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Original Research Article

An Observational Study on Maternal and Neonatal Outcomes in Patients with Gestational Diabetes Mellitus Treated with Metformin and Insulin

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Abstract: ***Background***: Gestational Diabetes Mellitus (GDM), characterized by glucose intolerance during pregnancy, has become increasingly prevalent worldwide, posing significant risks to both maternal and neonatal health. While Insulin has traditionally been the gold standard for pharmacological management, Metformin is gaining attention due to its ease of use, cost- effectiveness, and potentially fewer complications. This study aimed to compare maternal and neonatal outcomes among women with GDM treated with Metformin, Insulin, or a combination of both. ***Methods***: A six-month, hospital-based observational study was conducted at Pushpagiri Medical College Hospital, Thiruvalla, including 110 pregnant women aged 20–40 years with singleton pregnancies diagnosed with GDM. Participants were assigned to three groups: Metformin (n=62), Insulin (n=9), and Metformin+Insulin (n=39). Data were analysed using SPSS v23 with significance set at $p<0.05$. ***Results***: The mean participant age was 29.15 ± 3.77 years. Metformin was the most commonly used treatment (56.4%). Caesarean rates were highest in the Insulin group (100%) versus Metformin (43.5%) and combination (69.2%) (p=0.001). Labor induction was significantly more common with Metformin (46.8%) compared to Insulin (0%) (p=0.029). Maternal hypoglycaemia and polyhydramnios were more frequent in the Insulin group; however, differences were not statistically significant. Neonatal hypoglycaemia and preterm birth were also more prevalent in the Insulin group. Prior GDM and fertility treatment were linked to Insulin use, while family history of diabetes was associated with neonatal respiratory distress. ***Conclusion***: Metformin appears to be a safe and effective alternative to Insulin for GDM management, with fewer maternal and neonatal interventions. Individualized treatment is essential to optimize outcomes.

Keywords: Gestational Diabetes Mellitus; Metformin; Insulin; Maternal Outcome; Neonatal Outcome.

INTRODUCTION

Gestational Diabetes Mellitus (GDM) is a growing global health concern characterized by glucose intolerance first recognized during pregnancy. Its increasing incidence is attributed to rising maternal age, obesity, and sedentary lifestyles. GDM poses significant risks for both mother and neonate, including hypertensive disorders, caesarean delivery, neonatal hypoglycaemia, and long-term metabolic complications [1]. While Insulin has traditionally been the mainstay treatment for GDM, Metformin has emerged as a viable alternative due to its oral administration, cost-effectiveness, and favourable maternal and neonatal safety profile.

Previous studies have explored the comparative effectiveness of Metformin and Insulin, yet limited data exist in the Indian population evaluating maternal and neonatal outcomes across different treatment modalities [2,3]. By correlating clinical outcomes with existing literature and risk profiles, this study strengthens the understanding of optimal GDM management in the Indian context, where culturally specific data are critically needed. The objectives of the study were: (1) to identify

treatment modalities used in GDM management; (2) to observe associated maternal and neonatal outcomes; (3) to identify risk factors influencing these outcomes; and (4) to educate the patients on the importance of adherence and compliance to the treatment.

MATERIALS AND METHODS

A single centered, hospital based, observational study was conducted in the Department of Obstetrics and Gynaecology and Department of Paediatrics and Neonatology, Pushpagiri Medical College Hospital, Thiruvalla, Kerala, India for a duration of 6 months, including a total of 110 GDM patients.

Inclusion Criteria

- All women diagnosed with GDM aged between 20 - 40 years with a gestation period of 28 - 40 weeks.
- Those who gave consent voluntarily to participate in the study.

Exclusion Criteria

- Multiple pregnancy (including previous pregnancy)
- Patients who were not willing to give consent.

