**ORIGINAL RESEARCH**

# Comparison between Insulin and Glibenclamide for the Treatment of Gestational Diabetes

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**ABSTRACT**
**Introduction:** Glibenclamide may be an alternate treatment option for individuals with gestational diabetes mellitus in light of these findings and the fact that most pregnant women with the condition have relatively modest hyperglycemia. Therefore, the current study's goal was to assess the safety and effectiveness of glibenclamide versus insulin for treating gestational diabetes mellitus in the Indian population. **Materials & Methods:** The study included 500 female patients who visited the prenatal clinic in total. For the aim of the study, the patients were chosen at random. Indeed, the individuals who were included fell between the gestational age range of 10 to 35 weeks. According to the study's criteria, 70 out of the 500 patients had GDM. Ten of these patients were removed from the study because they did not provide consent to be part of it. Thirty of the sixty patients that remained received insulin therapy, and thirty received Glibenclamide tablets. The treatment regimen was followed, with these ladies being randomly assigned to receive either Glibenclamide or Insulin. **Results:** In both the insulin and glibenclamide groups, the proportion of pregnant women having a negative obstetric history and a positive family history of diabetes was nearly similar. Fasting plasma glucose greater than or equal to 95 mg/dl was present in 24 individuals in the insulin group and 4 participants in the glibenclamide group (fasting hyperglycemia). Random selection was used to treat the screened patients with either glibenclamide or insulin. **Discussion & Conclusion:** When treating GDM, glibenclamide may be a safe and effective substitute for insulin. The tiny sample size means that additional research is required to support this conclusion.

**Keywords:** Comparison, Insulin, Glibenclamide, Gestational Diabetes



## INTRODUCTION

Between 20% and 30% of pregnancies are complicated by diabetes mellitus. GDM accounts for 90% of these cases. Regardless of the use of insulin for therapy, gestational diabetes mellitus is defined as variable-severity glucose intolerance that has its onset or initial detection during pregnancy. Women with gestational diabetes mellitus who experience hyperglycemia are more likely to have unfavourable pregnancy outcomes. Before recently, insulin delivery was the conventional treatment for dietary failures. However, dietary therapy is now the main method to glycaemic control in pregnant women with diabetes. Pharmacological treatment is necessary for between 30 and 40 percent of individuals.[1,2]

Antihyperglycemic medications were avoided during pregnancy due to concerns of foetal abnormalities and hypoglycemia in neonates. This is primarily based on research conducted before to the development of widely used medications like glibenclamide and glipizide. Research has indicated that glibenclamide, unlike metformin and other sulfonylurea medications, does not enter the human placenta in significant amounts. The drawbacks of insulin therapy include injection discomfort, cost, and inconvenience for the patient, all of which may make compliance difficult.[3,4] Glibenclamide may be an alternate treatment option for individuals with gestational diabetes mellitus in light of these findings and the fact that most pregnant women with the condition have relatively modest hyperglycemia.[5] Therefore, the current study's goal was to assess the safety and effectiveness of glibenclamide versus insulin for treating gestational diabetes mellitus in the Indian population.

## MATERIALS & METHODS

The current investigation was conducted in the government medical college and its affiliated hospital over the course of a year. The outpatient department of the medical college collaborated with the gynaecology department to conduct the study. The study was conducted over a full year. Before the study began, the ethical committee was notified about it and the necessary ethical clearance was secured.

The following were the admission and exclusion criteria:

Women who were willing to give birth at RSRM Hospital and had a gestational age between 11 and 33 weeks were included in the criteria.

Women whose gestational ages are less than 11 weeks or more than 33 weeks are excluded. Women unwilling to give birth at RSRM.

The study included 500 female patients who visited the prenatal clinic in total. For the aim of the study, the patients were chosen at random. Indeed, the individuals who were included fell between the gestational age range of 10 to 35 weeks. Before being involved in the study, the patients who were enrolled were given comprehensive information about it in their native tongue, and they completed an informed consent form.

During the initial appointment, the patients received screening advice and were instructed to return for a 75 gramme oral glucose tolerance test following three days of an unrestricted diet. Each patient had two blood samples, each approximately 2 cc in volume, obtained when they were fasting and two hours after a glucose load of 75 g in 200 ml of water. In the lab, these samples were examined using a semi-automated analyzer. If fasting plasma glucose was determined to be more than or equal to 95 mg/dl or if two-hour PPG was more than or equal to 140 mg/dl, the patient was diagnosed with gestational diabetes mellitus.

According to the study's criteria, 70 out of the 500 patients had GDM. Ten of these patients were removed from the study because they did not provide consent to be part of it. Thirty of the sixty patients that remained received insulin therapy, and thirty received Glibenclamide tablets. The treatment regimen was followed, with these ladies being randomly assigned to receive either Glibenclamide or Insulin.

In this study, the incidence of GDM was 14%.

The typical nutritional guidance for three meals and three snacks per day was given to all of the pregnant women who were a part of the study. Each time a patient visited the clinic, their adherence to the prescribed diet was assessed and encouraged. With 40–45% of calories coming from carbohydrates, the diet was intended to give obese women (BMI>27) 25 kcal/kg of body weight and non-obese women (BMI<27) 35 kcal/kg.

Insulin is begun at a lower dose of 6 units in the women who are assigned to get it, and a maximum of 55 units was used in the trial. The dose was modified in accordance with the state of glycosemia. To establish acceptable glycaemic control, the glibenclamide group's oral dosage was gradually increased, with a maximum of 2.5 mg employed in the trial. The beginning dose was 0.625 mg. The patients were told to visit for their glycaemic profile every 15 days.

