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# Comparison of insulin and glibenclamide in gestational diabetes mellitus

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**Abstract**
**Background:** Gestational diabetes mellitus (GDM) is one of the common medical conditions that make pregnancy complicated. Pregnancy causes incremental improvements to the metabolism of the maternal carbohydrate to satisfy the increasing demands of the fetus and her mother. The progress of the pregnancy leads to a rise in insulin secretion as insulin tolerance and diabetic stress are attributed to hormones such as human placental lactogen (HPL). When this compensation results in insufficient gestational diabetes mellitus.
**Objectives:** To assess the efficacy and safety of treating gestational diabetes mellitus with Glibenclamide in comparison to Insulin.
**Methods:** A randomized study was performed on 100 GDM patients, split into two groups of 50 each. Insulin was administered for one group and glibenclamide therapy for another and their health condition and results were compared after treatment. All antenatal patients, except those with pre-existing diabetes, were tested for GDM. Each patient was advised of 75 g OGTT at her first antenatal appointment, according to institutional protocol.
**Results:** In both groups, post-delivery HbA1c was normal suggesting strong glycaemic function. The insulin and glibenclamide group demonstrated an equal incidence of PIH and cesarean delivery. In all the patients, post-delivery fasting and post-prandial plasma glucose were normal. In any of the characteristics represented by student t in each table, there were no major variations between the two groups, which meant that both medicines were relatively effective.
**Conclusion:** Because of its broad protein binding characteristics, short half-life, glibenclamide does not cross the placenta and functions as a substratum and inhibition for P-glycoprotein. Therefore, glibenclamide may be a safe and reliable alternative to Insulin therapy in GDM care.

**Keywords:** Gestational diabetes mellitus, GDM, glibenclamide, insulin, HPL

## Introduction
Gestational diabetes mellitus (GDM) is one of the common medical conditions that make pregnancy complicated. [1] Pregnancy causes incremental improvements to the metabolism of the maternal carbohydrate to satisfy the increasing demands of the foetus and her mother. [2] The progress of the pregnancy leads to a rise in insulin secretion as insulin tolerance and diabetic stress are attributed to hormones such as human placental lactogen (HPL). When this compensation results in insufficient gestational diabetes mellitus. [3]
Gestational diabetes mellitus is characterized as intolerance to carbohydrates. Extreme variable onset or first recognition during breastfeeding, when insulin is or is not used for treatment. [4] In women with gestational diabetes mellitus, hyperglycemia is associated with adverse effects of pregnancy. Diabetes treatment and insulin administration have until recently been the primary solution to glycaemic regulation in pregnant women with diabetes. During breastfeeding, antihyperglycemic has not been used due to fear of neonatal and maternal hypoglycemia. This is primarily focused on research on the availability of today widely used medicines like glibenclamide and glipizide. [5]
In hyperglycemia screening pregnant women, insulin was the preferred therapeutic agent. However, difficulties with the delivery of pharmaceutical drugs with several regular doses, hypoglycaemic ability, and rise of appetite and weight render this treatment alternative cumbersome for several patients pregnant. Increased use of oral diabetic agents such as metformin and glibenclamide has begun to shift normal focus though insulin remains the standard gold treatment for the regulation of maternal glycemia. [6]
Studies have shown that, compared to older sulfonylurea and metformin, glibenclamide does not

cross the human placenta in appreciable concentrations. The drawbacks of insulin therapy include patient pain, injection discomfort, and cost, which can compromise compliance. [7]

## Materials and Methods

A randomised study was performed in 100 GDM patients, split into two groups of 50 each. Insulin was administered for one group and glibenclamide therapy for another and their health condition and results were compared after treatment. All antenatal patients, except those with pre-existing diabetes, were tested for GDM. Each patient was advised of 75 g OGTT at her first antenatal appointment, according to institutional protocol.

### Inclusion Criteria

- Women with gestational age between 11-33 weeks and
- Who were willing to deliver at the hospital

### Exclusion Criteria

- Women with gestational age less than 11 weeks and more than 33 weeks.
- Women not willing to have their delivery at Dr. Patnam Mahender Reddy Institute of medical sciences.

## Observation and Results

**Table 1:** Distribution based on various characteristics

| | Group-I (Insulin) (N=50) | Group-II (Glibenclamide) (N=150) |
|---|---|---|
| Age | 26.78 ± 4.7 | 24.5 ± 3.5 |
| BMI | 25.3 ± 4.5 | 21.9 ± 3.55 |
| Pre-pregnancy weight | 59.5 ± 11.5 | 50.0 ± 11.0 |
| GA at entry into study | 24.5 ± 5.25 | 23.3 ± 8.45 |
| Bad Obesity History | 17 (34%) | 21 (42 %) |
| Positive family history | 21 (42%) | 17 (34 %) |
| Gravidity | | |
| Primi | 27 (54%) | 27 (54%) |
| Multi | 23 (46%) | 23 (46%) |

The majority of the patients belonged to the age group of 20 to 30 yrs. The maximum number of patients in both the Insulin and glibenclamide group had BMI in the range of 22 to 27. Primi and multi gravida were distributed equally in both insulin and a group of glibenclamides. In both insulin and glibenclamide groups, there was an almost equal distribution of antenatal women with bad obstetric history and positive family history.

