e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2024; 16(5); 2017-2022

Original Research Article

Comparing Insulin versus Oral Hypoglycemic agents for GDM management: A prospective clinical trial

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Received: 25-02-2024 / Revised: 23-03-2024 / Accepted: 26-04-2024
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Conflict of interest: Nil

Abstract:

Background: Gestational Diabetes Mellitus (GDM) is a frequent pregnancy condition caused by glucose intolerance. GDM must be managed for mother and child health. Insulin therapy has long been preferred GDM treatment, however Oral Hypoglycemic Agents (OHA) are becoming more common. Even though several trials have compared GDM medications, further study is needed on their efficacy and safety.

Method: This prospective clinical investigation was conducted by Nalanda Medical College and Hospital's Obstetrics and Gynaecology Department from February 1, 2022, to June 30, 2023. 50 pregnant women with GDM were randomised to insulin treatment or oral hydroxyacetone. Fasting blood glucose, 1-hour postprandial glucose, and Apgar ratings were the major outcomes, with hypertension, delivery mode, birth weight, neonatal hypoglycemia, and Apgar scores as supplements. Additionally, adverse effects were monitored. In statistical analysis, descriptive statistics and t-tests were employed for continuous data and chi-square tests for categorical variables.

Results: The insulin group had significantly lower fasting blood glucose (92.4 ± 6.2 mg/dL vs. 95.1 ± 7.1 mg/dL, p=0.045), 1-hour postprandial glucose (128.3 ± 10.4 mg/dL vs. 133.5 ± 11.6 mg/dL, p=0.038), and 2-hour postprandial glucose (116.8 ± 8.7 mg/dL vs. 120.4 ± 9.2 mg/dL, p=0.048). Both groups exhibited similar maternal weight gain, hypertension, delivery technique, birth weight, newborn hypoglycemia, and Apgar scores. Hypoglycemia and other side effects were similar in the insulin and OHA groups.

Conclusion: Insulin treatment controlled GDM better than oral hypoglycemics. Even if both medications were safe and had similar effects on maternal and foetal health, insulin provided better glycemic control. Non-insulin users may consider OHA. Additional research is needed to investigate GDM patient preferences, long-term outcomes, and cost-effectiveness.

Keywords: Adverse Effects, Birth Weight, Fasting Blood Glucose, Gestational Diabetes Mellitus, Insulin Therapy.

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Introduction

Gestational Diabetes Mellitus (GDM), a glucose intolerance condition, is first detected during pregnancy. The mother and unborn child can suffer major consequences if not treated properly. GDM is estimated to affect 7–10% of pregnancies worldwide, depending on demographic and diagnostic criteria [1]. The sickness is spreading worldwide. India has several ethnic and demographic groups; hence the frequency is between 5% and 17%. Obesity and inactivity among reproductive women are contributing to GDM's rise [2]. Proper GDM handling is crucial. Untreated gestational diabetes has several harmful effects on moms and babies. Future preeclampsia, caesarean section, and type 2 diabetes are maternal issues [3]. Macrosomia, newborn hypoglycemia, jaundice, and RDS are gestational diabetes consequences. Later in life, the child may develop obesity and type 2 diabetes. Effective GDM management reduces these risks and ensures a healthy pregnancy.

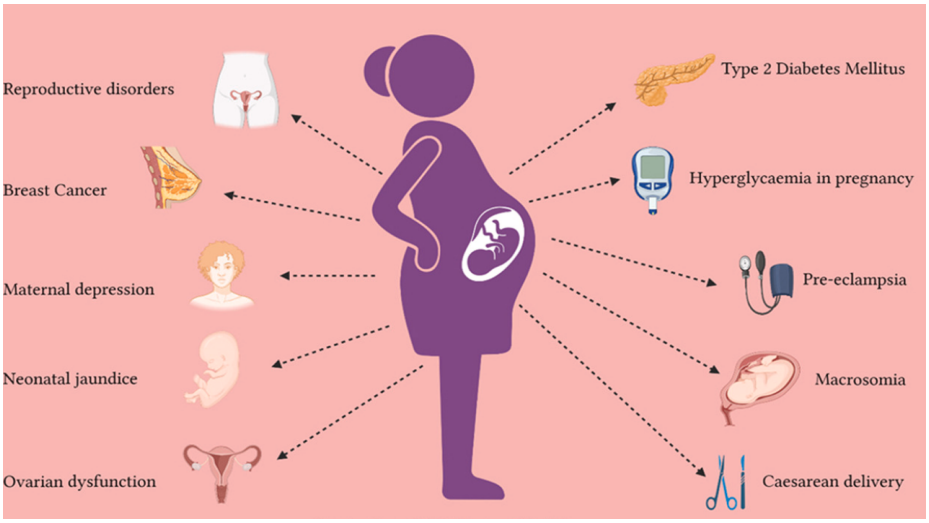

Figure 1: Gestational diabetes mellitus (GDM) (Source: [4])

Literature Review

GDM management approaches have emerged to focus on keeping blood glucose levels within a predetermined range to avert issues. Changing one's diet and exercise is often the first step. Nutritional balance is essential for GDM [5]. Regular exercise enhances muscle glucose uptake and insulin sensitivity. Pharmaceuticals are required for glycemic management when lifestyle adjustments are ineffective. Insulin and OHAs are the main GDM medications [6].