The sample size obtained was n =110 GDM patients using the formula;

$$\text{Sample size, } n = \frac{(Z\alpha^2)\, PQ}{d^2}$$

STUDY PROCEDURE

The study "An Observational Study on Maternal and Neonatal Outcomes in Patients with Gestational Diabetes Mellitus Treated with Metformin and Insulin" was conducted after getting approval from the Institutional Ethics Committee. Participants were informed about the study and confidentiality measures, and written informed consent was obtained. Subjects were selected based on specific inclusion and exclusion criteria. Data was collected using a structured questionnaire covering health history, lifestyle, mental health, and treatment. An educational leaflet was also provided to emphasize the importance of treatment adherence for better maternal and neonatal outcomes.

STATISTICAL ANALYSIS

Data were coded and entered in Microsoft Excel and analysed using SPSS version 23. Continuous variables were summarized using t-tests or ANOVA. Categorical variables were presented as frequencies and percentages. Associations between categorical variables and outcomes were analysed using the Chi-square or Fisher's exact test. A p-value <0.05 was considered statistically significant.

RESULTS

This study analyzed maternal and neonatal outcomes among 110 patients with GDM treated with either Metformin or Insulin or both. The findings provide insights into the different treatment modalities practiced, their effectiveness, and associated risk factors influencing maternal and neonatal health. The age of the participants ranged from 22 to 40 years, with a mean age of 29.15 ± 3.77 years. Majority of the study participants (52.7%, n=58) were in the 26-30 years age group, followed by 26.4% (n=29) in the 31-35 years age group.

Distribution of study population based on treatment modality followed

Among the 110 patients with GDM, Metformin was the most commonly used treatment modality, administered to 56.4% (n=62) of the participants. A combination of Metformin and Insulin was required in 35.5% (n=39) of cases, while only 8.2% (n=9) were managed exclusively with Insulin.

Distribution of study population based on maternal complications

The most common maternal complications were caesarean delivery (57.3%) and induction of labor (40.9%), indicating a high rate of obstetric interventions in this population. Maternal hypoglycaemia (7.3%) and polyhydramnios (4.5%) were less frequently observed.

Distribution of study population based on treatment modality followed and maternal complications

Induction of labor was more common in the Metformin (46.8%) and combination (41%) groups, with no inductions in the Insulin-only group (p=0.029). Caesarean delivery was significantly more frequent among Insulin users (100%), followed by the combination group (69.2%) and Metformin group (43.5%) (p=0.001.

Distribution of study population based on fetal complications

NICU admission was the most frequent fetal complication, occurring in 93.6% (n=103) of cases. Low birth weight (SGA) was observed in 52.7% (n=58) of the neonates, while jaundice was noted in 31.8% (n=35). Large for Gestational Age (LGA) infants accounted for 26.4% (n=29), and pre-term birth was observed in 17.3% (n=19) of cases.

Distribution of study population based on

treatment modality followed and fetal complications

NICU admission rates, low birth weight (SGA), Large for Gestational Age (LGA), jaundice, preterm birth, respiratory distress, neonatal hypoglycemia, and macrosomia were all comparable among the Metformin, Insulin, and combination therapy groups. Overall, treatment type did not significantly impact neonatal outcomes.

Distribution of study population based on past obstetric history

A history of Gestational Diabetes Mellitus in previous pregnancies was reported in 33.6% (n=37) of participants, indicating a significant recurrence risk for GDM in subsequent pregnancies. A history of abortion was noted in 20.0% (n=22), with the majority (86.4%, n=19) having experienced a single abortion and a smaller proportion (13.6%, n=3) reporting two abortions. Fertility treatment was required for 9.1% (n=10) of the participants, suggesting a possible association between subfertility and GDM, which required the need insulin therapy.

Factors associated with induction of labor requirement

The requirement for induction of labor was significantly associated with younger maternal age (p=0.023) and lower BMI (p=0.038).

Factors associated with polyhydramnios

Among the analysed factors, hypertension was significantly associated with polyhydramnios (p<0.001).

Factors associated with jaundice in newborn

A history of abortion (p=0.011) was significantly associated with the development of jaundice in newborns, with a lower incidence among those without a history of abortion.

Factors associated with neonatal hypoglycaemia

A higher maternal BMI was significantly associated with neonatal hypoglycaemia (p=0.002).

