International Journal of Reproduction, Contraception, Obstetrics and Gynecology
Bhujbal MP et al. Int J Reprod Contracept Obstet Gynecol. 2026 May;15(5):1656-1660
www.ijrcog.org
pISSN 2320-1770 | eISSN 2320-1789

DOI: https://dx.doi.org/ 10.18203/2320-1770.ijrcog20261263

Original Research Article

Comparison of different treatment modalities in gestational diabetes mellitus and their maternal and fetal outcomes

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Received: 25 February 2026
Revised: 08 April 2026
Accepted: 09 April 2026

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ABSTRACT

Background: Gestational diabetes mellitus (GDM) is associated with significant maternal and fetal morbidity. Optimal management strategies after failure of lifestyle modification remain debated. Objectives were to compare maternal and fetal outcomes among women with GDM managed with medical nutrition therapy (MNT) alone, MNT with metformin, and MNT with metformin plus insulin.

Methods: This prospective observational study was conducted in a tertiary care teaching hospital over 18 months. Ninety pregnant women diagnosed with GDM were enrolled and managed as per institutional protocol and endocrinology consultation. Participants were grouped based on treatment modality: diet alone (n=51), diet plus metformin (n=27), and diet plus metformin with insulin (n=12). Maternal outcomes (mode of delivery, pre-eclampsia, puerperal sepsis, shoulder dystocia) and fetal outcomes (birth weight, NICU admission, congenital malformations, perinatal mortality) were analysed. Appropriate statistical tests were applied with $p \leq 0.05$ considered significant.

Results: Majority of women (56.7%) were managed with diet alone. Post prandial blood sugar differed significantly across treatment groups ($p<0.001$). Caesarean section rates increased with treatment intensity (27.5% in diet alone versus 83.3% in insulin group; $p=0.004$). NICU admissions were significantly higher in the insulin group (41.7%; $p=0.027$). No statistically significant differences were observed in pre-eclampsia, congenital malformations, or perinatal mortality among groups.

Conclusions: Most women with GDM can be effectively managed with medical nutrition therapy alone. Requirement of pharmacotherapy reflects higher glycemic burden and is associated with increased operative deliveries and NICU admissions, without a significant increase in major adverse maternal or fetal outcomes.

Keywords: Gestational diabetes mellitus, Fetal outcome, Insulin, Maternal outcome, Metformin

INTRODUCTION

Gestational diabetes mellitus (GDM) is one of the most common metabolic disorders complicating pregnancy and is defined by glucose intolerance with onset or first recognition during gestation. It arises from a progressive increase in insulin resistance, mediated by placental hormones, superimposed on an inadequate compensatory insulin secretory response by pancreatic β-cells. In this regard, pregnancy serves as a physiological "metabolic stress test," unmasking underlying susceptibility to dysglycemia and future metabolic disease.[1]

The burden of GDM extends beyond transient hyperglycemia, as it is strongly associated with adverse maternal and perinatal outcomes. Even mild elevations in maternal glucose levels have been linked to fetal overgrowth, particularly macrosomia, which remains one of the most consistently reported complications and contributes to increased risks of shoulder dystocia, birth

trauma, and operative deliveries.[2,3] In addition, maternal complications such as hypertensive disorders, increased cesarean section rates, and peripartum morbidity further amplify its clinical significance.

Despite substantial advances in understanding, there remains considerable heterogeneity in the screening approaches and diagnostic criteria for GDM across different international guidelines. This lack of uniformity not only influences reported prevalence but also creates challenges in clinical decision-making and comparison of research outcomes.[4] Nevertheless, there is a clear consensus that effective glycemic control plays a pivotal role in reducing both maternal and fetal complications. Standard management strategies emphasize medical nutrition therapy (MNT), lifestyle modification, and structured glucose monitoring, with pharmacological therapy initiated when glycemic targets are not achieved.[5,6]

Insulin has traditionally been regarded as the gold standard for pharmacological management due to its efficacy and minimal placental transfer. However, its use may be limited by factors such as cost, need for injections, and issues with patient adherence. In recent years, oral hypoglycemic agents, particularly metformin and glyburide, have emerged as practical alternatives owing to their ease of administration and improved patient acceptability.[6] Evidence from recent studies suggests that these agents are generally safe when used in the second and third trimesters, with no significant increase in congenital anomalies or neonatal mortality.[7-9] Nonetheless, concerns persist regarding their transplacental passage, comparative effectiveness, and potential long-term metabolic effects on offspring, warranting further evaluation.

Importantly, GDM also represents a critical window for identifying women at high risk of future metabolic disease. A substantial proportion of affected women develop type 2 diabetes mellitus in the years following pregnancy, underscoring the importance of postpartum surveillance and preventive interventions.[10,11] Thus, GDM should be viewed not merely as a pregnancy-specific condition but as an early indicator of long-term metabolic vulnerability.

