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COMPARISON OF CLINICAL OUTCOMES OF SITAGLIPTIN AND GLICLAZIDE IN THE MANAGEMENT OF UNCOMPLICATED TYPE 2 DIABETES MELLITUS

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ABSTRACT: This study evaluated and compared the efficacy and safety of sitagliptin and gliclazide in patients with uncomplicated type 2 diabetes mellitus. A total of 291 patients were assigned to two treatment groups receiving either sitagliptin or gliclazide. Glycemic parameters, including fasting blood glucose, postprandial blood glucose, and glycated hemoglobin levels, were assessed over a period of six months. Adverse effects, particularly episodes of hypoglycemia, were also monitored to evaluate safety. Both treatment groups showed significant improvement in glycemic control over time. However, gliclazide demonstrated a more consistent and greater reduction in fasting and postprandial blood glucose levels. A statistically significant reduction in glycated hemoglobin was observed in the gliclazide group, whereas the reduction in the sitagliptin group did not reach statistical significance. In terms of safety, gliclazide was associated with a higher incidence of hypoglycemic episodes. Sitagliptin, although producing relatively modest improvements in glycemic parameters, exhibited a more favorable safety profile with fewer hypoglycemic events. In conclusion, gliclazide provides superior glycemic control in patients with uncomplicated type 2 diabetes mellitus, while sitagliptin may be preferred in patients where avoidance of hypoglycemia is a major concern. These findings highlight the importance of individualized therapy based on efficacy and safety considerations.

INTRODUCTION: Diabetes mellitus (DM) is a chronic metabolic disorder characterized by impaired insulin secretion, defective insulin action, or a combination of both, leading to persistent hyperglycemia [1-4]. It is associated with disturbances in carbohydrate, fat, and protein metabolism, and over time contributes to significant microvascular and macrovascular complications affecting the eyes, kidneys, nerves, and cardiovascular system.

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The global prevalence of diabetes has increased dramatically over the past few decades, making it a major public health concern. In India, the burden of diabetes is particularly alarming. The number of affected individuals was estimated to be approximately 32 million in the year 2000, and this figure is projected to rise to nearly 80 million by 2030 [5].

Rapid urbanization, sedentary lifestyle, dietary transitions, and genetic predisposition have all contributed to this increase. According to the World Health Organization (WHO), the global prevalence of diabetes is expected to exceed 200 million cases, with projections reaching approximately 300 million by 2025 [6-8]. These trends highlight the urgent need for effective and

sustainable therapeutic strategies. Despite the availability of multiple pharmacological agents, maintaining long-term glycemic control remains challenging. Progressive β-cell dysfunction, insulin resistance, and poor adherence to therapy often lead to deterioration of glycemic control over time [9]. The primary goal of diabetes management is to achieve and maintain optimal glycemic levels to prevent or delay complications, while minimizing adverse effects, particularly hypoglycemia [10].

Among oral antidiabetic drugs, sulfonylureas such as gliclazide have been widely used due to their efficacy in stimulating insulin secretion from pancreatic β-cells. Gliclazide is known for its relatively lower risk of hypoglycemia compared to older sulfonylureas and has additional benefits such as antioxidant properties. On the other hand, sitagliptin, a dipeptidyl peptidase-IV (DPP-4) inhibitor, represents a newer class of antidiabetic agents that enhance incretin hormone activity, thereby improving glucose-dependent insulin secretion and suppressing glucagon release [11, 12].

Given the differences in mechanism of action, efficacy, and safety profiles between these two agents, it is important to compare their clinical outcomes when used as monotherapy. Therefore, the present study was undertaken to evaluate and compare the effectiveness and safety of sitagliptin and gliclazide in patients with uncomplicated type 2 diabetes mellitus.

MATERIALS AND METHODS: The present study was conducted in the Department of Pharmacology at Geetanjali Medical College & Hospital and other tertiary care centers. Patients diagnosed with uncomplicated type 2 diabetes mellitus were recruited based on clinical evaluation, detailed medical history, and laboratory confirmation of elevated blood glucose levels. Patients aged between 18 and 70 years were included in the study to ensure representation of the adult diabetic population. Exclusion criteria included patients with type 1 diabetes mellitus (IDDM), pregnant or lactating women, individuals with hepatic or renal impairment, and those with known hypersensitivity to the study drugs. These criteria were applied to minimize confounding factors and ensure patient safety. Prior to enrollment, all participants provided written informed consent. Ethical approval for the study was obtained from the Institutional Ethics Committee (IEC), and the study was conducted in accordance with ethical principles outlined in the Declaration of Helsinki.

Study Design: This study was designed as a prospective, open-label, observational cohort study. A total of 291 patients with type 2 diabetes mellitus were enrolled and randomly assigned into two treatment groups:

- Group A received sitagliptin (100 mg once daily)
- Group B received gliclazide (30 mg once daily)

Baseline blood glucose levels were recorded one day prior to initiation of therapy. Patients were reviewed 10 days after starting treatment, and this time point was considered as the baseline (zero month) for subsequent follow-ups. Patients were then monitored monthly for a period of six months.