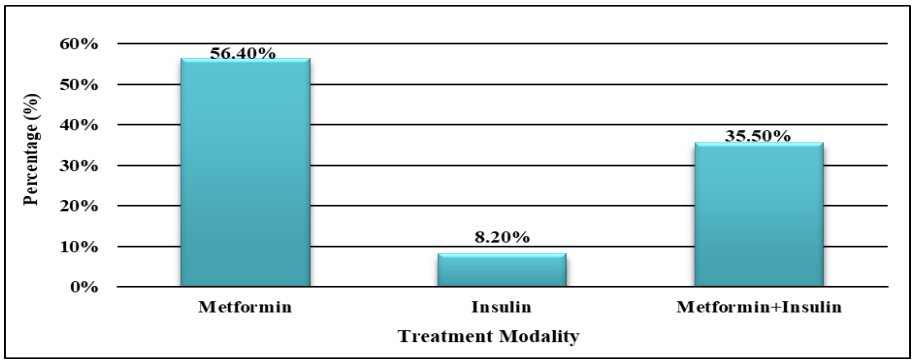

Figure 1: Distribution of study population based on treatment modality followed

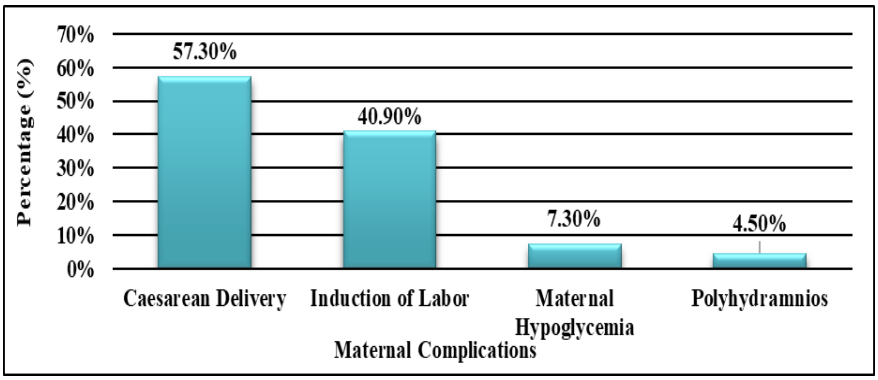

Figure 2: Distribution of study population based on maternal complications

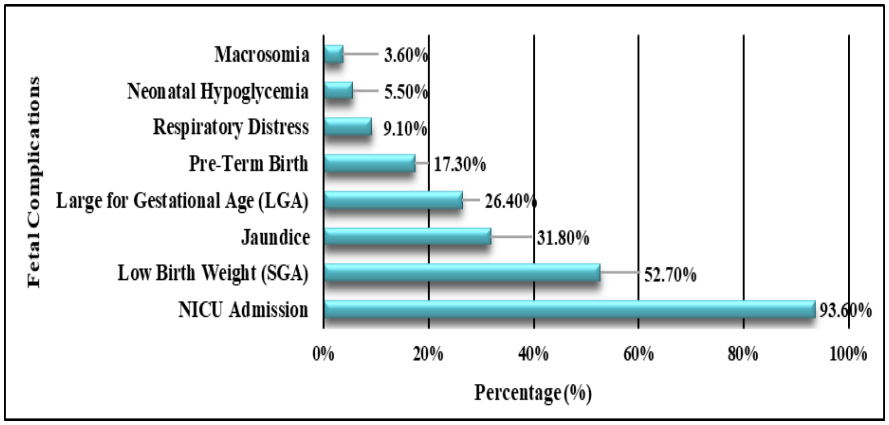

Figure 3: Distribution of study population based on fetal complications

Table 1: Distribution of study population based on treatment modality followed and maternal complications