Against this background, the present study was undertaken to compare different therapeutic modalities used in the management of GDM and to evaluate their association with maternal and fetal outcomes. By integrating clinical effectiveness with real-world applicability, this study aimed to contribute to identifying the most appropriate and evidence-based management strategies for optimizing both immediate and long-term outcomes in women with GDM.

METHODS

This prospective observational study was conducted in the department of obstetrics and gynecology of a tertiary care teaching hospital located in a metropolitan city over a period of 18 months. Pregnant women diagnosed with gestational diabetes mellitus (GDM) at any gestational age and fulfilling the inclusion and exclusion criteria were enrolled after obtaining informed written consent. The study aimed to compare different treatment modalities used in the management of GDM and to assess their association with maternal and fetal outcomes.

A total of 90 women with GDM were included in the study. Diagnosis of GDM was made based on glycemic status assessed using a 75-gm oral glucose tolerance test, and management decisions were taken in consultation with an endocrinologist. Participants were managed with one of the following treatment modalities: medical nutrition therapy (diet alone), diet plus metformin, or diet plus metformin with insulin. Of the total participants, 51 women were managed with diet alone, 27 received diet plus metformin, and 12 required insulin in addition to diet and metformin.

Women aged more than 19 years who were willing for prospective follow-up and provided informed consent were included in the study. Women with pregestational or uncontrolled diabetes mellitus, severe medical or surgical comorbidities, thromboembolic disorders, abnormal placentation, severe pregnancy complications, multiple gestations, or significant uterine pathology were excluded.

Data were collected using a structured case record form that included sociodemographic details, obstetric and medical history, antenatal details, biochemical parameters, and treatment-related information. All participants were followed until delivery, and maternal and fetal outcomes were recorded. Maternal outcomes assessed included preeclampsia, puerperal sepsis, wound complications, and shoulder dystocia. Fetal outcomes evaluated included birth weight, live or stillbirth, congenital anomalies, Apgar scores, and the need for neonatal intensive care unit (NICU) admission.

Statistical analysis was performed using appropriate statistical software. Qualitative variables were expressed as frequencies and percentages, while quantitative variables were expressed as mean±standard deviation or median with interquartile range, as appropriate. Associations between categorical variables were analyzed using the chi-square test or Fisher's exact test, while continuous variables were compared using the Kruskal-Wallis test. A p value of ≤ 0.05 was considered statistically significant.

RESULTS

Ninety women with gestational diabetes mellitus were included in the study. Of these, 56.7% were managed with medical nutrition therapy alone, 30.0% with diet plus metformin, and 13.3% required insulin in addition to diet and metformin. The mean age of participants was comparable across treatment groups, and age was not found to influence the choice of treatment modality.

Table 1: Distribution of study participants according to treatment modality (n=90).

Treatment modality	Number	Percentage
Medical nutrition therapy alone	51	56.7
Diet + metformin	27	30.0
Diet + metformin + insulin	12	13.3
Total	90	100

The majority of women were multigravida and had regular antenatal follow-up, although the number of antenatal visits differed significantly among treatment groups, with women receiving metformin having a higher mean number of visits. Gestational age at delivery and duration of marriage were comparable across groups.

Postprandial blood glucose levels differed significantly among treatment modalities, with higher values observed in women requiring pharmacological therapy, particularly insulin. Mode of delivery showed a significant association with treatment modality, with a higher rate of caesarean section observed in women requiring insulin therapy.

Table 2: Comparison of selected maternal characteristics across treatment modalities.

Variable	Diet alone (n=51)	Diet + Metformin (n=27)	Diet + Metformin + Insulin (n=12)	P value
Mean age (years)	Comparable	Comparable	Comparable	NS
Gravidity (multigravida)	Majority	Majority	Majority	NS
Antenatal visits (mean)	Lower	Higher	Moderate	Significant
Gestational age at delivery	Comparable	Comparable	Comparable	NS

NS: Not significant.

Table 3: Maternal outcomes according to treatment modality.

Outcome	Diet alone (n=51)	Diet + Metformin (n=27)	Diet + Metformin + Insulin (n=12)	P value
Vaginal delivery	37 (72.5%)	11 (40.7%)	2 (16.7%)	0.004
Caesarean section	14 (27.5%)	16 (59.3%)	10 (83.3%)	0.004
Preeclampsia	Few	Few	Few	NS
Puerperal sepsis/wound complication	Rare	Rare	Rare	NS
Shoulder dystocia	Absent	Absent	Absent	NS

Table 4: Fetal outcomes according to treatment modality.

Outcome	Diet alone (n=51)	Diet + Metformin (n=27)	Diet + Metformin + Insulin (n=12)	P value
Live birth	Majority	Majority	Majority	NS
Congenital anomalies	None	None	None	NS
NICU admission	6 (11.8%)	5 (18.5%)	5 (41.7%)	0.027
Macrosomia	Occasional	Occasional	Occasional	NS

Values expressed as number (%). NS: Not significant

Maternal complications such as preeclampsia, puerperal sepsis, wound complications, and shoulder dystocia were infrequent and did not differ significantly across treatment groups. Most pregnancies resulted in live births. Fetal outcomes, including congenital anomalies, NICU admission, and birth weight categories, were comparable across treatment modalities, although NICU admission was more frequent among neonates born to mothers requiring insulin therapy.

