore, early check-ups in pregnancy, particularly during the first trimester, play a crucial role in the timely identification of Early gestational glucose Intolerance and other pregnancy-related risk factors. This proactive approach allows healthcare professionals to develop early treatment plans or interventions aimed at optimizing pregnancy outcomes [11-13].

Methodology

Design of the study: A randomized cohort study was completed in the Department of Obstetrics and Gynecology, GSVM Medical College Kanpur, from Feb 2024 to March 2025. The pregnant women with Maternal fetal outcomes studied with various inclusion and exclusion criteria.

All pregnant women are being tested for 2hr PPBG at the 8th-10th Week of Pregnancy (2-month Amenorrhea), and those with ≥ 110 mg/dl were included in the study. After randomization, pregnant women were divided into two groups, one receiving Metformin and MNT and the other only MNT. The metformin was titrated up to 2 grams in divided doses to control Blood glucose. As a routine practice, OGCT was done on 8-10 weeks and 32 weeks. PPBG was repeated at 12, 16, and 24 weeks, and 75gm OGCT (DIPSI Test) was to determine the GDM status by 32 weeks. Postpartum screening was also done at 2-3 days and 6 weeks of Pregnancy in both groups to assess the sensitivity and specificity of the test.



Pregnant women Flow Chart

Ethical Issue

Approval from the Ethics Committee for Biomedical Health & Research was granted under reference number EC/BMHR/2024/12, dated January 4, 2024. We took care to explain the objectives and procedures of the study to all participants, ensuring that written informed consent was obtained from each individual before their participation. Confidentiality has been prioritized and upheld throughout all stages of the research. Participants also have the option to withdraw from the study at any time without facing any repercussions. Should a participant be diagnosed with gestational diabetes mellitus (GDM), she will receive management in accordance with the established clinical protocols of the department. Importantly, there are no additional risks associated with participation in this study, and participants will not incur any financial costs as a result of their involvement.

Statistical Methods & Sample Size: Data were coded in Microsoft Excel and analysed using SPSS version 21.0. Continuous variables

were presented as means and standard deviations (SD), while categorical data were expressed as percentages. An unpaired t-test or Mann-Whitney U test was utilized to compare means or medians. The association of categorical variables was assessed using the Chi-square test or Fisher's exact test. To ensure clarity, discrete variables were presented as percentages and continuous variables as means with SD. The independent t-test identified significant differences between groups, with a P-value of less than 0.05 considered statistically significant. The sample size was calculated based on the assumption that 30% of pregnant women might be at risk for gestational diabetes mellitus (GDM) with a 2-hour postprandial blood sugar (PPBS) of ≥110 mg/dL. It was estimated that 14.0% of high-risk women would have GDM, leading to a requirement of at least 186 high-risk pregnant women (with PPBS ≥110 mg/dL) divided into two groups: one receiving medical nutrition therapy (MNT) and the other MNT combined with Metformin.

Procedure

Inclusion Criteria: This study included pregnant women between 8 and 10 weeks of gestation with singleton pregnancies and those diagnosed with Impaired Glucose Tolerance (IGT) or Gestational Diabetes Mellitus (GDM). Base line Characteristics of the Groups at 8-10 weeks of pregnancy during screening of Post Prandial Blood Glucose were taken (**Table 1**).

Exclusion Criteria: Women on Metformin for Polycystic Ovary Syndrome (PCOS) or beyond 10 weeks of pregnancy were excluded. The women with Overt Diabetes or Pre-Gestational Diabetes (PGDM) were excluded. A Post Prandial Blood Glucose (PPBG) was performed at 8-10 weeks to screen for blood glucose levels of 110 mg/dL or higher.

