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ORIGINAL RESEARCH

A Comparative Study of Metformin and Insulin for Managing Gestational Diabetes Mellitus in Pregnancy

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ABSTRACT

Background: Diabetes mellitus poses a worldwide health issue that affects individuals of all ages and genders. The present study was conducted to compare metformin and insulin in managing glycaemic control in women with gestational diabetes mellitus. **Materials & Methods:** 90 pregnant women with gestational diabetes mellitus were divided into 2 groups of 45 each. Group I received metformin and group II received insulin. Parameters such as parity, socioeconomic status (SES), family history of DM, and past history of GDM were recorded. Assessment of BMI, BP, fasting blood sugar, and oral glucose tolerance was done. **Results:** Parity was Primi in 25 in group I and 30 in group II, 2nd gravida in 12 in group I and 9 in group II, and 3rd gravida in 8 in group I and 6 in group II. BMI <18 kg/m2 was seen in 19 in group I and 14 in group II, 18-24.9 kg/m2 in 21 in group I and 23 in group II, and >25 kg/m2 in 5 in group I and 8 in group II patients. The difference was non-significant (P< 0.05). Maternal hypoglycaemia was seen in 3 in group II. Gestational age at delivery ≤37 weeks was seen in 7 and 15 and >37 weeks in 38 and 30. Mode of delivery was cesarean in 32 and 34 and vaginal in 13 and 11 in group I and II respectively. The difference was significant (P< 0.05). **Caesarean section** was more common in the insulin group (75.56% vs. 71.11%), likely reflecting obstetric decisions influenced by foetal size and comorbidities. APGAR at 5 minutes ≥7 was seen in 42 and 45 and <7 in 3 and 0 in group I and group II, respectively. Neonatal hypoglycaemia was seen in 2 and 3 in group I and group II, respectively. Neonatal outcomes such as birth weight were significantly higher in the insulin group ($p = 0.004$), indicating a higher risk of macrosomia. Rates of neonatal hypoglycaemia and NICU admission were higher in the insulin group, although not statistically significant. **Conclusion:** Metformin as a pharmacological intervention for GDM demonstrated beneficial effects on maternal and neonatal health. Conversely, the cohort undergoing insulin treatment showed a greater prevalence of inadequate glycaemic control, and infants needing phototherapy.

Keywords: Hypoglycemia, Gestational diabetes mellitus, Metformin, Insulin, Macrosomia

INTRODUCTION

Diabetes mellitus poses a worldwide health issue that affects individuals of all ages and genders. Duncan first described gestational diabetes mellitus (GDM) in 1982 as a type of diabetes that occurs "only during pregnancy, being absent at other times.[1] The occurrence of diabetes during pregnancy varies widely, but it typically mirrors the prevalence of type 2 diabetes within the specific population. GDM refers to hyperglycemia that is first detected during pregnancy between the 24th and 28th weeks and does not meet the criteria for overt diabetes. In the past, the future risk of developing type 2 diabetes was used to validate the diagnostic cut-off.[2] During pregnancy, there is typically a gradual onset of insulin resistance that starts around the midpoint of gestation and continues to develop throughout the third trimester, reaching levels comparable to those observed in people

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with type 2 diabetes.[3] The insulin resistance appears to result from a combination of increased maternal adiposity and the insulin-desensitizing effects of hormonal products of the placenta. The rapid decline of insulin resistance after delivery indicates that placental hormones are likely the primary contributors to this state of resistance. The second point is that, in order to offset the insulin resistance seen during pregnancy, pancreatic β cells typically boost their insulin secretion.[4,5]

Maintaining appropriate glycaemic control has been shown to mitigate the likelihood of obstetric problems and minimise unfavourable perinatal outcomes. In cases where lifestyle modifications, such as diet and exercise, fail to achieve ideal glucose levels, implementing pharmacological therapy becomes necessary.[6]

AIM & OBJECTIVES

Aim

To compare the efficacy, maternal, and neonatal outcomes of metformin versus insulin in the treatment of gestational diabetes mellitus (GDM) during pregnancy.

