



Metformin versus Insulin in Gestational Diabetes Mellitus and its Effect on Prevention of Macrosomia in Fetus

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ABSTRACT

Introduction: Since insulin and metformin are the two most commonly used medications for gestational diabetes mellitus in our nation, it is still up for debate which is the safest and causes less fetal issues. Some professional associations, like the American Diabetes Association, still view insulin as the first line of treatment for GDM. The safety of metformin medication for expectant mothers and their fetuses must thus be regularly assessed. This study aims to assess the incidence of macrosomia in gestational diabetes mellitus between insulin and metformin usage. **Materials & Methods:** Total 224 pregnant women aged 16–40 years, with singleton pregnancy and gestational diabetes mellitus were included. Women with uncontrolled blood sugar, pregestational diabetes or overt diabetes, multiple pregnancies, babies with known chromosomal abnormalities or severe congenital defects incompatible with life, fetuses with growth restriction, mothers with comorbid conditions such as severe pre-eclampsia, SLE, chronic hypertension, preterm labor, and premature rupture of membranes were all excluded. Patients in group A received frequent subcutaneous insulin injections, while patients in group B received oral metformin 500 mg tablets. Following then, patients were monitored every two weeks until delivery, at which point macrosomia (yes/no) was recorded. **Results:** Mean age was 27.53 ± 4.31 years. The average age of the women in groups A and B was 27.40 ± 3.99 and 27.60 ± 5.16 years, respectively. Group A and Group B had mean gestational ages of 36.37 ± 1.40 weeks and 35.57 ± 1.38 weeks, respectively. 3.29 ± 1.17 was the mean parity. In this study, macrosomia was observed in 23 (20.54%) women in group A (insulin) and 09 (8.04%) women in group B (metformin), with a p-value of 0.007. **Conclusion:** According to this study, using metformin instead of insulin during gestational diabetes mellitus reduces the frequency of macrosomia.

INTRODUCTION

One known potential pregnancy problem is gestational diabetes mellitus (GDM).¹ Maternal hyperglycemia brought on by uncontrolled GDM can raise the risk of newborn problems, including macrosomia and neonatal hypoglycemia.² Treatment of GDM usually starts with dietary adjustments, home glucose monitoring, increased exercise, and other lifestyle changes to prevent maternal hyperglycemia. However, there are currently no defined best practice standards for the management of GDM if the mother's hyperglycemia continues after two weeks of lifestyle changes.³

With a healthy diet and regular exercise, the majority of women can manage their blood sugar. Otherwise, insulin injection is thought to be the best treatment option for GDM.⁴ However, there are a number of known drawbacks of insulin therapy, including the need for more frequent injections, the chance of hypoglycemia, and the expense, all of which may make patients less compliant.⁵ On the other

hand, oral medications (metformin and glyburide) offer the benefits of simpler administration and reduced expense, making them a desirable substitute for insulin with more acceptability, which improves treatment compliance.⁶ When comparing insulin and metformin in gestational diabetes mellitus, macrosomia was observed in 5.1% and 13.4% of cases, respectively, in a study by Wasim T et al.⁷ When comparing insulin and metformin in maternal diabetes mellitus, macrosomia was observed in 30.8% and 16.7% of cases, respectively, in a different study by Abd El-Aziz EA et al.⁸ A meta-analysis⁹ found that metformin enhanced maternal outcomes and decreased the incidence of macrosomia ($p < 0.00001$; $RR = 0.62$; 95% CI [0.51, 0.76]) and preeclampsia ($p < 0.00001$; $RR = 0.52$; confidence interval (95% CI) [0.40, 0.67]).

Since insulin and metformin are the two most commonly used medications for gestational diabetes mellitus in our nation, it is still up for debate which is the safest and causes less fetal issues. Some professional associations, like the

American Diabetes Association, still view insulin as the first line of treatment for GDM. The safety of metformin medication for expectant mothers and their fetuses must thus be regularly assessed. This study aims to assess the incidence of macrosomia in gestational diabetes mellitus between insulin and metformin usage. Because the number of pregnancies exposed to metformin has been rising globally, this information is very crucial. We can thus give our people a medication with less fetal adverse effects based on these findings. In addition to determining the problem's local scope, this study will contribute to the body of existing literature. Additionally, my study's findings will assist medical professionals in creating a screening and treatment plan for gestational diabetes mellitus, which will enhance outcomes and lower the morbidity and mortality of both the mother and the fetus.