**Table 2:** Screening Plasma Glucose levels before treatment and during treatment

| | Group-I (Insulin) (N=50) | Group-II (Glibenclamide) (N=50) | P-Value |
|---|---|---|---|
| **Pre-Treatment** | | | |
| Fasting Plasma Glucose | 91.00 ± 21.9 | 75.75 ± 22 | 0.072 |
| 2 hrs. Post Prandial Plasma Glucose | 178.0 ± 28.5 | 173.5 ± 25.33 | 0.65 |
| **Post – Treatment** | | | |
| Fasting Plasma Glucose | 68.55 ± 13.3 | 62.30 ± 6.9 | 0.96 |
| 2 hrs. Post Prandial Plasma Glucose | 98.5 ± 10.0 | 96.0 ± 6.0 | 0.44 |

The mean fasting plasma glucose level in pre-treatment in the Insulin group was 91+21.9 and during treatment was 68.55 ± 13.3 and in the glibenclamide group, the mean fasting plasma glucose level was 75.75+22 and during the treatment, it was 62.30 ± 6.9. The p-value was statistically significant.

The mean 2 hrs Postprandial plasma glucose level during pre-treatment in the Insulin group was 178.0 ± 28.5 and during treatment was 98.5 ± 10.0. In the glibenclamide group, the mean 2 hrs Postprandial plasma glucose level during pre-treatment was 173.5 ± 25.33 and during treatment, it was 96.0 ± 6.0.

**Table 3:** Comparison of HbA1c pre- and post-treatment

| | Group-I (Insulin) (N=50) | Group-II (Glibenclamide) (N=50) | P-Value |
|---|---|---|---|
| Pre – Treatment HbA1c | 5.4 ± 0.90 | 5.0 ± 0.45 | 0.45 |
| Post Treatment HbA1c | 5.5 ± 0.55 | 5.40 ± 0.30 | 0.60 |

The HbA1c values were both identical in the treatment groups. The values of both pre- and post-treatment HbA1c were not significant and suggest that HbA1c may not be particularly effective in GDM because of the decreased level of GDM hypoglycemia.

**Table 4:** Neonatal Outcomes

| | Group-I (Insulin) (N = 50) | Group-II (Glibenclamide) (N = 50) | P-Value |
|---|---|---|---|
| Birth weight | 2.90 ± 0.46 | 2.55 ± 0.85 | 0.23 |
| New born Plasma Glucose | 72.85 ± 28.5 | 69.0 ± 14.40 | 0.78 |
| Cord Blood Insulin | 5.25 ± 2.5 | 4.85 ± 4.7 | 0.89 |
| NICU Admission for phototherapy | 10(20%) | 4(8%) | - |

In both groups, the pregnancy outcome was identical. In neither group of babies, hypoglycemia was observed. Ten neonates in insulin and four neonates in the glibenclamide group needed therapeutic jaundice phototherapy for 1-2 days. In all groups, cord blood insulin was normal, suggesting that there was no hyperinsulinemia. No congenital abnormalities were reported in the study.

**Table 5:** Maternal Outcomes

| | Group-I (Insulin) (N = 50) | Group-II (Glibenclamide) (N = 50) |
|---|---|---|
| PIH | 7 (14%) | 4 (8%) |
| Polyhydraminos | Nil | Nil |
| Retinopathy | Nil | Nil |
| Caesarean Deliveries | 33 (66%) | 34 (68%) |

In both groups, post-delivery HbA1c was normal suggesting strong glycaemic function. The insulin and glibenclamide group demonstrated an equal incidence of PIH and cesarean delivery.

**Table 6:** FPG and PPPG before discharge

| | Group-I (Insulin) | Group-II (Glibenclamide) | P-Value |
|---|---|---|---|
| Fasting Plasma Glucose | 68.09 ± 17.0 | 66.30 ± 6.9 | 0.53 |
| 2 hr Post Prandial Plasma Glucose | 95.45 ± 10.95 | 95.7 ± 6.0 | 0.89 |

In all the patients, post-delivery fasting and post-prandial plasma glucose were normal. In any of the characteristics represented by student t in each table, there were no major variations between the two groups, which meant that both medicines were relatively effective.

## Discussion

Pregnancy is a period of elevated tolerance to insulin due to significant hormone changes. Gestational diabetes is caused by a lack of insulin secrecy in order to combat insulin resistance, frequently related to aged and overweight age, and complex history of prior obstetrics. The good care of these patients includes early diagnosis, sufficient treatment, and follow-up. [8]

In this study, the potency of glibenclamide over insulin was examined, the maternal and fetal outcome was analyzed for treatment with GDM, the failure rate was measured and the compliance and comfort level and costs of the treatment were calculated. This study sought to detect insulin efficacy. The findings were analyzed.

In our study, the age range is marginally lower but identical to Langer *et al*. The age range in the present sample is marginally lower due to the younger age of marriage. In this study, more patients were non-obese with BMI <27 when compared with Langer *et al*, in which the study included more obese patients, both in insulin (65%) and glibenclamide (70%). In the present sample and in the Langer *et al* study the gestational age is identical and comparable. [9]

In both insulin and glibenclamide groups, in this study, sufficient glycaemic control was obtained and no patient was introduced to insulin with poor control. Other patients with a maximum dose of glibenclamides (20 mg) in the Langer *et al* sample were substituted by insulin due to bad glycaemic regulation and maintained strong glycaemic control in most of the patients (4%). In both the current study and Langer *et al* study, pre-pregnant HbA1c is identical and is in the normal range. There has not been a case of stillbirth or neonatal death compared with that of Langer *et al*, where each insulin and glibenclamide group has experienced one case of stillbirth and neonatal death. [9]

Few studies have been carried out using glibenclamide in GDM and therefore less information about its effectiveness is known. More research is still required in clinical practice before it is used. [10]

## Conclusion

Maternal hyperglycemia is transferred to the fetus, which is more harmful to the fetus than the opioid impact in the treatment of GDM. GDM is a consequence of fetal hyperglycemia. In addition, because of its broad protein binding characteristics, short half-life, glibenclamide does not cross the placenta and functions as a substratum and inhibition for P-glycoprotein. Therefore, glibenclamide may be a safe and reliable alternative to Insulin therapy in GDM care.

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