Objectives

1. To assess and compare maternal baseline characteristics between pregnant women treated with metformin and those treated with insulin.
2. To evaluate and compare weight gain during pregnancy in both treatment groups.
3. To compare maternal outcomes such as gestational age at delivery, mode of delivery, hypoglycemia, and maternal complications between the metformin and insulin groups.
4. To assess and compare neonatal outcomes including birth weight, APGAR score, neonatal hypoglycemia, need for phototherapy, NICU admission, and incidence of macrosomia between the two treatment groups.

MATERIALS AND METHODS

Study Design

This was a prospective, comparative, interventional study conducted to evaluate and compare the effectiveness of metformin and insulin in glycaemic control among women with singleton pregnancy diagnosed with gestational diabetes mellitus (GDM) and gestational age between 24 and 34 weeks who did not achieve glycemic control on diet were assigned randomly to receive either metformin or insulin.

Study Population

The study population consisted of 90 pregnant women diagnosed with GDM who attended the antenatal clinic of the institution. All participants voluntarily consented to participate in the study.

Study Place

The study was conducted in the Department of Obstetrics and Gynaecology, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India, a tertiary care centre providing obstetric and endocrinological care.

Study Duration

The study was carried out over a period of 12 months, November 2023 to October 2024.

Inclusion Criteria

- Pregnant women diagnosed with gestational diabetes mellitus (based on OGTT as per IADPSG/WHO criteria).
- Age range of Pregnant women diagnosed with GDM was 30-35 years.
- Gestational age between 24 and 34 weeks.
- Singleton pregnancy.
- Willingness to comply with the treatment protocol and follow-up.

Exclusion Criteria

- Pre-existing diabetes mellitus (Type 1 or Type 2).
- Multiple pregnancy.
- Known allergy or contraindication to metformin or insulin.
- Significant comorbidities such as renal failure, hepatic dysfunction, or cardiovascular disease.
- History of chronic steroid use.

Ethical Considerations

Ethical clearance was obtained from the Institutional Ethics Committee prior to the commencement of the study. Informed written consent was obtained from each participant. Confidentiality and privacy of patient data were strictly maintained.

Study Procedure

- After obtaining informed consent, 90 women diagnosed with GDM were enrolled.
- Detailed history including age, parity, socioeconomic status, family history of diabetes, and past history of GDM was taken.
- Thorough clinical examination was performed for all patients, including measurement of BMI and blood pressure.
- Participants were randomly allocated into two groups:
  - **Group I (n = 45):** Received oral metformin.

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- **Group II (n = 45):** Received subcutaneous insulin therapy.
- Both groups were counselled on dietary management and exercise.
- Baseline investigations were recorded including:
  - Fasting Blood Sugar (FBS)
  - 2-hour Postprandial Blood Sugar (PPBS)
  - Oral Glucose Tolerance Test (OGTT)

Study method

This was a non-surgical interventional study involving pharmacological management.

Outcome Measures

Primary and secondary outcome measures included:

- Improvement in fasting and postprandial glucose levels.
- Achievement of target glycaemic control (as per ADA guidelines).
- Maternal outcomes (e.g., preeclampsia, preterm labour).
- Foetal outcomes (e.g., birth weight, neonatal hypoglycaemia).
- Adverse effects related to metformin or insulin therapy.

Statistical Analysis

- Data were recorded and analyzed using SPSS 22.0 version.
- Descriptive statistics (mean, SD) were used for quantitative variables.
- Chi-square test/ Fisher's exact test and unpaired t-test were used to compare categorical and continuous variables between groups.
- A p-value < 0.05 was considered statistically significant.