A prospective analytical cohort study was conducted in the Department of Obstetrics and Gynaecology at GSVM Medical College, Kanpur, India. After obtaining Ethics Committee approval, eligible women provided written informed consent and underwent a thorough medical history and physical examination. Gestational age was determined by the last menstrual period or ultrasound. Participants were advised to have a 2-hour Post-Prandial Blood Glucose (PPBG) test after breakfast at 8-10, 12, 16, and 24 weeks. Blood glucose levels were measured using a plasma-calibrated glucometer, and participants were monitored in the antenatal clinic. GDM screening occurred between 32 and 34 weeks using the Diabetes in Pregnancy Study Group India (DIPSI) test. GDM is diagnosed if a non-fasting blood glucose level exceeds ≥140 mg/dL two hours after a 75 g glucose challenge. Women with a post-prandial blood glucose level of ≥ 110 mg/dL were assigned randomly to two intervention groups: one receiving Metformin and Medical Nutritional Therapy (MNT) and the other receiving MNT only. All women were monitored until delivery, with the baby's weight and any maternal Neonatal complications recorded at that time (**Table 2**).

Results

Primary Maternal Neonatal outcomes

A study involving 482 pregnant women measured postprandial blood glucose levels at 8 to 10 weeks of gestation. Among these women, 256 had levels ≥ 110 mg/dl, and 231 were followed up until delivery. Twenty-five participants were lost to follow-up. The focus was on the 231 women with postprandial blood glucose levels (PPBS) ≥ 110 mg/dl, who were divided into two intervention groups: 123 received Medical Nutrition Therapy (MNT) combined with Metformin, while 108 received MNT only as the control group. This was a randomized prospective cohort study that included regular monitoring of blood glucose levels and other maternal outcomes.

The findings indicated that the mean ages were 25.33 ± 3.01 years for the Metformin MNT group and 24.78 ± 1.84 years for the MNT-only group (p 0.31). The mean PPBS at 8 to 10 weeks was 129 ± 8.32 mg/dl for the Metformin group and 127.98 ± 9.07 mg/dl for the MNT group (**Table 2 & Figure 1**), the difference in mean PPBS values between the groups during the initial weeks (8 to 12) was non-significant (**Table 2**). However, a gradual decrease in mean PPBS was observed in the Metformin + MNT intervention group, while the MNT group's mean values remained relatively stable. At the 12th week, the PPBS values were 126.77 ± 6.55 mg/dl for the Metformin MNT group compared to 134.1 ± 10.74 mg/dl for the MNT group, showing significant differences emerging thereafter. Notable mean ± SD PPBG values were reported at 16 weeks (122.95 ± 8.47 vs. 126.65 ± 13.2), 24 weeks (117.80 ± 4.91 vs. 124.76 ± 11.03), and 32 weeks OGCT (113.92 ± 8.94 vs. 127.71 ± 17.65). The mean value of the Oral Glucose Challenge Test (OGCT) was significantly different between groups (P ≤ 0.001) and remained significant up to 32 weeks, indicating the intervention's substantial impact on glycemic levels in the Metformin group compared to the control group, (**Table 2 & Figure 1**).

There were significant differences in primary adverse neonatal composite outcomes between the two groups, with 21 (17.07%) in the MNT + Metformin group compared to 35 (32.41%) in the MNT group (P ≤ 0.0067).

The incidence of phototherapy due to hyperbilirubinemia was notably higher in the Medical Nutrition Therapy (MNT) group, with 10 cases (9.26%) compared to only 4 cases (3.25%) in the Metformin + MNT group. Additionally, the percentage of neonatal morbidity was significantly lower in the Metformin + MNT group, with 42 cases (34.15%) compared to 56 cases (51.85%) in the MNT group (P < 0.027).

Table 1: Base line Characteristics of the Groups at 8-10 weeks of pregnancy during screening of Post Prandial Blood Glucose

	N = 123 **PPBS at 8-10 wks. ≥110(mg/dl) (Mean ± SD) No (%)** MNT+ Metformin	**N = 108** **PPBS at 8-10 wks. ≥110 (mg/dl) (Mean ±S D) No (%)** MNT only	**P-value**
Age(years)	25.33 ± 3.01	24.78 ± 1.84	0.31
IUD/Spontaneous abortion 8-28 Weeks	0(0)	0(0)	
Still birth > 28 weeks	1(0.81)	3 (2.78)	0.25
Gestational week birth			
<37	6(4.88)	7(6.48)	0.343
37+	10(8.1)	6(5.56)	0.44
38+	62(50.41)	52(48.15)	0.73
39+	39(31.7)	32(29.62)	0.73

