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Original Article

Comparison of clinical outcomes of sitagliptin and glimepride in the management of uncomplicated type-2 diabetes mellitus patients

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ABSTRACT

This study has recruited 295 uncomplicated Type-2 diabetes mellitus patients who were allocated to two treatment groups viz group A and B. Group A received Sitagliptin and group B received Glimepride respectively. The most common admitting outcomes assessed were glycemia control, and the incidence of complications. The mean blood glucose levels (fasting and postprandial) obtained a day before starting the treatment has significantly($P<0.05$) reduced when compared to mean blood glucose levels (fasting and mean postprandial) obtained after the treatment in patients who received sitagliptin. However, a significant ($P<0.01$) but gradual decrease was noted in mean blood glucose levels from zero month to six month in a group who were treated with Glimepride alone with comparatively high incidence of hypoglycemic episodes as compared to Sitagliptin group. In addition a significant difference ($P<0.01$) in *HbA1c* was also recorded in patients who were treated with Glimepride alone whereas insignificant difference ($P>0.05$) in HbA1c was recorded in patients who received Sitagliptin alone. The results of this study reveals that a better glycemia control was achieved by Glimepride with comparatively higher incidence of hypoglycemic episodes than Sitagliptin alone in the management of uncomplicated type-2 diabetic patients.

Key Words: Sitagliptin, Glimepride, glycemia control, Type 2 Diabetes Mellitus patients.

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INTRODUCTION

Diabetes mellitus (DM) is a metabolic disorder characterized by defect in insulin secretion, insulin action, or both.[1-4] India had 32 million diabetic patients in the year 2000 and this number would increase to 80 million by the year 2030.[5] According to WHO, more than 200 million people worldwide will have DM and 300 million will subsequently have the disease by 2025.[6-8] Despite the wide array of treatment options available for the treatment of type-2 diabetes, the glycemic control declines over time.[9] The primary goal of treatment is to target glycemic control so as to decrease the incidence of microvascular and macrovascular complications without predisposing patients to hypoglycemia.[10] Different antidiabetics including Glimepride is the most commonly used oral antidiabetic monotherapy regimen to control hyperglycemia and its associated complications in type 2 diabetes. Sitagliptin a dipeptidyl peptidase - IV inhibitor is approved in many countries for the treatment of patients with type-2 diabetes. [11-12] Hence, it was found worthwhile to assess and compare the clinical outcomes of Sitagliptin and Glimepride alone in the management of uncomplicated type 2 diabetics.

MATERIALS AND METHODS

This study was carried out in the Department of Pharmacology at Geetanjali Medical College & Hospital and other Tertiary care Hospitals on uncomplicated type 2 diabetes mellitus patients. The blood glucose estimation with history and clinical examination were undertaken to diagnose the type-2 diabetes mellitus. The uncomplicated Type-2 diabetes mellitus patients of age between 18–70 years were included into the study. However, Type-I diabetes (IDDM), pregnant women, patients with impaired renal/ liver functions and the patient with history of hypersensitivity to the study drugs were excluded. Written, informed consent of all the patients and approval of Institutional Ethics Committee (IEC) was taken before starting the study.

Study design

This study was a prospective, open label, observational clinical cohort study carried out on type-2 diabetes mellitus patients. It enrolled a total of 295 type-2 diabetes mellitus patients who were randomly allocated to two groups viz group A and group B respectively. Group A received sitagliptin/100mg daily and group B received Glimepride/1 mg daily. After starting the treatment Before Breakfast (BBF) and Post Prandial (PP) blood glucose (BG) levels of all the patients enrolled in to this study were measured for a period of 6 months to assess the glycaemia control. A day before starting the treatment before breakfast (BBF) blood sugar was measured and treatment started. The patients were advised to come after 10 days from start of treatment for measurement of blood sugar and HbA1c. The data collected on the day 10 from the start of the treatment was considered as zero month and follow up was started every month upto the period of six months in each patient. In addition HbA1c was also measured & assessed after every 3 months. Any increase or decrease in dose requirement of the antidiabetic regime was noted and compared. In addition, BG was measured at any time if a patient experienced symptoms of hypoglycaemia (BG<60 mg/dl) or if requested by treating physician. Apart from glycaemia profile the complications attributable to the treatment regimes were also recorded in both the groups to assess the safety parameter.