RESULTS

Table 1: Comparison of Maternal Characteristics between Group I (Metformin) and Group II (Insulin) (n = 90)

Parameter	Group I: Metformin (n=45)	Group II: Insulin (n=45)	*p*-value	Statistical Test Used
Mean Age (years)	32.4 ± 2.8	32.7 ± 3.1	0.62	Independent *t*-test
Mean Gestational Age (weeks)	28.3 ± 2.5	28.1 ± 2.7	0.74	
Parity				
- Nulliparous (n, %)	18 (40%)	20 (44.4%)	0.68	Chi-square test
- Multiparous (n, %)	27 (60%)	25 55.6%)		

Table 1 show that there was no statistically significant difference between the two groups in terms of mean age, gestational age at check-up, or parity status ($p > 0.05$). This suggests that randomization effectively balanced the baseline characteristics between women receiving metformin and those receiving insulin.

Table 2: Baseline characteristics

Parameters	Variables	Group I: Metformin (n=45)	Group II: Insulin (n=45)	P value
Parity	Primi	25	30	0.39
	2nd gravida	12	9	
	3rd gravida	8	6	
BMI (kg/m2)	<18	19	14	0.47
	18-24.9	21	23	
	>25	5	8	

Table 2 shows that the parity was primi in 25 in group I and 30 in group II, 2nd gravida in 12 in group I and 9 in group II, and 3rd gravida in 8 in group I and 6 in group II. BMI < 18 kg/m² was seen in 19 in group I and 14 in group II; 18-24.9 kg/m² in 21 in group I and 23 in group II; and > 25 kg/m² in 5 in group I and 8 in group II patients. The difference was non-significant (P< 0.05).

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Table 3: Comparison of Weight Gain in Pregnancy between Group I (Metformin) and Group II (Insulin) (n = 90)

Parameter	Group I: Metformin (n=45)	Group II: Insulin (n=45)	*p*-value	Statistical Test Used
Mean Weight Gain (kg)	8.2 ± 2.1	11.3 ± 2.5	<0.001	Independent *t*-test
Women with Excessive Weight Gain (>12 kg), n (%)	6 (13.3%)	17 (37.7%)	0.008	Chi-square test
Women with Adequate Weight Gain (8–12 kg), n (%)	28 (62.2%)	20 (44.4%)	0.07	Chi-square test
Women with Insufficient Weight Gain (<8 kg), n (%)	11 (24.5%)	8 (17.7%)	0.42	Chi-square test

Table 3 shows that the women treated with metformin had significantly lower mean weight gain during pregnancy compared to those receiving insulin (*8.2 kg vs. 11.3 kg*, $p < 0.001$). A higher proportion of excessive weight gain (>12 kg) was observed in the insulin group (37.7%) than the metformin group (13.3%), which was statistically significant ($p = 0.008$). The proportion of women achieving adequate weight gain was higher in the metformin group, though the difference did not reach statistical significance.

Table 4: Assessment of maternal outcomes between metformin and insulin groups

Parameters	Variables	Group I: Metformin (n=45)	Group II: Insulin (n=45)	P value
Maternal hypoglycaemia, n (%)	Yes	0	3 (6.67%)	0.01
	No	45 (100%)	42 (93.33%)	
Gestational age at delivery, n (%)	≤37 weeks	7 (15.56%)	15 (33.33%)	0.02
	>37 weeks	38 (84.44%)	30 (66.67%)	
Mode of delivery, n (%)	Cesarean	32 (71.11%)	34 (75.56%)	0.05
	Vaginal	13 (28.89%)	11 (24.44%)	
Postpartum Hemorrhage (PPH), n (%)	Yes	1 (2.2%)	2 (4.4%)	0.55
	No	44 (97.78%)	43 (95.56%)	
Pregnancy-Induced Hypertension (PIH), n (%)	Yes	2 (4.4%)	5 (11.1%)	0.23
	No	43(95.56%)	40 (88.89%)	