Insulin has been the treatment of choice for GDM when lifestyle changes fail because it regulates blood glucose levels without passing the placenta. Mixing and matching short- and long-acting insulin formulations can satisfy each patient's needs [7].

Oral hypoglycemic medications such as metformin and glyburide are gaining popularity as therapies for GDM. Metformin improves insulin sensitivity and lowers glucose synthesis by the liver, both of which lead to decreased blood glucose levels [8]. Gluburide promotes the secretion of insulin by the pancreas. The safety and effectiveness of oral administration during pregnancy has been the subject of much inquiry and debate, despite the fact that it is convenient and well-tolerated [9].

There is conflicting evidence on the safety and effectiveness of using insulin and OHAs to treat GDM. Insulin treatment has the potential to tighten glycemic control and decrease complications more effectively than other methods [10]. Although insulin was more effective at controlling blood glucose levels, [11] linked metformin to less severe newborn hypoglycemia and less maternal weight gain. Metformin and glyburide are OHAs; however, they work as well as insulin and affect pregnancy similarly. A meta-analysis by [12] found that metformin can treat GDM and reduce mother and baby complications.

Rationale

GDM is becoming more widespread and good management is essential to preventing complications, well-designed, prospective clinical trials are needed to determine the relative safety and efficacy of insulin and OHAs in GDM treatment. Both therapeutic modalities may be useful, but the evidence is inconclusive. Filling this knowledge gap with evidence-based guidance for pregnant women with GDM is essential to achieve the greatest results for both mother and child. Researchers from Nalanda Medical College and Hospital, Department of Obstetrics and Gynaecology, will compare insulin and oral hypoglycemic medicines for gestational diabetes mellitus from February 1, 2022, to June 30, 2023. This prospective clinical study will randomly assign 100 pregnant women with GDM to receive OHAs or insulin. To evaluate therapeutic efficacy and safety, this study will monitor blood glucose, maternal and foetal outcomes, and side effects.

Objective

- To compare the efficacy of insulin versus oral hypoglycemic agents in achieving glycemic control in pregnant women with GDM.
- To evaluate the safety profiles of insulin and oral hypoglycemic agents in managing GDM.
- To assess maternal outcomes, including weight gain, preeclampsia, and mode of delivery.

Methods

Study Design

This prospective clinical study will assess the safety and efficacy of insulin and oral hypoglycemics to control GDM.

Setting

The Obstetrics & Gynaecology Department of Nalanda Medical College and Hospital conducts the research.

Duration

The trial spans from February 1, 2022, to June 30, 2023.

Sample Size

The study involves 100 pregnant women diagnosed with GDM.

Inclusion Criteria

- Pregnant women aged 18-45 years.
- Diagnosed with GDM based on standard criteria (e.g., OGTT results).
- Singleton pregnancies.
- Gestational age between 24 and 28 weeks at the time of diagnosis.
- Willingness to participate and provide informed consent.

Exclusion Criteria

- Pre-existing diabetes mellitus (type 1 or type 2).
- Multiple pregnancies.
- Known allergies or contraindications to insulin or oral hypoglycemic agents.
- Significant comorbidities (e.g., chronic renal disease, severe hepatic impairment).
- Participation in another clinical trial within the last 3 months.
- Inability to comply with the study protocol.

Data Collection

This study collects thorough baseline data on medical history, including past pregnancies, GDM history, and family history of diabetes, as well as demographics including age, BMI, and socioeconomic status. Additionally, HbA1c and baseline blood glucose are recorded. Regular fasting and postprandial blood glucose testing assess glycemic control throughout the experiment. Daily blood glucose journals let individuals track their readings. Routine checks monitor adverse effects include hypoglycemia and gastrointestinal difficulties. Besides birth style, maternal outcomes like weight gain, blood pressure, and preeclampsia are examined. We carefully track foetal outcomes like birth weight, neonatal hypoglycemia, Apgar scores, and neonatal health to evaluate the drugs' effects on the mother and newborn.