40	5(4.1)	8(7.41)	0.27
Gravida			
Primi	39(31.71)	33(30.56)	0.94
Multi	84(68.29)	68 (69.44)	0.94
EGGI at 8-10th Week	123(100)	108(100)	1
Hist of GDM	9(7.3)	15(12.0)	0.10
Hist of PCOS	10(8.1)	9(8.3)	0.9
Fetal loss hist			0.132
present	34(27.64)	30(27.78)	0.98
Absent	89(72.36)	78 (72.22)	
Type of delivery			
NVD	86(69.92)	70 (64.81)	0.40
LSCS	37 (30.08)	38 (35.19)	0.40
Term of delivery			1.000
Preterm	6(4.88)	7(6.48)	0.34
Term	117(95.12)	101 (93.52)	
Family history of DM			0.75
YES	9(7.3)	7(6.48)	
NO	114 (92.68)	101 (93.52)	
BMI kg/m2	22.06 ± 1.3	22.10 ± 1.34	0.81
BMI category			
Normal (18.5-22.9)	79(64.23)	69(63.89)	0.95
Over weight (23.0-24.9)	38(30.89)	33(30.56)	0.96
Obese (25.0-29.9)	6(4.88)	5(4.63)	0.93
Morbid obese (30-40)	0(0)	1(0.92)	0.28

Table 2 Primary Pregnancy & Neonatal outcomes

Pregnancy Outcome	**Post Prandial Blood Glucose ≥110mg/dl and pregnancy Outcomes with Metformin + MNT [Mean ± SD, N= 123 (%)]**	**Post Prandial Blood Glucose ≥110mg/dl and pregnancy Outcomes with MNT [Mean ± SD, N=108 (%)]**	**P-value**
Primary pregnancy outcomes			
PPBG– 8-10 weeks	129 ±8.32	127.98 ±9.07	0.197
OGCT- 8-10 weeks	151.05 ± 13.67	150.8 ± 10.43	0.157
PPBG– 12 weeks	126.77 ± 6.55	134.1 ± 10.74	0.001
PPBG – 16 weeks	122.95 ±8.47	126.65 ±13.2	0.0134
PPBG – 24 weeks	117.80 ±4.91	124.76 ±11.03	0.0001
OGCT – 32 weeks	113.92 ±8.94	127.71 ± 17.65	0.0001
Glycated Haemoglobin % 8-10 weeks (HBA1c)	5.17±0.39	5.14±0.35	**0.53**
Primary Adverse-neonatal outcomes*[a,b,c,d,e]	**21 (17.07)**	**35 (32.41)**	**0.0067**
Birth weight (kg.)	2.92 ± 0.4	3.04 ± 0.4	**0.042**
<2.5 kg	10(6.5)	18(16.6)	**0.047**
2.5 – 3.44	106(86.17)	80(74.1)	0.020
≥3.45[a]	7(5.69)	10(9.26)	0.30
Indication of LSCS			0.55
No indication	**37**	**38**	0.41
CPD	6	6	
FD	6	7	
MSL	7	7	
MSFD	2	2	
PROM	5	5	
Breech	4	5	
Previous LSCS	7	6	
Neonatal morbidity	**42(34.15)**	**56(51.85)**	**0.0065**
Still birth[b]	1(0.81)	3(2.78)	0.25
Hyperbilirubinemia with Phototherapy[c]	4(3.251)	10(9.26)	0.056
Hypoglycemia	2(1.63)	2(1.85)	0.89

RDS[d]	3(2.25)	5(4.63)	0.36
Preterm Birth <37th week Gestation[e]	6(4.88)	7(6.48)	**0.59**
LGA	7(5.69)	10(9.26)	0.42
NICU	19(15.45)	19(17.59)	0.23
GDM in 32 weeks ≥140 mg/dl	0(0.0)	6(5.56)	0.008