Maternal Complications	Treatment modality followed			Test statistic& P value
	Metformin n (%)	Insulin n (%)	Metformin + Insulin n (%)	
Induction of Labor	29(46.8%)	0(0%)	16(41%)	χ^2= 7.113, p=0.029*
Caesarean Delivery	27(43.5%)	9(100%)	27(69.2%)	χ^2= 13.765, p=0.001*
Maternal Hypoglycaemia	7(11.3%)	0(0%)	1(2.6%)	χ^2= 3.472, p=0.176
Polyhydramnios	2(3.2%)	1(11.1%)	2(5.1%)	χ^2= 1.174, p=0.556

**Statistically significant at p<0.05*

Table 2: Distribution of study population based on fetal complications

Condition	Frequency(n)	Percentage(%)
NICU Admission	103	93.6
Low Birth Weight (SGA)	58	52.7
Jaundice	35	31.8
Large for gestational Age (LGA)	29	26.4
Pre-Term Birth	19	17.3
Respiratory Distress	10	9.1
Neonatal Hypoglycemia	6	5.5
Macrosomia	4	3.6

Table 3: Factors associated with induction of labor requirement

Factor		Induction of Labor		Total
		Required	Not Required	
Age- Mean (SD)		28.18(3.03)	29.83(4.08)	t= 2.308, p=0.023*
BMI- Mean (SD)		25.21(3.58)	26.92(4.58)	t= 2.095, p=0.038*
Family h/o DM	Present- n(%)	27(37%)	46(63%)	χ^2= 1.382, p=0.240
	Absent- n(%)	18(48.6%)	19(51.4%)	
PCOD	Present- n(%)	10(41.7%)	14(58.3%)	χ^2= 0.007, p=0.932
	Absent- n(%)	35(40.7%)	51(59.3%)	
Thyroid disorder	Present- n(%)	8(36.4%)	14(63.6%)	χ^2= 0.235, p=0.628
	Absent- n(%)	37(42%)	51(58%)	
Stress	Present- n(%)	6(40%)	9(60%)	χ^2= 0.006, p=0.939
	Absent- n(%)	39(41.1%)	56(58.9%)	
Hypertension	Present- n(%)	1(16.7%)	5(83.3%)	χ^2= 1.543, p=0.214
	Absent- n(%)	44(42.3%)	60(57.7%)	
H/o steroid therapy	Present- n(%)	2(33.3%)	4(66.7%)	χ^2= 0.151, p=0.698
	Absent- n(%)	43(41.3%)	61(58.7%)	
Previous GDM	Present- n(%)	13(35.1%)	24(64.9%)	χ^2= 0.769, p=0.381
	Absent- n(%)	32(43.8%)	41(56.2%)	
H/o Abortion	Present- n(%)	9(40.9%)	13(59.1%)	χ^2= 0.001, p=1.000
	Absent- n(%)	36(40.9%)	52(59.1%)	
Fertility treatment-	Present- n(%)	3(30%)	7(70%)	χ^2= 0.542, p=0.462
	Absent- n(%)	42(42%)	58(58%)	
H/o Preterm labour	Present- n(%)	2(25%)	6(75%)	χ^2= 0.903, p=0.342
	Absent- n(%)	43(42.2%)	59(57.8%)	

