International Journal of Reproduction, Contraception, Obstetrics and Gynecology
Dharshan GB et al. Int J Reprod Contracept Obstet Gynecol. 2026 Oct;15(10):3857-3863
www.ijrcog.org
pISSN 2320-1770 | eISSN 2320-1789

DOI: https://dx.doi.org/10.18203/2320-1770.ijrcog20263417

Original Research Article

Neonatal outcomes in gestational diabetes mellitus: metformin alone versus metformin with insulin: a retrospective cohort study in India

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Received: 17 June 2026
Revised: 25 August 2026
Accepted: 01 September 2026

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ABSTRACT

Background: Gestational diabetes mellitus (GDM) is associated with adverse neonatal outcomes, including increased neonatal intensive care unit (NICU) admissions and differences in birth weight. Although metformin is commonly used for glycemic control in GDM, some patients require adjunctive insulin therapy. Comparative data on neonatal outcomes between these regimens remain inadequate.
Methods: This retrospective cohort study was conducted at a tertiary care center in Bengaluru, India. Medical records of women with singleton GDM pregnancies were analyzed and categorized into two groups: metformin monotherapy and metformin plus insulin. Primary outcomes were NICU admission and neonatal birth weight. Logistic regression was utilized to determine predictors of NICU admission, and linear regression estimated determinants of birth weight.
Results: Among 123 GDM pregnancies, 52.8% received metformin alone and 47.2% received combination therapy. NICU admissions were significantly lower in the metformin group compared to the combination group (46.2% versus. 74.1%, p=0.002). After adjusting for gestational age, metformin monotherapy was associated with reduced odds of NICU admission (OR=0.41, p=0.032), though maternal HbA1C emerged as the strongest predictor (AUC=0.751). When both HbA1C and birth weight were included in the model, treatment regimen lost statistical significance (p=0.056). Neonatal birth weight was significantly lower in the combination group (mean difference -0.30 kg), with gestational age showing a stronger association (0.151 kg/week, p<0.001).
Conclusions: Although NICU admissions were lower in the metformin monotherapy group, maternal glycemic control particularly HbA1C appears to be the principal determinant of neonatal outcomes in GDM pregnancies.

Keywords: Gestational diabetes mellitus, Metformin, Insulin, Neonatal outcomes, NICU admission, Birth weight

INTRODUCTION

Gestational diabetes mellitus (GDM) is defined as glucose intolerance first recognized during pregnancy and represents one of the most common metabolic complications of pregnancy and an increasing global health concern. The burden of hyperglycaemia during pregnancy has increased substantially over recent decades, with contributing factors including increasing maternal age, obesity, and improved detection and diagnostic practices. The condition is particularly important in low- and middle-income countries, including India, where the increasing prevalence of metabolic risk factors places a substantial burden on maternal and neonatal healthcare.[1-3]

The metabolic changes associated with GDM are characterized by increasing insulin resistance during pregnancy combined with inadequate pancreatic β-cell compensation. Consequently, maternal hyperglycaemia

can result in increased transplacental glucose transfer and subsequent fetal hyperinsulinaemia. This metabolic environment may contribute to excessive fetal growth and altered neonatal metabolic adaptation, increasing the risk of macrosomia, neonatal hypoglycaemia, respiratory distress, and admission to the neonatal intensive care unit (NICU).[4-6] GDM is also associated with maternal complications, including pre-eclampsia and increased rates of caesarean delivery, further contributing to adverse pregnancy outcomes.[7]

Although fetal overgrowth and macrosomia are well-recognized complications of GDM, neonatal consequences are not restricted to excessive birth weight. Altered placental function and maternal vascular or metabolic complications may also contribute to impaired fetal growth in selected pregnancies, including intrauterine growth restriction.[8,9] Neonatal hypoglycaemia and respiratory morbidity remain important short-term complications, particularly in the presence of maternal hyperglycaemia and fetal hyperinsulinaemia.[5,10] Therefore, assessment of neonatal outcomes in GDM should extend beyond birth weight and consider the overall maternal glycaemic profile, gestational maturity, and other clinical factors that may influence neonatal adaptation.