*Primary Adverse neonatal outcomes involves Macrosomia with newborn wt > 3450 grams; newborn received Phototherapy for hyperbilirubinemia, Still birth >28 weeks of Pregnancy, preterm delivery less than 37 weeks, or any trauma to newborn during delivery or RDS(respiratory distress in newborn); +Pregnancy related hypertension includes composite of gestational hypertension(GHTN) and preeclampsia and eclampsia; MSL(Meconium stain liquor);Hypoglycemia includes blood sugar <40 during 4 hour of birth; FD(Fetal distress);PROM (Premature rupture of membrane); CPD (Cephalic Pelvic Disproportionate);OGCT(Oral Glucose challenge Test); LGA Large for gestational age; NICU (Neonatal Intensive care Unit)

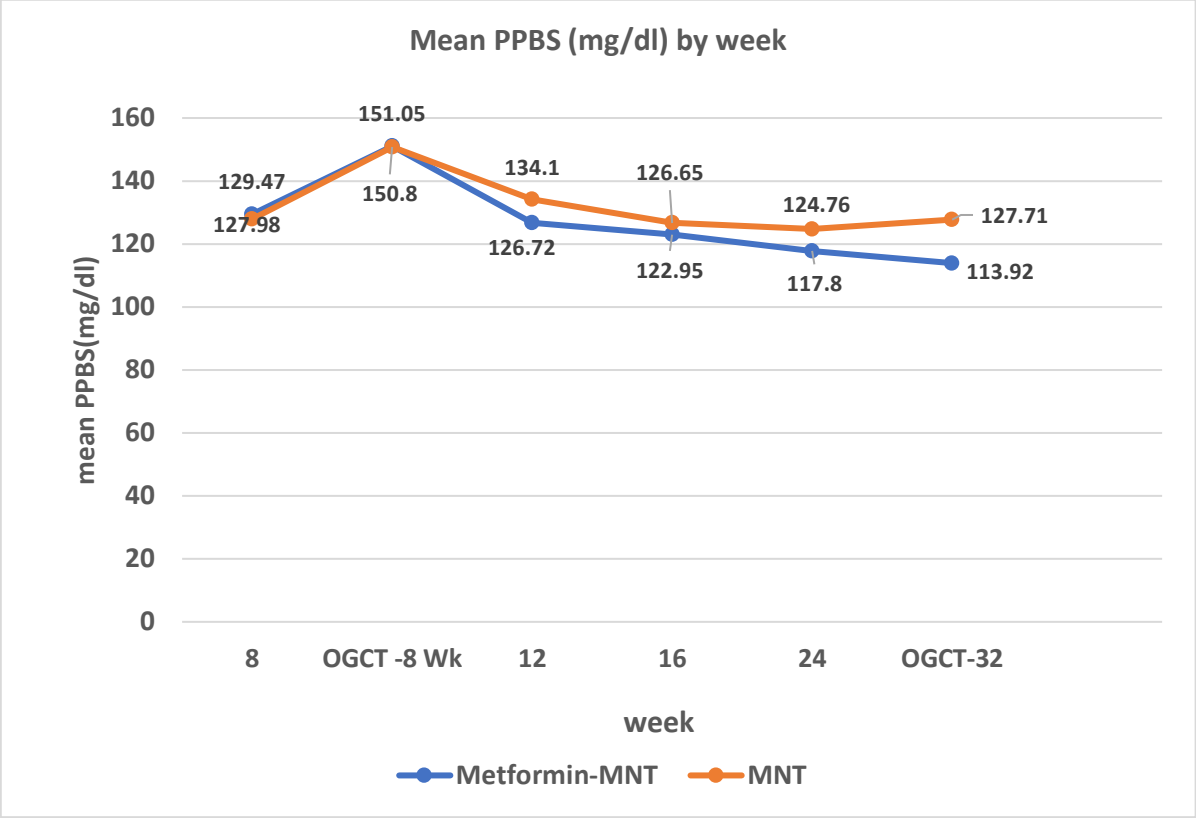


Figure 1: Mean Post Prandial Blood Glucose (PPBG) level (mg/dl) Continuum in the Two groups during pregnancy

Discussion

A significant positive correlation ($p < 0.001$) was identified between two-hour postprandial blood sugar (PPBS) levels at 8 to 10 weeks and the diagnosis of gestational diabetes mellitus (GDM) at 32 weeks, as assessed by the oral glucose challenge test (DIPSI test). Notably, the area under the curve (AUC) for PPBS was an impressive 0.969 ($p < 0.001$). A PPBS level exceeding 110 mg/dL exhibited remarkable predictive capabilities, with a sensitivity of 95.9%, specificity of 95.6%, and an outstanding diagnostic accuracy of 95.77% for GDM. This data underscores the critical importance of early PPBS monitoring in effectively predicting GDM outcomes [14].