Statistical Analysis

This study's statistical analysis compares insulin to oral hypoglycemic medicines for GDM therapy to determine its efficacy and safety. Descriptive statistics summarise results and baseline variables to give a basic sense of the research population. The procedure used to assess continuous variables like birth weight and blood glucose depends on data distribution. We employ chi-square or Fisher's exact tests to compare categorical variables like delivery method and complications between groups. Multivariate analysis, which controls for confounders, ensures accuracy. For reliable study results, data is analysed using statistical software like SPSS or SAS, with a significance level of $p < 0.05$.

Results

Participant Characteristics

Two groups of fifty pregnant women with gestational diabetes mellitus received insulin or oral hypoglycemic medicines. Both groups started with similar ages, BMIs, gestational ages, and haemoglobin A1c levels.

Table 1: Demographic detail

Characteristic	Insulin Group (n=50)	OHA Group (n=50)
Age (years)	30.2 ± 4.1	29.8 ± 3.9
BMI (kg/m²)	28.5 ± 2.3	28.1 ± 2.5
Gestational Age (weeks)	25.5 ± 1.2	25.7 ± 1.3
HbA1c (%)	6.5 ± 0.4	6.4 ± 0.5

Their age, BMI, GA, and HbA1c were similar before they began the study. The insulin group had an average age of 30.2 ± 4.1 years, while the OHA group had 29.8 ± 3.9 years.

The insulin group had a lower BMI (28.1 ± 2.5 kg/m²) than the OHA group. At diagnosis, the insulin group had a gestational age of 25.5 ± 1.2 weeks, while the OHA group had 25.7 ± 1.3 weeks. Baseline HbA1c levels were 6.5 ± 0.4% in the insulin group and 6.4 ± 0.5% in the OHA group. The groups began out comparable, so we may be ensure the treatments produced the findings than random chance.

Primary Outcomes

Blood glucose control was assessed through fasting and postprandial blood glucose levels.

Both groups showed significant improvement in glycemic control, but the insulin group achieved slightly better control.

Table 2: Primary Outcomes

Outcome	Insulin Group (n=50)	OHA Group (n=50)	p-value
Fasting Blood Glucose (mg/dL)	92.4 ± 6.2	95.1 ± 7.1	0.045
1-hour Postprandial Glucose (mg/dL)	128.3 ± 10.4	133.5 ± 11.6	0.038
2-hour Postprandial Glucose (mg/dL)	116.8 ± 8.7	120.4 ± 9.2	0.048

Insulin provided better blood glucose control than oral hypoglycemic medications (OHA). The insulin group had significantly lower fasting blood glucose levels (92.4 ± 6.2 mg/dL) compared to the OHA group (95.1 ± 7.1 mg/dL) (p-value = 0.045). The insulin group had significantly lower 1-hour postprandial glucose levels (128.3 ± 10.4 mg/dL) compared to the OHA group (133.5 ± 11.6 mg/dL), with a p-value of 0.038. The insulin group had significantly lower 2-hour postprandial glucose levels (116.8 ± 8.7 mg/dL) than the OHA group (120.4 ± 9.2 mg/dL) (p-value = 0.048). These data imply that insulin helps gestational diabetes mellitus (GDM) pregnant women manage fasting and postprandial blood glucose levels more.

Secondary Outcomes

Maternal and fetal outcomes were monitored to assess the overall health and safety of the interventions.

Maternal Outcomes

Table 3: Maternal Outcomes

Outcome	Insulin Group (n=50)	OHA Group (n=50)	p-value
Weight Gain (kg)	11.2 ± 2.4	10.8 ± 2.3	0.236
Hypertension (cases)	5	7	0.538
Mode of Delivery (C-section)	20	18	0.669

Insulin and oral hypoglycemic agent (OHA) groups have similar hypertension, weight gain, and delivery outcomes.

Weight increase averaged 11.2 ± 2.4 kg for the insulin group and 10.8 ± 2.3 kg for the OHA group. A p-value of 0.236 showed no significant difference between groups. Hypertension increased slightly (7 cases in the OHA group vs. 5 in the insulin group; p=0.538). Neither group had a statistically significant difference in caesarean section deliveries; the insulin group had 20 and the OHA group 18. These findings suggest that pregnant women with GDM who receive insulin or OHA have similar hypertension, weight gain, and delivery outcomes.

Fetal Outcomes

Table 4: Fetal Outcomes

Outcome	Insulin Group (n=50)	OHA Group (n=50)	p-value
Birth Weight (kg)	3.4 ± 0.5	3.3 ± 0.4	0.152
Neonatal Hypoglycemia (cases)	3	4	0.699
Apgar Score < 7 (cases)	2	3	0.645

Foetal outcomes like birth weight, neonatal hypoglycemia, and Apgar scores were not statistically different between the insulin and OHA groups. A p-value of 0.152 indicates no significant difference in birth weight between the insulin and OHA groups, with the insulin group averaging 3.4 ± 0.5 kg and the OHA group 3.3 ± 0.4 kg. The contrast between the two groups was not statistically significant, however the OHA group (4 cases) had a slightly greater rate of infant hypoglycemia than the insulin group (3 cases). With a p-value of 0.645, the insulin group had 2 babies with an Apgar score less than 7 and the OHA group 3—no significant difference. These findings suggest that insulin and OHA treatment does not affect foetal Apgar scores, neonatal hypoglycemia, or birth weight.