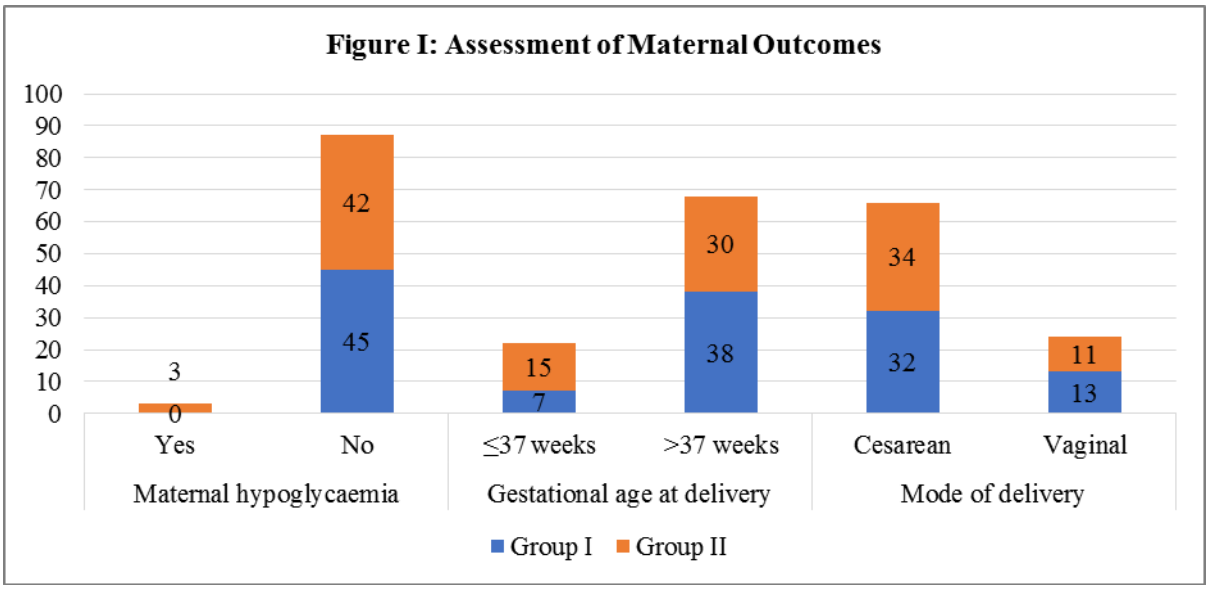

Table 4 and figure I show that the maternal hypoglycaemia was seen in 3 in group II. Gestational age at delivery ≤37 weeks was seen in 7 and 15 and >37 weeks in 38 and 30. The mode of delivery was caesarean in 32 and 34 and vaginal in 13 and 11 in groups I and II, respectively. The difference was significant (P< 0.05). **Maternal complications** such as

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pregnancy-induced hypertension and polyhydramnios were more frequent in the insulin group but without statistical significance. **Caesarean section** was more common in the insulin group (75.56% vs. 71.11%), likely reflecting obstetric decisions influenced by foetal size and comorbidities.

Table 5: Comparison of neonatal outcomes between metformin and insulin groups

Outcome	Variables	Group I: Metformin (n=45)	Group II: Insulin (n=45)	P value
Mean birth weight (g)		2960 ± 320	3210 ± 340	0.004
APGAR at 5 minutes	≥7	42	45	0.38
	<7	3	0	
Neonatal hypoglycaemia	Yes	2	3	0.74
	No	43	42	
Phototherapy	Yes	14	22	0.05
	No	31	23	
NICU admission	Yes	8	10	0.24
	No	37	35	
Macrosomia (>4000 g), n (%)		2 (4.4%)	6 (13.3%)	0.14

Table 5 shows that APGAR at 5 minutes ≥7 was seen in 42 and 45 and <7 in 3 and 0 in group I and group II, respectively. Neonatal hypoglycaemia was seen in 2 and 3 in group I and group II, respectively. Phototherapy was seen in 14 and 22 in group I and group II, respectively. NICU admission was seen in 8 and 10 subjects in groups I and II, respectively. The difference was significant (P< 0.05). Neonatal outcomes such as birth weight were significantly higher in the insulin group ($p = 0.004$), indicating a higher risk of macrosomia. Rates of neonatal hypoglycaemia and NICU admission were higher in the insulin group, although not statistically significant.