A study conducted by Tiwari et al. (2024) [15,16] found that administering metformin during the early weeks of pregnancy, specifically starting at 8 to 10 weeks of gestation, effectively kept postprandial blood glucose levels below 110 mg/dL and reduced the risk of adverse neonatal outcomes, similar study from Chennai resulted in non-conversion to GDM in Metformin group [17].

In this study, none of the participants in the Metformin Medical Nutritional Therapy (MNT) Group developed gestational diabetes mellitus (GDM) by 32 weeks, nor did they experience impaired glucose tolerance (IGT) in postpartum assessments. In contrast, 5.56% of the women in the MNT intervention group were diagnosed with GDM [**Table 2, Figure 1**].

A recent TOGOGM study indicated that immediate treatment of gestational diabetes before 20 weeks' gestation resulted in a modestly lower incidence of a composite of adverse neonatal outcomes compared to no immediate treatment [18], Our study specifically targeted women at 8-10 weeks of gestation, as it is essential to recognize that fetal hyperinsulinemia which is activated after this period. This timing is pivotal for understanding the condition and its significant implications for fetal development.

Limitation of study

Since our study is conducted at a single center, we require a larger sample size and a multicenter approach to validate our findings on pregnancy outcomes. Nonetheless, our results can still serve as a guide for researchers looking to implement eGDM interventions as early as 8 to 10 weeks in order to positively influence the course of the disease.

Conclusion

One Centre Prospective Cohort study with screening as early as 8-10 weeks with PPBG ≥110 mg/dl and managing with Metformin and

Medical Nutrition Therapy (MNT) results in reduction in Primary composite Neonatal outcomes, Gestational Diabetes Mellitus during pregnancy and Postpartum IGT conversion, which may support in prevention of GDM diabetes in pregnant women and future Diabetes.

Declarations

Authors' contributions

Shweta Verma: Data Collection, Draft Preparation, Investigations; Shaily Agarwal: Supervision, drafting write up, Methodology, supervision; Sadhana Tiwari: Data collection, Investigations; Renu Gupta: Methodology, Supervision, Project Administration; Divya Tripathi: Methodology, Supervision, Editing; Neena Gupta: Reviewing and editing, Validation correction; V Seshiah: Conceptualization, Methodology ; Palak Taneja: Visualization, Investigations, Write-up; Priti Kumar: Methodology, Supervision, Project Administration, Rajesh Jain: Curation, Review, correction, write up

Conflicts of Interest

The authors reaffirm that they have no conflicts of interest to disclose. They also confirm the absence of any financial relationships with organizations that could be perceived to have an interest in this work, both currently and within the last three years. Importantly, no funding was received from any source, institution, or pharmaceutical agency for this study or its publication.

Author Approval

All authors have thoroughly reviewed the final manuscript, had full access to the underlying data, and unanimously approve it for publication.

Financial Relationships

The authors affirm that they have no financial relationships with any organizations that may have an interest in this submitted work, either presently or within the past three years.

Funding

This study received no funding from any source, institution, or pharmaceutical agency, ensuring its independence and integrity.

Consent to Participate

All human subjects provided their written informed consent, guaranteeing strict confidentiality. The Institutional Ethics Committee at GSVM Medical College, Kanpur, granted approval for the study (Approval No. EC/BMHR/2024/12) on 29 Jan 2024 during a formal meeting.

Ethical Considerations

The research strictly adhered to the ethical principles outlined in the Declaration of Helsinki, underscoring our commitment to ethical standards.

Data Availability

All data and materials were made available to every author, each of whom has consented to publication, further ensuring transparency and accountability.

Human Rights Declaration

All authors wholeheartedly affirm their commitment to the UN's Declaration of Human Rights as a foundational principle guiding the submission of this manuscript. This Research strengthens the phrasing to create a more compelling and convincing effect, emphasizing clarity and commitment to ethical research practices.

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