The principal goal of GDM management is to achieve adequate maternal glycaemic control while minimizing adverse maternal and fetal outcomes. Initial management generally involves dietary modification and physical activity; pharmacological treatment is considered when glycaemic targets are not achieved with lifestyle measures alone. Insulin has traditionally been regarded as the standard pharmacological treatment for GDM because it effectively lowers maternal blood glucose and does not cross the placenta. However, the requirement for injections, frequent glucose monitoring, and dose adjustments may reduce treatment convenience and adherence, while maternal hypoglycaemia and weight gain remain relevant considerations.[11]

Metformin has emerged as an important pharmacological option for the management of GDM because of its ability to reduce hepatic glucose production and improve peripheral insulin sensitivity. Compared with insulin, its oral route of administration and lower propensity for maternal hypoglycaemia and weight gain may offer practical advantages.[12] However, unlike insulin, metformin crosses the placenta, which has generated continuing interest regarding its effects on fetal and long-term offspring outcomes. Available evidence has not established major adverse long-term effects, but the placental transfer of metformin remains an important consideration when selecting therapy.[13] Current clinical guidance recognizes metformin as an appropriate pharmacological option for GDM in women who do not achieve adequate glycaemic control with lifestyle measures, while insulin remains an important treatment option when additional glycaemic control is required.[15,19]

Evidence comparing metformin and insulin has largely focused on whether metformin can provide glycaemic control and neonatal outcomes comparable to insulin. Randomized trials and systematic reviews have generally reported comparable short-term neonatal outcomes, with some studies suggesting lower risks of selected neonatal complications, including hypoglycaemia and NICU admission, among women receiving metformin.[16,17] However, findings from comparisons of treatment regimens in routine clinical practice may be influenced by the clinical characteristics that determine treatment selection. Women who require insulin in addition to metformin may have greater insulin resistance, poorer glycaemic control, or other indicators of more severe GDM than women adequately controlled with metformin alone.[18-20] Consequently, an observed difference in neonatal outcomes between treatment groups cannot necessarily be interpreted as a direct effect of the pharmacological regimen itself.

This distinction is particularly relevant when evaluating NICU admission and neonatal birth weight, as both outcomes may be influenced by several interrelated maternal and obstetric factors. Maternal glycaemic control, gestational age at delivery, and the clinical severity of GDM may independently influence neonatal morbidity.[18-20] Thus, comparing treatment groups without considering these factors may overestimate the apparent effect of treatment choice. In clinical practice, understanding whether differences in neonatal outcomes are attributable to the treatment regimen itself or to the underlying maternal metabolic and obstetric characteristics is important for appropriate interpretation of treatment effectiveness.

Despite the growing evidence surrounding metformin use in GDM, there remains a need for real-world evidence from clinical settings, particularly from low- and middle-income countries such as India. Data directly comparing neonatal outcomes among women receiving metformin monotherapy with those receiving metformin combined with insulin, while also considering important clinical factors such as maternal glycaemic control and gestational age, remain limited. Evaluating these outcomes in a routine-care setting may therefore provide a more clinically relevant understanding of the relationship between treatment strategy and neonatal outcomes.

The present study was therefore undertaken to compare neonatal outcomes among women with GDM treated with metformin monotherapy and those treated with metformin plus insulin, with particular emphasis on NICU admission and neonatal birth weight. The study also aimed to examine whether maternal glycaemic control and other relevant clinical factors contributed to differences in neonatal outcomes between the treatment groups. By accounting for these potential confounding factors, the study sought to distinguish the apparent association of treatment regimen with neonatal outcomes from the

influence of underlying maternal and obstetric characteristics.