METHODOLOGY

Following ethical review committee approval, pregnant women aged 16–40 years who presented to the Department of Gynecology and Obstetrics at Sughra Shafi Medical Complex, Narowal, from 27 March 2025 to 26 June 2025, with singleton pregnancy (measured on USG) and gestational diabetes mellitus (defined as women with no history of diabetes mellitus and diagnosed during pregnancy and based on at least two out of three abnormally high plasma glucose value measurements in the 75 gm OGTT (fasting >120, 1 hour >180, and 2 hours >160 mg/100 ml) were included. Using the WHO calculator for two proportions with a 5% level of significance, an 80% power of study, and a percentage of macrosomia of 16.7% in the metformin group and 30.8% in the insulin group, the sample size will be determined to be 224, or 112 in each group.⁸ Women with uncontrolled blood sugar, pregestational diabetes or overt diabetes, multiple pregnancies, babies with known chromosomal abnormalities or severe congenital defects incompatible with life, fetuses with growth restriction, mothers with comorbid conditions such as severe pre-eclampsia, SLE, chronic hypertension, preterm labor, and premature rupture of membranes were all excluded.

Every patient gave their informed permission. Following this, a lottery was used to divide all of the patients into groups A and B. Every patient was given the opportunity to select a slip from the total mixed-up slips (half of the slips had the letter "A," and the other half had the letter "B"), and she was assigned to the appropriate group. Patients in group A received frequent subcutaneous insulin injections, while patients in group B received oral metformin 500 mg tablets. Maternal weight was multiplied by 0.7 in the second and 0.8 in the third trimesters to determine the dose of total insulin needed. Three short-acting (Humulin R) doses were administered prior to each meal, and one intermediate-acting (NPH) dose was administered before bed. To attain glycemic control, insulin units were increased in accordance with response. Following then, patients were monitored every two weeks until delivery, at which point macrosomia (yes/no) was recorded in accordance with the operational criteria. All of this information was documented on a proforma that was specifically created.

SPSS version 25.0 was used for statistical analysis. The

data's normality was examined using the Shapiro-Wilk test. Age, gestational age, and BMI were shown as mean and SD or median (IQR). Place of residence (rural/urban), education level (illiterate/primary/middle/matric & above), monthly income (<50000/50001-750000/750000), and macrosomia (yes/no) were all shown with frequency and percentage. The chi square test was used to compare the macrosomia of the two groups, and a p-value of less than 0.05 was deemed significant. Age, gestational age, parity, BMI, place of residence (rural/urban), education level (illiterate/primary/middle/matric & above), monthly income (<50000/50001-750000/>750000), and post-stratification chi square were used to examine their impact on macrosomia. A P-value of less than 0.05 was deemed significant.

RESULTS

Mean age was 27.53 ± 4.31 years. The average age of the women in groups A and B was 27.40 ± 3.99 and 27.60 ± 5.16 years, respectively. Group A and Group B had mean gestational ages of 36.37 ± 1.40 weeks and 35.57 ± 1.38 weeks, respectively. 3.29 ± 1.17 was the mean parity. Table I shows the mean BMI of 28.39 ± 2.71 . Distribution of different variables is shown in Table I.

In this study, macrosomia was observed in 23 (20.54%) women in group A (insulin) and 09 (8.04%) women in group B (metformin), with a p-value of 0.007 (Table II). Table III displays the stratification of macrosomia in relation to effect modifiers.

Table 1

Distribution of Different Variables (n=224)

		Group A (n=112) Group B (n=112)	
		Number (%)	Number (%)
Age (years)	16-30	65 (58.04%)	61 (54.46%)
	31-40	47 (41.96%)	51 (45.54%)
Gestational age (weeks)	24-32	41 (36.61%)	46 (41.07%)
	>32	71 (63.39%)	66 (58.93%)
Parity	≤3	69 (61.61%)	65 (58.04%)
	>3	43 (38.39%)	47 (41.96%)
BMI (kg/m ²)	≤25	52 (46.43%)	50 (44.64%)
	>25	60 (53.57%)	62 (55.36%)
Residence	Rural	54 (48.21%)	52 (46.43%)
	Urban	58 (51.79%)	60 (53.57%)
Monthly income	<50000	35 (31.25%)	32 (28.57%)
	50000-750000	53 (47.32%)	49 (43.75%)
	>75000	24 (21.43%)	31 (27.68%)
Education	Illiterate	25 (22.32%)	22 (19.64%)
	Primary	42 (37.50%)	41 (36.61%)
	Middle	26 (23.21%)	23 (20.54%)
	Matric & above	19 (16.96%)	26 (23.21%)

Table 2

Comparison of macrosomia between both Groups (n=224)

		Group A (n=112)		Group B (n=112)	
		No. of Patients	%age	No. of Patients	%age
Macrosomia	Yes	23	20.54	09	8.04
	No	89	79.46	103	91.96