Glycemic parameters assessed included fasting blood glucose (before breakfast) and postprandial blood glucose levels. HbA1c levels were measured at baseline, three months, and six months to assess long-term glycemic control. Any dose adjustments and treatment-related adverse effects were carefully documented throughout the study.

Blood glucose estimation was also performed whenever patients presented with symptoms suggestive of hypoglycemia, defined as blood glucose levels below 60 mg/dl, or when clinically indicated.

Study Protocol: All patients underwent routine investigations, including fasting, random, and postprandial blood glucose measurements on two separate occasions to confirm diagnosis. Patients were counseled regarding lifestyle modifications, dietary restrictions, and the importance of adherence to therapy prior to initiation of treatment. Blood glucose levels were measured using the glucose oxidase method in the central laboratory with an Olympus AU 640 auto-analyzer. A blood sample of 10 µl was analyzed within 30 minutes of collection to ensure accuracy and reliability of results. A structured proforma was used for systematic data collection.

Information was obtained through direct patient interviews, interaction with attendants when necessary, and retrospective review of medical records to assess disease duration, prior treatment history, and compliance.

The sample size was calculated based on regional prevalence data of type 2 diabetes mellitus, ensuring a study power of more than 80%. Statistical analysis was carried out using SPSS version 10.0 software. The unpaired t-test was used for comparison between groups, and a p-value of less than 0.05 ($P<0.05$) was considered statistically significant.

RESULTS: Diabetes mellitus continues to be one of the most prevalent endocrine disorders worldwide, primarily resulting from absolute or relative insulin deficiency. The increasing availability of therapeutic options has improved the ability to manage this condition effectively, yet optimal glycemic control remains a challenge.

In the present study, both sitagliptin and gliclazide demonstrated significant reductions in fasting and postprandial blood glucose levels following initiation of therapy. In patients treated with sitagliptin, a statistically significant reduction ($P<0.05$) in blood glucose levels was observed when compared with baseline values. Similarly, patients receiving gliclazide showed a statistically significant reduction ($P<0.01$), with a gradual and sustained decline observed over the six-month study period.

When the two groups were compared, gliclazide demonstrated a more consistent and greater reduction in mean blood glucose levels throughout the follow-up period than sitagliptin ($P<0.05$). These findings are consistent with previous studies that have reported superior glycemic control with sulfonylurea therapy [13].

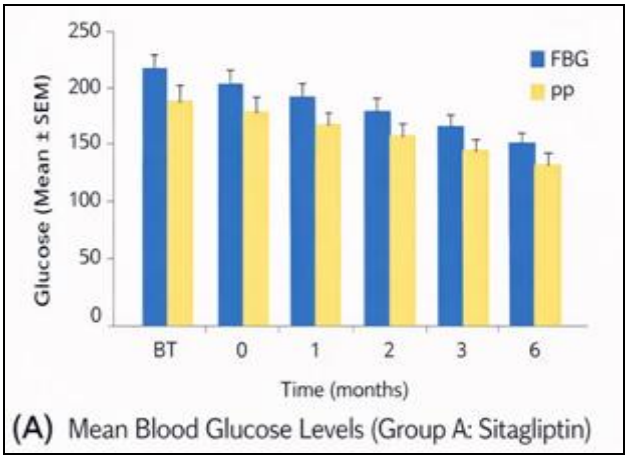
Evaluation of HbA1c levels further supported these findings. In the gliclazide group, a significant reduction ($P<0.01$) was observed at both three and six months when compared to baseline values. In contrast, the sitagliptin group did not show a statistically significant reduction in HbA1c levels ($P>0.05$). These observations are in agreement with earlier studies reporting similar outcomes [14].

Safety Profile: With regard to safety, hypoglycemic episodes were reported in 2.01% of patients receiving sitagliptin, whereas a significantly higher incidence of 8.06% was observed in the gliclazide group ($P<0.01$). This difference highlights the increased risk of hypoglycemia associated with sulfonylurea therapy.

Gastrointestinal adverse effects, including nausea, vomiting, and abdominal discomfort, were reported in both groups, with a slightly higher incidence in the gliclazide group (6.1%) compared to the sitagliptin group (4.69%).

Weight reduction was observed in 8.10% of patients treated with sitagliptin, whereas no significant change in body weight was noted in patients receiving gliclazide.

Overall, these findings indicate that while gliclazide provides superior glycemic control, sitagliptin offers a more favorable safety profile with a lower risk of hypoglycemia.