METHODS

Study design and setting

This retrospective cohort study evaluated medical records of pregnant women diagnosed with GDM who delivered at a tertiary care hospital in Bengaluru, India, between April and October 2025. The study was approved by the institutional ethics committee (Approval No. PESUIMSR/IEC/010/24-25 [Ver1.0]), with a waiver of individual informed consent granted for the use of de-identified data.

Participant eligibility and selection

Women aged 18-35 years with singleton pregnancies diagnosed with GDM during the index pregnancy, who delivered at the study hospital and had complete maternal and neonatal medical records, were included in the study. Women with pre-existing type 1 or type 2 diabetes, multiple pregnancies, major maternal comorbidities that could independently influence neonatal outcomes (such as end-stage renal disease or active malignancy), or incomplete primary outcome data despite retrieval attempts were excluded.

Hospital delivery logs and electronic medical records (EMRs) were screened for GDM diagnoses based on oral glucose tolerance test (OGTT), fasting/postprandial glucose, or HbA1c values meeting institutional thresholds. Eligible mother-infant pairs were assigned unique study IDs. A STROBE-style flow diagram was prepared to document screening, exclusions (with reasons), and final inclusion.

Exposure classification and medication data

The participants were grouped into two categories according to their pharmacologic treatment regimens:

Group I (Metformin only)

Participants received metformin-only treatment during pregnancy. This included data regarding the gestational week of initiation, dose range, and dosing increments of metformin.

Group II (metformin + insulin)

Participants received metformin in combination with any insulin formulation. This included data regarding the formulation of insulin (short/rapid-acting, intermediate, long-acting), total daily dose of insulin (units and units/kg), and the initiation of insulin in relation to metformin initiation.

Data regarding the medications were obtained from antenatal prescription records, inpatient medication records, and pharmacy records. Reasons for insulin dose escalation, such as inability to attain glycemic targets, and adverse drug reaction data were also obtained.

Diagnostic criteria and variable definitions

The diagnosis of GDM was made according to institutional criteria using values for OGTT. In cases where multiple criteria for diagnosing GDM were used in the past, the criterion used for each individual was recorded and used as a covariate.

Primary outcome

NICU admission status within 72 hours of birth (yes/no) and reason for admission.

Secondary outcomes

Birth weight (kg), categorized as low birth weight (<2.5 kg), normal (2.5-4.0 kg), or macrosomia (>4.0 kg), neonatal hypoglycemia (blood glucose <47 mg/dl), preterm birth (<37 weeks), Apgar scores at 1 and 5 minutes, respiratory distress syndrome (RDS) diagnosis, length of NICU stay (days), neonatal death or stillbirth.

Covariates

Maternal age, maternal parity, pre-pregnancy BMI, gestational age at delivery (obstetric estimate), mode of delivery, maternal HbA1c at diagnosis and close to delivery, fasting and postprandial blood glucose values, hypertensive disorders in pregnancy, steroids used in pregnancy, sex of neonate.

Data collection and quality control

Data was extracted using a standardized electronic form from antenatal clinic records, inpatient delivery notes, neonatal records, lab systems, and pharmacy systems. Inter-rater reliability was assessed using a 10-20% random sample of data extraction, and two reviewers extracted data independently.

The extracted data was entered into a password-protected database using Microsoft excel with data range checks and validation.

Missing data

The amount and nature of missing data were recorded. If missing data were less than 5% and considered to be missing completely at random, complete case analysis was employed.

For data with higher percentages of missing data and non-random missing data, multiple imputation using chained equations was carried out as sensitivity analysis.

Statistical analysis

All analyses were conducted using IBM statistical package for the social sciences (SPSS) statistics version 30.0.0.0(172).

Descriptive statistics

Continuous variables are presented as mean±SD or median (IQR), and categorical variables as counts and percentages.

Group comparisons

Categorical variables were compared using the Chi-square test; continuous variables using independent-samples t-test (for normally distributed data) or Mann-Whitney U test (for non-normal data). Effect sizes were reported as odds ratios (OR) with 95% confidence intervals (CI) for categorical outcomes and Cohen's d for continuous outcomes.