P value is 0.007 which is statistically significant

Table 3
Stratification of Macrosomia with respect to Effect Modifiers

		Group A (n=112)		Group B (n=112)		P-value
		Efficacy		Efficacy		
		Yes	No	Yes	No	
Age (years)	16-30	11 (16.92%)	54 (83.08%)	05 (8.20%)	56 (91.80%)	0.141
	31-40	12 (25.53%)	35 (74.47%)	04 (7.84%)	47 (92.16%)	0.018
Gestational age (weeks)	24-32	07 (17.07%)	34 (82.93%)	03 (6.52%)	43 (93.48%)	0.124
	>32	16 (22.54%)	55 (77.46%)	06 (9.09%)	60 (90.91%)	0.032
Parity	≤3	10 (14.49%)	59 (85.51%)	05 (7.69%)	60 (92.31%)	0.212
	>3	13 (30.23%)	30 (69.77%)	04 (8.51%)	43 (91.43%)	0.008
BMI (kg/m ²)	≤25	08 (15.38%)	44 (84.62%)	02 (4.0%)	48 (96.0%)	0.053
	>25	15 (25.0%)	45 (75.0%)	07 (11.29%)	55 (88.71%)	0.049
Residence	Rural	12 (22.22%)	42 (77.78%)	03 (5.77%)	49 (94.23%)	0.015
	Urban	11 (18.97%)	47 (81.03%)	06 (10.0%)	54 (90.0%)	0.166
Monthly income	<50000	05 (14.29%)	30 (85.71%)	03 (9.38%)	29 (90.62%)	0.536
	50000-750000	09 (16.98%)	44 (83.02%)	02 (4.08%)	47 (95.92%)	0.036
	>75000	09 (37.50%)	15 (62.50%)	02 (6.45%)	29 (93.55%)	0.004
	Illiterate	04 (16.0%)	21 (84.0%)	02 (9.09%)	20 (90.91%)	0.479
Education	Primary	08 (19.05%)	34 (80.95%)	02 (4.88%)	39 (95.12%)	0.047
	Middle	06 (23.08%)	20 (76.92%)	01 (4.35%)	22 (95.65%)	0.062
	Matric & above	05 (26.32%)	14 (73.68%)	04 (15.38%)	22 (84.62%)	0.365

DISCUSSION

Achieving euglycemia and reducing unfavorable perinatal outcomes is the main objective of treatment for gestational diabetes mellitus (GDM). The percentage of patients who need medication to attain this outcome depends on the diagnostic standards applied. Nonetheless, the percentage of patients who need pharmacotherapy is lower now due to low diagnostic thresholds than in the past, when insulin was the go-to treatment for GDM after dietary and lifestyle changes failed. Insulin sensitizers should have been the best treatment for GDM in theory, but until recently, fetal concerns outweighed their usefulness. Considering that insulin resistance is probably the primary pathogenetic mechanism in GDM, oral hypoglycemic medications are more physiological, affordable, patient-friendly, and may improve compliance.¹⁰ For many years, people with type II diabetes and those with insulin-resistant polycystic ovarian syndrome (PCOS) have been using metformin. Its usage during pregnancy has been restricted, nevertheless.¹¹

The purpose of this study is to examine the incidence of macrosomia in gestational diabetes mellitus between insulin and metformin therapy. The women in groups A and B were, respectively, 27.40 ± 3.99 and 27.60 ± 5.16 years old. The mean gestational ages of Group A and Group B were 36.37 ± 1.40 weeks and 35.57 ± 1.38 weeks, respectively. With a p-value of 0.007, macrosomia was noted in 23 (20.54%) of the women in group A (insulin) and 09 (8.04%) of the women in group B (metformin) of

this study. When comparing insulin and metformin in gestational diabetes mellitus, macrosomia was observed in 5.1% and 13.4% of cases, respectively, in a study by Wasim T et al.⁷ When comparing insulin and metformin in maternal diabetes mellitus, macrosomia was observed in 30.8% and 16.7% of cases, respectively, in a different study by Abd El-Aziz EA et al.⁸

According to research conducted by Hyer et al. and Balani et al., the metformin group's birth weight percentile was significantly lower than that of the insulin group.^{12,13} According to two other investigations, there was no statistically significant difference between the two insulin and metformin groups when taking birth weight and macrosomia into account.^{14,15} According to Koning et al., women with GDM treated with insulin had a comparable risk of problems to those with diet-treated GDM, and both groups experienced greater rates of complications than the normal cohort.¹⁶ Even after adjusting for covariates, Benhalima et al. observed that women with GDM receiving insulin had an increased risk of LGA and C-section.¹⁷