DISCUSSION

In the present study, the majority of women with gestational diabetes mellitus (GDM) were successfully managed with medical nutrition therapy alone, while a smaller proportion required pharmacological treatment with metformin or insulin. The trend of increased caesarean section rates and higher post-prandial glucose levels in women treated with more intensive therapy reflects greater severity of hyperglycemia rather than adverse effects of the treatment itself.

Our findings are broadly consistent with several Indian observational studies that have compared maternal and fetal outcomes among women treated with diet, metformin, and insulin. In a study from Kerala, outcomes including neonatal birthweight and fetomaternal complications were broadly similar across diet, metformin,

and insulin groups, though the insulin group showed higher rates of cesarean delivery and NICU admissions, mirroring the pattern observed in our cohort.[2] Similarly, a recent comparative study from a tertiary care centre in New Delhi demonstrated that metformin achieved effective glycemic control with fewer neonatal complications relative to insulin.[1] These findings support the notion that oral agents like metformin can be effective alternatives to insulin in appropriate clinical settings.

International evidence also corroborates these observations. A randomized clinical trial comparing metformin with insulin in GDM found that metformin provided adequate glycemic control with lower maternal weight gain and fewer hypoglycemic episodes, though most obstetric and perinatal outcomes were similar between groups.[10] A meta-analysis of randomized controlled trials reported that metformin was associated with lower rates of neonatal hypoglycemia, reduced maternal weight gain, and a tendency toward reduced macrosomia compared with insulin, suggesting potential maternal and fetal benefits with metformin use.[9]

Regarding mode of delivery, our study showed higher caesarean section rates among women requiring insulin. This aligns with findings from larger meta-analyses demonstrating that metformin treatment is associated with a lower rate of caesarean deliveries compared to insulin. One possible explanation is that better overall metabolic control and less maternal weight gain in metformin-treated women may contribute to fewer obstetric interventions.

In terms of fetal outcomes, while macrosomia and NICU admissions were more frequent in the insulin group in our cohort, these differences were not statistically significant for most fetal outcomes. This is consistent with some studies that report no significant difference in mean birth weight or overall neonatal morbidity between metformin and insulin treatments.[2] However, certain studies have noted reduced macrosomia and better neonatal outcomes with metformin, which may reflect improved metabolic profiles.[9-14]

The present study supports the accumulating evidence that metformin is a safe and effective option in the management of GDM for many women, with maternal and fetal outcomes comparable to those observed with insulin therapy and diet alone when appropriately indicated. These findings are particularly relevant in resource-constrained settings where the cost, storage, and administration challenges of insulin may limit its use.

Nevertheless, treatment should be individualized, as some women may require insulin supplementation due to inadequate glycemic control with metformin alone, and long-term follow-up data remain limited.

A key strength of this study is its prospective design with systematic follow-up of participants until delivery. The comparison of multiple treatment modalities within the same clinical setting allows for meaningful assessment of real-world management strategies and their associated maternal and fetal outcomes. Additionally, uniform diagnostic criteria and management protocols enhance the internal validity of the findings.

The relatively small sample size, particularly in the insulin-treated group, limits the power to detect differences in less frequent maternal and neonatal outcomes. Being a single-center observational study, the findings may not be generalizable to all populations. Long-term maternal and neonatal outcomes were not assessed.

CONCLUSION

The present study demonstrated that the majority of women with gestational diabetes mellitus can be effectively managed with medical nutrition therapy alone. Pharmacological treatment with metformin or insulin was required in a smaller subset of women with higher glycemic burden and was associated with increased rates of caesarean delivery and neonatal intensive care admission, likely reflecting disease severity rather than treatment-related adverse effects. Overall, maternal and fetal outcomes were comparable across treatment modalities, supporting the use of metformin as a safe and effective alternative to insulin in appropriately selected patients. Individualized treatment and close glycemic monitoring remain essential to optimize pregnancy outcomes in women with GDM.

Recommendations

Medical nutrition therapy should remain the first-line treatment for gestational diabetes mellitus. Metformin may be considered a safe and effective alternative to insulin in women who fail to achieve glycemic targets with diet alone, provided there is appropriate counselling and close monitoring. Larger multicentric studies with long-term follow-up are recommended to further evaluate maternal and offspring outcomes associated with different treatment modalities.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee (approval number: IEC(II)/OUT/144/2021)

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Cite this article as: Bhujbal MP, Dwivedi JS, Rane PB, Mayadeo NM. Comparison of different treatment modalities in gestational diabetes mellitus and their maternal and foetal outcomes. Int J Reprod Contracept Obstet Gynecol 2026;15:1656-60.