Multivariable modeling

Primary model

Logistic regression for NICU admission. Models were built sequentially that is unadjusted model with treatment group only, Adjusted model including gestational age, maternal HbA1c, birth weight, mode of delivery, maternal age, and parity. Model performance was assessed using the Omnibus test, Nagelkerke R^2, classification accuracy, and receiver operating characteristic (ROC) curve with area under the curve (AUC).

Secondary models

Linear regression model for continuous outcomes (e.g., birth weight) with predictors such as treatment group and gestational age. Outputs including R^2, adjusted R^2, regression coefficients, and p values. Assumptions of linearity, homoscedasticity, normality of residuals, and multicollinearity (variance inflation factor) were assessed.

Interaction and sensitivity analyses: pre-defined interactions (e.g., treatment × HbA1c) were assessed. Sensitivity analyses included the exclusion of pre-term births (<37 weeks), stratification on HbA1c categories, and, if feasible, propensity score matching (nearest neighbor, with or without caliper) or weighting. Statistical significance was considered if two-tailed $p<0.05$. Adjustments for multiple testing (e.g., Bonferroni method) were used appropriately.

RESULTS

Participant characteristics

A total of 123 women with GDM fulfilled the inclusion criteria. Of these, 65 (52.8%) women were treated with metformin monotherapy, and 58 (47.2%) women received combination therapy with metformin and insulin. Baseline demographic and clinical characteristics were similar in the two groups. The mean age of the women in the metformin and combination therapy groups was 28.7±4.5 and 29.1±4.8 years, respectively (p=0.70). Pre-pregnancy BMI (27.3±5.2 versus 28.0±5.5 kg/m², p=0.50), parity, and baseline HbA1c levels (6.8%±0.4 versus 7.0%±0.5, p=0.60) were comparable between the two groups. The gestational age at delivery was slightly longer in the metformin group compared with the combination therapy group (38.9±1.2 versus 38.3±1.5 weeks, p=0.08) (Table 1).

Table 1: Baseline maternal characteristics according to treatment group (metformin monotherapy versus metformin plus insulin combination therapy).

Characteristics	Metfor-min (n=65)	Metformin + insulin (n=58)	P value
Age (years)	28.7±4.5	29.1±4.8	0.70
BMI (kg/m²)	27.3±5.2	28.0±5.5	0.50
GA at delivery (weeks)	38.9±1.2	38.3±1.5	0.08
HbA1c (%)	6.8±0.4	7.0±0.5	0.60

All values as mean±SD or %; differences non-significant

Neonatal outcomes

Mean birth weight did not differ significantly between groups (2921±317 g versus. 2856±328 g, p=0.15). NICU admission rates were significantly lower in the metformin group (46.2%) compared to the combination group (74.1%) (χ^2=9.95, p=0.002). Other neonatal outcomes including Apgar score <7 at 1minute, neonatal hypoglycemia, and preterm birth did not differ significantly between groups (Table 2).

Adjusted analysis

Multivariable logistic regression analysis was used to control for potential confounders. In the model adjusted for gestational age, metformin monotherapy was significantly associated with reduced odds of NICU admission compared with combination therapy (OR=0.32; 95% CI: 0.12-0.86; p=0.03). Gestational age was also significantly associated with reduced odds of NICU admission (OR=0.67; p=0.006 for each additional gestational week).

In the model adjusted for all potential confounders, the relationship between treatment group and NICU admission was no longer statistically significant (aOR: 0.28; 95% CI: 0.04-2.0; p=0.20), although it was somewhat stronger in magnitude. Elevated maternal HbA1c (>7%) was the strongest predictor of NICU admission in the model (aOR: 11.88; 95% CI: 1.40-101; p=0.024), with gestational age and birth weight category not being significant in the model. These data support the idea that the apparent advantage of metformin monotherapy may be related to

better glycemic control and gestational age at delivery (Table 3).

Table 2: Comparison of neonatal outcomes between pregnancies treated with metformin monotherapy and metformin plus insulin combination therapy.