**Significant at p<0.05*

Table 4: Factors associated with polyhydramnios

Factor		Polyhydramnios		Total
		Present	Absent	
Age- Mean (SD)		30.6(2.88)	29.09(3.80)	t= 0.877, p=0.382
BMI- Mean (SD)		29.46(4.61)	26.07(4.21)	t= 1.754, p=0.082
Family h/o DM	Present- n(%)	5(6.8%)	68(93.2%)	χ^2= 2.655, p=0.103
	Absent- n(%)	0(0%)	37(100%)	
PCOD	Present- n(%)	2(8.3%)	22(91.7%)	χ^2= 1.015, p=0.314
	Absent- n(%)	3(3.5%)	83(96.5%)	
Thyroid disorder	Present- n(%)	1(4.5%)	21(95.5%)	χ^2= 0.001, p=1.000
	Absent- n(%)	4(4.5%)	84(95.5%)	
Stress	Present- n(%)	2(13.3%)	13(86.7%)	χ^2= 3.091, p=0.079
	Absent- n(%)	3(3.2%)	92(96.8%)	
Hypertension	Present- n(%)	2(33.3%)	4(66.7%)	χ^2= 12.121, p<0.001*
	Absent- n(%)	3(2.9%)	101(97.1%)	
H/o steroid therapy	Present- n(%)	1(16.7%)	5(83.3%)	χ^2= 2.149, p=0.143
	Absent- n(%)	4(3.8%)	100(96.2%)	
Previous GDM	Present- n(%)	0(0%)	37(100%)	χ^2= 2.655, p=0.103
	Absent- n(%)	5(6.8%)	68(93.2%)	
H/o Abortion	Present- n(%)	0(0%)	22(100%)	χ^2= 1.310, p=0.252
	Absent- n(%)	5(5.7%)	83(94.3%)	
Fertility treatment-	Present- n(%)	1(10%)	9(90%)	χ^2= 0.754, p=0.385
	Absent- n(%)	4(4%)	96(96%)	
H/o Preterm labour	Present- n(%)	0(0%)	8(100%)	χ^2= 0.411, p=0.522
	Absent- n(%)	5(4.9%)	97(95.1%)	

**Significant at p<0.05*

Table 5: Factors associated with jaundice in newborn

Factor		Jaundice		Total
		Developed	Not Developed	
Age- Mean (SD)		29.34(3.21)	29.07(4.02)	t= 0.357, p=0.722
BMI- Mean (SD)		25.9(4.055)	26.37(4.38)	t= 0.536, p=0.593
Family h/o DM	Present- n(%)	24(32.9%)	49(67.1%)	χ^2= 0.112, p=0.738
	Absent- n(%)	11(29.7%)	26(70.3%)	
PCOD	Present- n(%)	7(29.2%)	17(70.8%)	χ^2= 0.099, p=0.752
	Absent- n(%)	28(32.6%)	58(67.4%)	
Thyroid disorder	Present- n(%)	7(31.8%)	15(68.2%)	χ^2= 0.001, p=1.000
	Absent- n(%)	28(31.8%)	60(68.2%)	
Stress	Present- n(%)	5(33.3%)	10(66.7%)	χ^2= 0.018, p=0.892
	Absent- n(%)	30(31.6%)	65(68.4%)	
Hypertension	Present- n(%)	3(50%)	3(50%)	χ^2= 0.969, p=0.325
	Absent- n(%)	32(30.8%)	72(69.2%)	
H/o steroid therapy	Present- n(%)	2(33.3%)	4(66.7%)	χ^2= 0.007, p=0.935
	Absent- n(%)	33(31.7%)	71(68.3%)	
Previous GDM	Present- n(%)	12(32.4%)	25(67.6%)	χ^2= 0.010, p=0.922
	Absent- n(%)	23(31.5%)	50(68.5%)	
H/o Abortion	Present- n(%)	2(9.1%)	20(90.9%)	χ^2= 6.548, p=0.011
	Absent- n(%)	33(37.5%)	55(62.5%)	
Fertility treatment-	Present- n(%)	2(20%)	8(80%)	χ^2= 0.708, p=0.400
	Absent- n(%)	33(33%)	67(67%)	
H/o Preterm labour	Present- n(%)	2(25%)	6(75%)	χ^2= 0.185, p=0.667
	Absent- n(%)	33(32.4%)	69(67.6%)	