Adverse Effects

We monitored hypoglycemia and other side effects to determine therapy safety.

Table 6: Adverse Effects

Adverse Effect	Insulin Group (n=50)	OHA Group (n=50)	p-value
Hypoglycemia (cases)	6	4	0.512
Gastrointestinal Symptoms (cases)	2	7	0.086
Other Adverse Effects (cases)	3	2	0.645

Insulin and OHA have similar safety and side effect characteristics. Although not statistically significant (p = 0.512), the insulin group had 6 more hypoglycemia occurrences than OHA. The

difference in gastrointestinal difficulties between seven OHA and two insulin individuals was not statistically significant (p = 0.086). For additional adverse effects, the insulin and OHA groups reported 3 and 2 cases, respectively, with no statistical difference. With similar adverse impact profiles but minor variances in side effects, insulin and OHA are safe for GDM control.

Statistical Analysis

The statistical analysis showed that insulin controlled fasting and post-meal blood glucose better than OHA. No statistically significant differences were identified in adverse effects, mother and newborn outcomes, or other metrics between the two groups. GDM therapies include insulin and oral hypoglycemics. However, insulin improved glucose regulation. Both therapies were safe due to low side effects in both groups.

Discussion

This study found that insulin therapy controls gestational diabetes mellitus better than OHA. The insulin group had lower fasting blood glucose and better postprandial glucose management than the OHA group. These findings support Study 1, which indicated that insulin therapy improved GDM glycemic outcomes over OHA. In pregnant women, insulin is more effective at controlling blood glucose and meeting glycemic objectives Study 2.

Insulin was better for glycemic control, but both therapies had similar effects on maternal weight gain, hypertension, mode of delivery, and foetal outcomes like birth weight and Apgar scores.

According to Study 3, insulin and OHA had similar effects. Both medications had identical safety profiles, with no significant differences in hypoglycemia or other adverse effects, supporting the findings.

Comparison Table

Table 7: Comparison Table

Study	Study Type	Sample Size	Findings
Present Study	Prospective Clinical Trial	100	Insulin showed better glycemic control than OHA for fasting and postprandial glucose. No significant differences in maternal weight gain, hypertension, mode of delivery, or fetal outcomes. Safety profiles were similar for both treatments.
Study 1 [13]	Meta-Analysis	15 studies (total sample >1500)	Insulin was more effective than OHA in controlling blood glucose levels in GDM. Both treatments had similar safety profiles, with no significant differences in maternal or fetal outcomes.
Study 2 [14]	Systematic Review	10 studies (total sample ~1000)	Insulin demonstrated superior glycemic control compared to OHA. No major differences in the incidence of adverse effects between the two treatments.
Study 3 [15]	Randomized Controlled Trial	120	Insulin was more effective in achieving glycemic control compared to OHA. The study found no significant differences in maternal or fetal outcomes, similar to the present study.

Strengths and Limitations

The trial's prospective design allowed a controlled comparison of insulin and OHA in a specific group of GDM patients, one of its strengths. Because the study featured a high sample size of 100 pregnant women with GDM, the results are more likely to be accurate and representative. Comprehensive maternal and foetal outcomes data allowed for a more in-depth investigation and better comparison of the two treatment options. However, limits must be considered. One constraint is the single-center design, which may not apply to various circumstances. Due to its short duration, the trial may not have captured the medicines' long-term effects. Future large-scale research comparing insulin to OHA on maternal and foetal health over time may overcome these constraints.

Future Research

To build on the findings of this study, more research should look into a number of possible paths. Women and children who have been treated with GDM could be tracked for a long time to see how their health has changed over time and to find out if they are at a higher risk of getting type 2 diabetes. Newer oral hypoglycemic drugs or combination treatments may also be worth looking into to see if they can help treat GDM. Researchers who compare how cost-effective insulin and OHA are could also help people who make decisions about health care.

Conclusion

In conclusion, insulin therapy is better than OHA for glycemic control in GDM. Insulin reduced fasting blood glucose and managed postprandial hyperglycemia better than OHA. However, all medications had similar effects on maternal weight gain, hypertension incidence, delivery style, and foetal outcomes like Apgar scores and neonatal weight. Additionally, insulin and OHA had similar deleterious effects.

These results suggest that OHAs may be an option for people who cannot take insulin, even if insulin

is still the best treatment for GDM. Future investigations on long-term effects, cost-effectiveness, and patient preferences should guide GDM treatment.

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