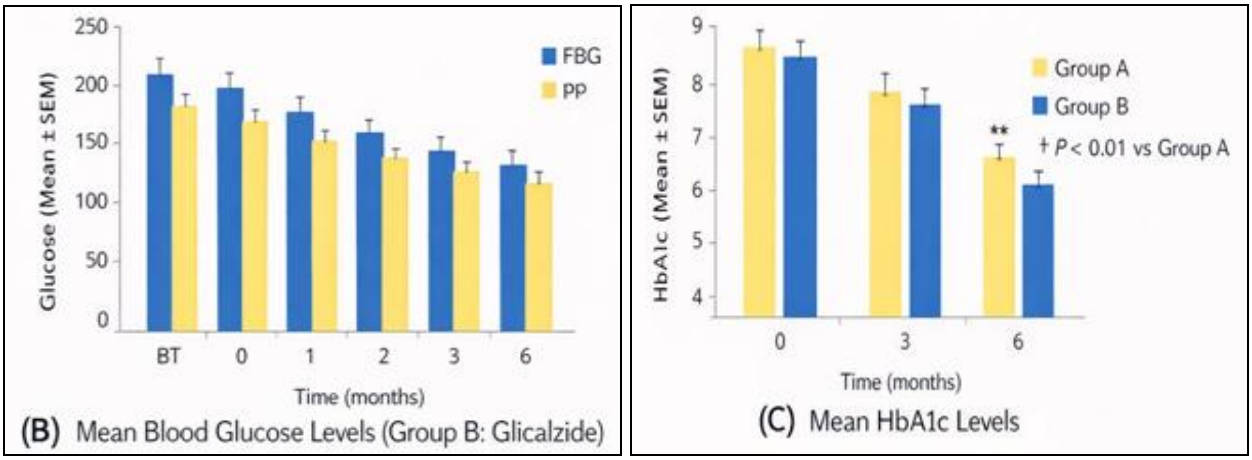


FIG. 1: COMPARISON OF MEAN FASTING BLOOD GLUCOSE (FBG) AND POSTPRANDIAL BLOOD GLUCOSE (PP) LEVELS IN GROUP A (SITAGLIPTIN) OVER 6 MONTHS. Values are expressed as mean ± SEM.

DISCUSSION: Diabetes mellitus is a rapidly growing global health concern, characterized by chronic hyperglycemia and associated metabolic disturbances. The management of type 2 diabetes requires a balance between achieving optimal glycemic control and minimizing adverse effects associated with therapy. The present study compared the efficacy and safety of sitagliptin and gliclazide as monotherapy in patients with uncomplicated type 2 diabetes mellitus. Both drugs were effective in reducing blood glucose levels; however, differences were observed in the magnitude and consistency of their effects. Sitagliptin, a DPP-IV inhibitor, enhances incretin hormone activity, leading to glucose-dependent insulin secretion and suppression of glucagon release. This mechanism reduces the risk of hypoglycemia and contributes to its favorable safety profile. In the present study, sitagliptin demonstrated a significant reduction in fasting and postprandial glucose levels, although the overall reduction was less pronounced compared to gliclazide. Gliclazide, a sulfonylurea, acts by stimulating insulin secretion from pancreatic β-cells. This results in a more robust reduction in blood glucose levels, as observed in the present study. The significant decline in HbA1c levels in the gliclazide group further confirms its effectiveness in achieving long-term glycemic control. These findings are supported by previous studies [13].

However, the increased efficacy of gliclazide was associated with a higher incidence of hypoglycemia, which remains a major limitation of sulfonylurea therapy. In contrast, sitagliptin demonstrated a lower risk of hypoglycemia, making it a safer option, particularly in elderly patients or those at risk of hypoglycemic episodes.

Gastrointestinal side effects were observed in both groups but were generally mild and manageable. Weight reduction observed with sitagliptin may offer an additional benefit in overweight or obese patients.

Some earlier studies have reported no significant difference between the two drugs in terms of glycemic control and HbA1c reduction, highlighting variability in clinical outcomes [14].

The study has certain limitations, including a relatively short duration and resource constraints. Long-term studies with larger sample sizes are required to further evaluate the comparative effectiveness and safety of these agents.

CONCLUSION: The findings of the present study demonstrate that gliclazide provides superior glycemic control compared to sitagliptin in patients with uncomplicated type 2 diabetes mellitus. This is evidenced by a more consistent and significant reduction in both blood glucose levels and HbA1c.

However, this improved efficacy is accompanied by a higher incidence of hypoglycemic episodes, which may limit its use in certain patient populations. Sitagliptin, although less effective in reducing glycemic parameters, offers a safer profile with a lower risk of hypoglycemia and additional benefits such as weight reduction. Therefore, the choice of therapy should be individualized based on patient characteristics, clinical priorities, and

risk factors. Gliclazide may be preferred in patients requiring stronger glycemic control, whereas sitagliptin may be more suitable for patients where safety and avoidance of hypoglycemia are of greater concern.

Further large-scale and long-term studies are recommended to confirm these findings and guide clinical decision-making.

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CONFLICTS OF INTEREST: Nil

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