**Significant at p<0.05*

Table 6: Factors associated with neonatal hypoglycemia

Factor		Neonatal hypoglycaemia		Total
		Developed	Not Developed	
Age- Mean (SD)		29.17(4.17)	29.15(3.76)	t= 0.008, p=0.994
BMI- Mean (SD)		31.45(4.79)	25.918(4.06)	t= 3.218, p=0.002*
Family h/o DM	Present- n(%)	6(8.2%)	67(91.8%)	χ^2= 3.217, p=0.073
	Absent- n(%)	0(0%)	37(100%)	
PCOD	Present- n(%)	1(4.2%)	23(95.8%)	χ^2= 0.099, p=0.753
	Absent- n(%)	5(5.8%)	81(94.2%)	
Thyroid disorder	Present- n(%)	1(4.5%)	21(95.5%)	χ^2= 0.044, p=0.834
	Absent- n(%)	5(5.7%)	83(94.3%)	
Stress	Present- n(%)	0(0%)	15(100%)	χ^2= 1.002, p=0.317
	Absent- n(%)	6(6.3%)	89(93.7%)	
Hypertension	Present- n(%)	0(0%)	6(100%)	χ^2= 0.366, p=0.545
	Absent- n(%)	6(5.8%)	98(94.2%)	
H/o steroid therapy	Present- n(%)	0(0%)	6(100%)	χ^2= 0.366, p=0.545
	Absent- n(%)	6(5.8%)	98(94.2%)	
Previous GDM	Present- n(%)	2(5.4%)	35(94.6%)	χ^2= 0.001, p=0.987
	Absent- n(%)	4(5.5%)	69(94.5%)	
H/o Abortion	Present- n(%)	0(0%)	22(100%)	χ^2= 1.587, p=0.208
	Absent- n(%)	6(6.8%)	82(93.2%)	
Fertility treatment-	Present- n(%)	0(0%)	10(100%)	χ^2= 0.635, p=0.426
	Absent- n(%)	6(6%)	94(94%)	
H/o Preterm labour	Present- n(%)	0(0%)	8(100%)	χ^2= 0.498, p=0.480
	Absent- n(%)	6(5.9%)	96(94.1%)	

**Significant at p<0.05*

DISCUSSION

In this study, the majority of participants were aged 26–30 years and had insulin resistance. Higher BMI and a family history of diabetes were more common in the Insulin group, along with PCOD and fertility treatment, indicating greater metabolic risk [4,5]. Metformin was the most commonly used drug (56.4%), reflecting a shift in clinical practice toward

its favorable profile. Cesarean section rates were highest among Insulin-treated women (100%), with significantly lower rates in the Metformin group (43.5%) (p=0.001) [6]. Labor induction was more frequent in the Metformin and combination groups, possibly due to better glycemic control. Overall, Metformin was associated with fewer maternal complications [7,8].

Neonatal outcomes showed high NICU admission rates across all groups (>88%), likely due to precautionary institutional protocols [9]. Neonatal hypoglycemia was more frequent in the Insulin group (11.1%) versus the Metformin (4.8%) [10]. No notable differences were found in birth weight or jaundice rates [6]. Compared with prior studies, Vidyasri Bailore et al., (2024) [11], Abdel Monem Mohamad Zakaria et al., (2022) [12], Federico Pigato et al., (2019) [13], Slagjana Simeonova-Krstevska et al., (2018) [14], Metformin demonstrated a safer maternal-neonatal profile, including fewer complications and interventions. These findings support Metformin as a strong first-line option for GDM management, though further research on institutional practices, long-term outcomes is warranted and individualized treatment remains essential [15].

CONCLUSION

This study underscores the significant impact of GDM on maternal and neonatal health. Key findings include a high caesarean section rate, especially in the Insulin-only group, suggesting more severe metabolic conditions. In contrast, Metformin use was associated with fewer maternal complications and lower caesarean rates, indicating more favourable pregnancy outcomes when glycaemic control is achieved. Neonatal hypoglycaemia was more frequent in the Insulin group, supporting concerns about fetal hyperinsulinism. High NICU admission rates across all groups were likely influenced by hospital policy rather than clinical necessity. Risk factors such as a family history of diabetes and prior GDM were more common in women requiring Insulin or combination therapy, highlighting the need for more intensive management in these cases. Overall, the study supports Metformin as a safe, cost-effective, and convenient treatment option for many women with GDM. However, individualized care remains essential.

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Conflict of Interest

The authors declared no potential conflicts of interest concerning the research, authorship, and/publication of this article.

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Ethical consideration

Institutional Research/ Human Ethics Committee approval was obtained.

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