In a pilot investigation, Moore et al.¹¹⁸ evaluated maternal outcomes and newborn features in GDM patients who were randomly assigned to either insulin or metformin. There was no difference between the metformin and insulin groups' mean fasting and 2-hour glucose measurements during therapy. Additionally, there were no differences between the groups in terms of postpartum hemorrhage, shoulder dystocia incidence, or delivery method. Additionally, there was no difference in the newborn outcomes of birth weight, NICU hospitalization, hypoglycemia, respiratory distress syndrome, and hyperbilirubinemia across the groups.¹¹⁸

One more meta-analysis¹⁹ has examined 15 articles with a total of 2509 topics. Birth weight (mean difference 109 g (95% confidence interval 35.9 to 181)), macrosomia (risk ratio 2.62 (1.35 to 5.08)), and newborn hypoglycemia (risk ratio 2.04 (1.30 to 3.20)) were the main outcomes that showed significant differences between glibenclamide and insulin. Maternal weight gain (mean difference -1.14 kg (-2.22 to -0.06)), gestational age at delivery (mean difference -0.16 weeks (-0.30 to -0.02)), preterm birth (risk ratio 1.50 (1.04 to 2.16)), and neonatal hypoglycemia (risk ratio 0.78 (0.60 to 1.01)) were all significant when comparing metformin and insulin. Maternal weight gain (mean difference -2.06 kg (-3.98 to -0.14)), birth weight (mean difference -209 g (-314 to -104)), macrosomia (risk ratio 0.33 (0.13 to 0.81)), and large for gestational age newborn (risk ratio 0.44 (0.21 to 0.92)) were all significant in the metformin vs. glibenclamide comparison.¹⁹

The mean birth weight of neonates did not differ substantially between the insulin and metformin groups, according to a small, randomized trial by Ijas et al.²⁰ There was no difference between the metformin and insulin groups in the incidence of newborn hypoglycemia (P = 0.439), hyperbilirubinemia (P = 0.38), or the need for NICU care (P = 0.37). Due to the small sample population, this study's ability to identify differences in characteristics such brachial plexus injuries, perinatal death, or congenital malformations was limited. These researchers came to the conclusion that while insulin might be necessary in cases involving obese women, high fasting blood glucose levels, and the early need for

pharmacological treatment, metformin might be a safe and effective substitute for insulin in mild GDM cases, particularly those involving lean or moderately overweight women in late gestation.²⁰

Women with GDM who were randomly assigned to either metformin or insulin had superior glycemic control, according to a small, randomized, controlled study by Spaulonci et al.²¹ With less weight gain and no differences in other maternal outcomes including preeclampsia, preterm, or caesarean delivery, the metformin group also had superior maternal and newborn outcomes than the insulin group. newborn outcomes such as gestational age at birth, 1-minute and 5-minute Apgar scores, umbilical artery pH at birth, and birth weight did not differ, while the metformin group had a lower occurrence of newborn hypoglycemia ($P = 0.03$). The sample size was limited, nevertheless, and comparable research with bigger sample sizes might support the findings.²¹

The post-randomization exclusion of women who were unable to maintain glycemia with metformin was a problem in another randomized, controlled trial by Mesdaghinia et al.²² that compared newborn outcomes between women randomized to either insulin or metformin. Therefore, while there were no significant differences between the insulin and metformin groups in terms of birth weight, LGA status, macrosomia, Apgar scores, shoulder dystocia, neonatal hypoglycemia, or sepsis, the insulin group was more likely to experience

neonatal respiratory distress ($P = 0.038$), neonatal jaundice, and hyperbilirubinemia ($P = 0.02$), which may be a result of the study's poor design. Similarly, the poor design might have led to a higher NICU admission rate in the insulin group ($P = 0.002$).²²

Three primary factors may have contributed to the GDM-T group's lower incidence of macrosomia: metformin, minimal gestational weight gain, and possibly an early diagnosis of GDM. When Balani et al. compared 324 GDM women taking metformin with 174 GDM women on diet, they found that the metformin group had a significantly decreased rate of macrosomia.²³

Lack of information on other potential confounders, such as a family history of diabetes, exercise, smoking, corticosteroid usage, self-monitoring blood glucose levels, and the gestational age at which metformin was started, is the primary drawback of this study. One of our study's advantages is that a sizable portion of the women with GDM were treated by the same team.

CONCLUSION

According to this study, using metformin instead of insulin during gestational diabetes mellitus reduces the frequency of macrosomia. Therefore, we recommend utilizing metformin as the first line of treatment for gestational diabetes mellitus in order to reduce the issues of macrosomia as well as the morbidity and mortality of these individuals.

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