DISCUSSION

The mean maternal age was similar in both groups (32.4 ± 2.8 years in the metformin group and 32.7 ± 3.1 years in the insulin group; $p = 0.62$). This is consistent with previous studies, such as the Metformin in Gestational Diabetes (MiG) trial by Rowan et al. (2008), where the average maternal age ranged between 30 and 35 years among women randomised to receive either metformin or insulin.[7] The gestational age at which participants were enrolled was also comparable between the two groups (28.3 ± 2.5 weeks for metformin vs. 28.1 ± 2.7 weeks for insulin; $p = 0.74$). A similar timing of GDM diagnosis and initiation of pharmacological intervention was reported in other randomised controlled trials, such as a study by Tertti et al. (2013), where the mean gestational age at recruitment was approximately 28 weeks.[8] In terms of parity, both groups showed an even distribution between nulliparous and multiparous women, with no significant difference observed ($p = 0.68$). Nulliparous women constituted 40% of the metformin group and 44.4% of the insulin group. The parity distribution is consistent with findings by Ainuddin et al. (2015), who reported similar parity profiles among women treated with insulin and metformin in a randomised trial conducted in Pakistan.[9]

The International Association of Diabetes and Pregnancy Study Group (IADPSG) proposed more stringent diagnostic thresholds for GDM.[10] These new diagnostic criteria (fasting plasma glucose level ≥ 5.1 mmol/l and/or 1-h plasma glucose level ≥ 10.0 mmol/l and/or 2-hours plasma glucose level ≥ 8.5 mmol/l) have been adopted by the American Diabetes Association in 2010, the World Health Organisation (WHO) in 2013 and the International Federation of Gynaecology and Obstetrics in 2015.[11,12] The present study was conducted to assess and compare metformin and insulin in managing glycaemic control in women with gestational diabetes mellitus.

We found that parity was primi in 25 in Metformin group and 30 in Insulin group, 2nd gravida in 12 in Metformin group and 9 in Insulin group, and 3rd gravida in 8 in Metformin group and 6 in Insulin group. BMI < 18 kg/m² was seen in 19 in Metformin group and 14 in Insulin group, 18-24.9 kg/m² in 21 in Metformin group and 23 in Insulin group, and > 25 kg/m² in 5 in Metformin group and 8 in Insulin group patients. APGAR at 5 minutes ≥7 was seen in 42 and 45 and <7 in 3 and 0. Prabhu et al.[13]

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evaluated and compared the effectiveness of metformin and insulin in managing glycaemic control and assessing maternal and newborn outcomes among women diagnosed with GDM. Among the study population, 338 (91.6%) patients were on metformin, while 31 (8.40%) patients were on insulin. The metformin group exhibited good glycaemic control, whereas those on insulin had inadequate glycaemic control.

The findings from this study demonstrate a statistically significant difference in weight gain during pregnancy between women with gestational diabetes mellitus (GDM) treated with metformin versus those treated with insulin. On average, the metformin group gained less weight (8.2 ± 2.1 kg) compared to the insulin group (11.3 ± 2.5 kg), consistent with earlier research showing that metformin is associated with less maternal weight gain during pregnancy. Rowan et al. (2008), in the landmark MiG trial, reported that women treated with metformin gained significantly less weight than those receiving insulin, with a mean difference of approximately 1.7 kg.[7] Excessive maternal weight gain in pregnancy is associated with increased risks of macrosomia, caesarean section, and postpartum weight retention.[14]

We observed that maternal hypoglycaemia was seen in 3 (6.67%) in Insulin group. Gestational age at delivery ≤37 weeks was seen in 7 (15.56%) in Metformin group and 15 (33.33%) in Insulin group and >37 weeks in 38 (84.44%) in Metformin group and 30 (66.67%) in Insulin group. The mode of delivery was caesarean in 32 (71.11%) and 34 (75.56%) and vaginal in 13 (28.89%) and 11 (24.44%) in Metformin groups and Insulin group, respectively. Hakeem discovered that the occurrence of gestational diabetes mellitus was 8.6%. Spontaneous vertex deliveries accounted for 511 (74.6%), while 148 (21.6%) were delivered via lower segment caesarean section. The maternal morbidity rate among these women was 1.2%. These 685 women delivered a total of 697 babies, including 675 singleton pregnancies, 9 sets of twins, and one set of quadruplets. 687 infants were born alive, while 7 died in utero and 3 during the neonatal period. The rate of admission to neonatal intensive care was 4.9%. The average duration of stay in the NICU was 16 days. The most frequent reason for neonatal NICU admission was hyperbilirubinemia, accounting for 41.2% of cases. The risk factors for NICU admission were delivery by non-SVD procedure, preterm deliveries, and induction of labour.[15]