Outcomes	Metformin (n=65)	Metformin + insulin (n=58)	P value
NICU admission (%)	46.2 (30/65)	74.1 (43/58)	0.002
Apgar <7 at 1 min (%)	3.07 (5/65)	20.68 (12/58)	0.56
Neonatal hypoglycemia (%)	1.5 (1/65)	3.44 (2/58)	0.47
Preterm birth (<37 weeks) (%)	21.5 (14/65)	32.7 (19/58)	0.71
Birth weight (kg)	2.92± 0.32	2.86±0.33	0.15

Data are presented as number (percentage) for categorical variables and mean±SD for continuous variables

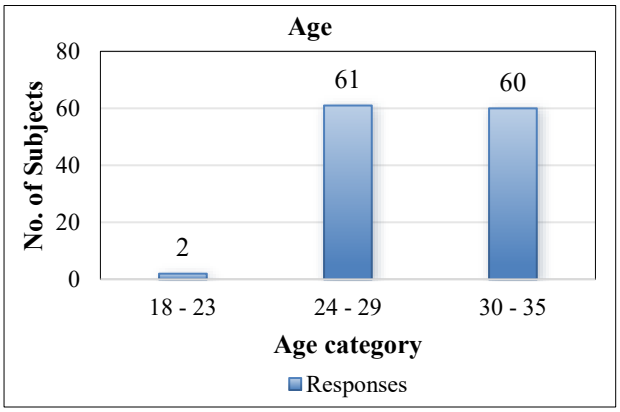

Figure 1: Distribution of maternal age among women diagnosed with gestational diabetes mellitus included in the study.

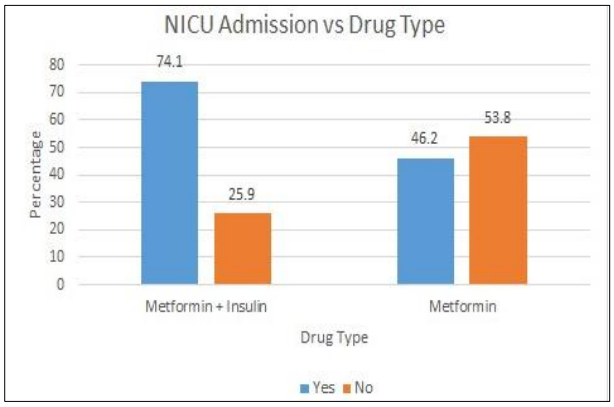

Figure 2: Neonatal intensive care unit admission rates according to treatment group.

Table 3: Multivariable logistic regression analysis for predictors of NICU admission.

Predictors	aOR (95% CI)	P value
Metformin versus met+ins	0.28 (0.04-2.0)	0.20
Gestational age (weeks)	0.67 (0.47-0.97)	0.03
HbA1c ≥7%	11.88 (1.40-101)	0.024

DISCUSSION

This study investigated neonatal outcomes in pregnancies complicated by GDM and treated with either metformin monotherapy or metformin and insulin therapy. From the study's findings, it is clear that metformin monotherapy was linked with reduced neonatal intensive care unit (NICU) admission compared with metformin and insulin therapy; however, once maternal glycemic control and other covariates were adjusted for, such an association was no longer evident.

Another interesting finding was the lower NICU admission rate among neonates born to mothers on metformin monotherapy. After adjusting for gestational age, metformin monotherapy was linked with a 58% reduction in the odds for NICU admission. Our findings are consistent with those of Picón-César et al who reported comparable neonatal outcomes among women treated with metformin and insulin. Similarly, Sheng et al in a systematic review and meta-analysis, found that metformin was associated with favourable short-term neonatal outcomes without an increase in adverse neonatal events.[16,17] These findings support our observation that metformin monotherapy was associated with lower NICU admission rates before adjustment for maternal and clinical factors. The pharmacological properties of metformin, such as decreased hepatic glucose output and enhanced insulin sensitivity without inducing fetal hyperinsulinism, may account for these favorable effects.