The goal was to maintain mean plasma glucose at 105 mg/dl assessed at any time of the day, fasting plasma glucose below 90 mg/dl, and postprandial plasma glucose below 120 mg/dl. HbA1c was assessed before therapy began and again after the baby was delivered. The patient receives a thorough general and obstetric examination at every appointment. Age at gestation was calculated using the menstrual history and, if available, the early ultrasound. At 22, 28, 32, and 36 weeks, ultrasounds were conducted to rule out macrosomia. All newborns were assessed by the neonatal staff at delivery. A baby with macrosomia weighs more than or equivalent to 3.5 kg at birth.

If the cord blood insulin level is higher than 20 mIu/ml, it is deemed abnormal. When there was clinical signs of jaundice in infants, serum bilirubin was tested, and phototherapy was administered as needed.

## RESULTS

Patients who met the criteria for inclusion in the study were classified with GDM if their fasting plasma glucose level was greater than or equal to 95 mg/dl or if their glucose level two hours after the test was greater than or equal to 140 mg/dl. Thirty patients received glibenclamide and another thirty were started on insulin medication per the therapy plan.

The groups receiving glibenclamide and insulin had similar demographic profiles. The maximum number of patients in the glibenclamide and insulin groups are in the 20–30 year age range. The maximum number of individuals in the glibenclamide and insulin groups have BMIs between 22 and 27.

In both the insulin and glibenclamide groups, the proportion of pregnant women having a negative obstetric history and a positive family history of diabetes was nearly similar. Fasting plasma glucose greater than or equal to 95 mg/dl was present in 24 individuals in the insulin group and 4 participants in the glibenclamide group (fasting hyperglycemia). Random selection was used to treat the screened patients with either glibenclamide or insulin.

The aim of treatment was to keep fasting plasma glucose below 90 mg / dl and Post Prandial plasma glucose below 120 mg / dl and mean plasma glucose 105 mg / dl measured at any time of the day. Adequate glycaemic control was achieved in both insulin and glibenclamide group. A maximum dose of 2.5 mg of glibenclamide was needed in the study to achieve desired glycaemic level.

The HbA1c readings in both therapy groups were comparable before and after treatment.Because there is less hypoglycemia in GDM, the values were not significant, which suggests that HbA1c may not be

very helpful in treating the condition.The patients were monitored until delivery, and the specifics of the pregnancy outcome were documented.

Both groups' cord blood insulin levels were within the normal range, suggesting that hyperinsulinemia was not present. In the study, there were no instances of congenital abnormalities. Both groups' post-delivery HbA1c values were normal, indicating that their glycaemic management during treatment was good. The insulin and glibenclamide groups had the same incidence of PIH and caesarean deliveries.

All patients had normal postprandial plasma glucose levels and postdelivery fasting.According to the student's t-test, there were no significant differences between the two groups in any of the attributes shown in any of the tables, indicating the similar effectiveness of both medications.

**Table 1: The screening plasma sugar values in both the groups patients**

| | Group 1 (n = 15) | Group II (n = 15) | P value |
|---|---|---|---|
| Fasting plasma glucose | 92.05 ± 19.8 | 72.76 ± 26 | 0.068 |
| 2 hr Post Glucose Plasma Glucose | 173.8 ± 24.2 | 169.6 ± 21.29 | 0.54 |

**Table 2: The Fasting and post prandial plasma glucose before discharge from the hospital.**

| | Group 1 (n = 15) | Group II (n = 15) | P value |
|---|---|---|---|
| Fasting plasma glucose | 69.10 ± 18.4 | 67.45 ± 2.0 | 0.42 |
| 2 hr Post Glucose Plasma Glucose | 96.12 ± 14.20 | 97.36 ± 7.2 | 0.92 |

## DISCUSSION

Any level of glucose intolerance that developed during pregnancy or is identified for the first time is known as gestational diabetes mellitus, or GDM. Approximately 3–6% of pregnancies are affected by it. Even under the best circumstances, there is a 2.5–5 times greater chance of foetal abnormalities and mortality with GDM than with a typical pregnancy.[6,7] GDM is still a major problem for both the mother and the foetus. Women with untreated gestational diabetes have a greater risk of developing some fetal,neonatal, and maternal outcomes. Congenital anomalies, macrosomia, hypoglycemia, respiratory distress syndrome, hypocalcemia, and hyperbilirubinemia are the neonatal consequences of this complication.[8,9]

Although slightly smaller than in the previous study, the age distribution in this one was nonetheless comparable. Our society's tendency towards younger marriageable ages may be the cause of the current study's somewhat smaller age spread. In contrast to the study conducted by a different author, which included a greater number of obese patients in both the insulin (65%) and glibenclamide (70%) groups, the current study included a greater number of non-obese patients with a BMI <27. The authors of the current study and the other author had similar and comparable gestational ages at study entrance.[10,11]

In the current trial, both the glibenclamide and insulin groups achieved adequate glycaemic control, and no patient was transferred to insulin due to inadequate glycaemic control.In both trials, cord blood insulin was within normal limits, suggesting that hyperinsulinemia was not present.In the current study, the incidence of preeclampsia was 5.4% in the glibenclamide group and 11.9% in the insulin group; in both groups, the preeclampsia incidence was 8%.In the current study, the rate of caesarean sections was 61.2% for the insulin group and 61.8% for the glibenclamide group.

## CONCLUSION

When treating GDM, glibenclamide may be a safe and effective substitute for insulin. The tiny sample size means that additional research is required to support this conclusion.

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