In terms of maternal outcomes, complications such as pregnancy-induced hypertension and polyhydramnios were more prevalent in the insulin group. Several studies, including a systematic review by Butalia et al. (2017), have indicated that metformin is associated with lower maternal weight gain and a potentially reduced risk of hypertensive disorders compared to insulin.[16] Caesarean delivery rates were higher in the insulin group (75.56% vs. 71.11%), possibly due to increased foetal weight and associated obstetric risks. Although the difference was not statistically significant, this trend has been observed in other trials and supports the hypothesis that metformin may help reduce surgical delivery rates in GDM patients.[9]

We found that neonatal hypoglycaemia was seen in 2 and 3 and Phototherapy was seen in 14 and 22; NICU admission was seen in 8 and 10 subjects in Metformin groups I and II, respectively. Women in the insulin group had neonates with significantly higher mean birth weights compared to the metformin group (3210 g vs. 2960 g, p = 0.004). This finding is consistent with the MiG trial by Rowan et al. (2008), which reported lower birth weights and a reduced incidence of macrosomia in the metformin group.[7] Tertti et al. (2013) found that the increased birth weight and higher risk of macrosomia in insulin-treated women may be due to the anabolic effects of insulin and greater maternal weight gain, which promotes foetal overgrowth.[8] Neonatal hypoglycaemia occurred more often in the insulin group (6.67% vs. 4.44%), though not statistically significant. Insulin therapy is associated with a higher risk of neonatal hypoglycaemia due to foetal hyperinsulinaemia resulting from maternal glucose fluctuations.[17]

In their research, Casey and colleagues discovered that 61,209 nondiabetic women with singleton cephalic pregnancies were delivered in total, and 874 of them were diagnosed with class A1 gestational diabetes. Women classified as having gestational diabetes of class A1 were significantly older, had greater weight and parity, and were more frequently of Hispanic ethnicity. These women exhibited a significant increase in hypertension (17% vs. 12%), caesarean delivery (30% vs. 17%), and shoulder dystocia (3% vs. 1%) compared to the general obstetric population. Infants born to women with class A1 gestational diabetes were significantly larger (mean birth weight 3581 ± 616 versus 3290 ± 546 g, P < .001), and this accounted for the

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increased incidence of dystocia. The attributable risk for large for gestational age (LGA) infants due to class A1 gestational diabetes was 12%.[18]

LIMITATIONS OF THE STUDY

- Small sample size limited the generalizability of the findings.
- Single-centre study.
- Short duration of follow-up; long-term maternal and neonatal outcomes were not assessed.
- Patient adherence to diet and medication was self-reported and may have introduced bias.
- Randomization method not blinded, introducing potential allocation bias.

CONCLUSION

Authors found that the current study demonstrates that metformin is a safe and effective alternative to insulin in the management of gestational diabetes mellitus. Women treated with metformin had significantly lower mean weight gain and a lower incidence of excessive weight gain during pregnancy. Additionally, maternal hypoglycemia and preterm deliveries were more common in the insulin group. While cesarean section rates were slightly higher in the insulin group, the difference was not statistically significant. Neonatal birth weight was significantly higher in the insulin group, with a greater tendency toward macrosomia. Although neonatal hypoglycemia and NICU admissions were more frequent in the insulin group, these differences were not statistically significant. Overall, metformin showed favorable maternal and neonatal outcomes compared to insulin, making it a viable first-line therapy in selected patients with GDM.

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