However, maternal glycemic control has been found to be the most significant factor in influencing neonatal outcomes.[18-20] It has been found that high HbA1c levels, particularly ≥7%, are strongly correlated with NICU admissions, regardless of the treatment modality.[18,19] A similar observation was reported by Al-Shahrani et al who identified poor maternal glycaemic control as an important predictor of NICU admission and adverse neonatal outcomes in pregnancies complicated by gestational diabetes mellitus.[18] ROC analysis has shown moderate predictive capability of HbA1c for NICU admissions. When the variables maternal HbA1c and birth weight were included in the multivariate model, the association between the type of treatment and NICU admissions was no longer statistically significant. This has reinforced the need for effective control of maternal hyperglycemia to prevent neonatal morbidity, as has been highlighted in the literature, which has shown the impact of poor maternal

glucose control on neonatal outcomes such as hypoglycemia, respiratory distress, and preterm birth.[19,20]

With regard to birth weight, the infants of the combination therapy group had slightly lower birth weights compared to those of the metformin-only group. This finding is in agreement with the observations of Karcz and Królak-Olejnik who reported that fetal growth is influenced primarily by maternal metabolic control and gestational age rather than the choice of pharmacological therapy.[9]

Similar findings were also described by Preda et al who highlighted the importance of maternal glycaemic control in determining neonatal outcomes.[11] However, gestational age was the most significant predictor of birth weight, with each additional week of gestation making a significant contribution to the weight gain of the newborn. This emphasizes the need to ensure the longest pregnancy duration, as preterm birth is a known factor for poor outcomes in the newborn.

The differences in the outcomes could also be explained by the differences in the severity of the disease process. The patients in the combination therapy group could be considered to be at higher risk and could be having more severe insulin resistance or poor glycemic control, which could independently be causing poor outcomes. This could be the reason for the higher rates of admission to the NICU in the combination therapy group.

From a clinical perspective, this study supports the use of metformin as a viable first-line pharmacologic agent for GDM management in well-selected patients, This observation is consistent with the current NICE guideline, which recommends metformin as an appropriate first-line pharmacological option when lifestyle modification alone does not achieve adequate glycaemic control.[15] Its ease of use, low risk of inducing hypoglycemia in mothers, and weight profile make it an attractive alternative to insulin therapy. It is essential to reiterate that above all else, it is critical to attain and maintain optimal glycemic control, as it appears to be the major determinant of neonatal outcome regardless of therapy modality used.

Limitations

Overall, there are a number of limitations to this study. One of the major limitations of this study is its retrospective nature, which lends it to selection and information bias. Furthermore, there is a relatively small sample population of patients, which may impact statistical significance of less common events. There were also some confounding factors that were not well accounted for in this study, such as glycemic trends, weight gain, and socioeconomic factors. It would be interesting to see a prospective study with a larger sample population of patients with more well-rounded data to determine the effects of various pharmacologic regimens on neonatal outcomes.

CONCLUSION

This retrospective cohort study of pregnancies complicated by GDM showed that metformin monotherapy had lower NICU admission rates compared to combination therapy with insulin. Women requiring insulin likely had more severe hyperglycaemia, which may explain higher NICU admission rates rather than treatment effect alone. The maternal glucose levels, as measured by HbA1c, were the strongest predictors of neonatal outcomes. The importance of glucose control during pregnancy is emphasized.

ACKNOWLEDGEMENTS

Authors would like to thank PES University Institute of Pharmacy, and PES University Institute of Medical Sciences and Research for the academic, clinical, and research assistance provided for this study.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Dharshan GB, Rao RS, Vijaya Shambhavi B, Shreya DP, Bharathi KR, Dalal VI. Neonatal outcomes in gestational diabetes mellitus: metformin alone versus metformin with insulin: a retrospective cohort study in India. Int J Reprod Contracept Obstet Gynecol 2026;15:3857-63.