Study Protocol

As the patient turned out to be diabetic, routine investigation of fasting, random and post prandial blood glucose was done twice for confirmation. After being educated on diet, importance of treatment regimen with special emphasis on need to adhere to treatment, the patient was started with one of the two regimes. The blood glucose estimation was done by glucose oxidase test in the central laboratory of the concerned hospitals by using Olympus AU 640 auto-analyser. A blood sample of 10µl for estimation of blood glucose was done within half an hour after the sample collection. HbA1C was also used as a comparative criteria for the assessment of glycaemia control in each patient. A Proforma was developed for collecting the data required for this study. Face to face interview technique was used for interviewing the patients and / or their closest attendants. The other technique applied was that of retrospective analysis of the records. It was done with an intention to provide supplementary information on the data collected. In this study, it was contemplated to analyze the records of previous treatment with the history of diabetes mellitus to test the reliability about the duration of disease and compliance to treatment. The patient sample for this study was calculated as per the incidence of Type 2 Diabetes mellitus in the projected area and the power of study is more than 80%. Unpaired *t-test* was employed for statistical analysis of the data. Statistical analysis was done by SPSS version 10.0 statistical software. A probability value of less than 0.05 ($P<0.05$) was considered to be statistically significant.

RESULTS AND DISCUSSION

Diabetes mellitus is the most common endocrine disorder which is characterized by relative or absolute deficiency of insulin. The incidence of

diabetes is intensifying globally. Various treatment modalities and new drugs are introduced as monotherapy or fixed dose combinations for precise control of elevated blood glucose levels in type 2 diabetics. One such newly introduced drug is Sitagliptin: a DPP-IV inhibitor. DPP-IV inhibitors are approved as monotherapy or as an add-on therapy to ongoing oral antidiabetic regimen in type 2 diabetics. Hence, it was found worthwhile to study and compare the clinical outcomes of Sitagliptin and Glimepride alone in terms of glycaemia control achieved and incidence of complications. The most common admitting outcomes assessed were glycemia control, and the incidence of complications.

The mean blood glucose levels (fasting and postprandial) obtained a day before starting the treatment has significantly reduced ($P<0.05$) in patients who received sitagliptin whereas a significant ($P<0.01$) but gradual decrease was noted when compared to mean blood glucose levels (fasting and postprandial) obtained on zero month till a period of six months in patients who received Glimepride alone (Fig-1 & 2). These results are in support of a study mentioning that a significant decrease was noted in mean blood glucose levels in patients who were treated with Sitagliptin alone and Glimepride alone[13] While comparing the glycemia control achieved between groups, a significant ($P<0.05$) but gradual decrease was noted in all the mean blood glucose levels recorded from zero month to six month in patients who were treated with Glimepride after starting the treatment than a group who was treated with Sitagliptin alone (Fig-2). These results are similar to the outcomes of the study mentioning similar glycemia control achieved by Glimepride[13]. However, an adequate significant control in mean fasting and mean post prandial blood glucose levels was not achieved even at a period of six month therapy with Sitagliptin alone (Fig-1). In addition each patient was assessed for the HbA1c and used as an additional comparative criteria for the assessment of glycaemia control in both the groups. A significant difference ($p<0.01$) existed in HbA1c values recorded after three and six months period when compared to HbA1c values recorded on zero month period in group who were treated with Glimepride alone (Fig-3). These results are in accordance to a study mentioning the significant decrease in HbA1c values in patients treated with Glimepride[13]. However, Insignificant ($P>0.05$) difference was noted in HbA1c values recorded before or after treatment in a group who were treated with Sitagliptin alone (Fig-3). However some previous studies has shown insignificant result between both the groups in terms of glycemia control as well as in HbA1c level[14]. 2.04 percent hypoglycaemic episodes were recorded in patients who were treated with Sitagliptin alone. While as 8.10 percent hypoglycaemic episodes were recorded in patients who were treated with Glimepride alone. However, this difference in incidence of hypoglycaemic episodes between groups was statistically significant ($P<0.01$). 4.76 and 6.08 percent of the patients treated with Sitagliptin and Glimepride suffered GIT complications like nausea, vomiting and abdominal discomfort respectively. Weight loss was recorded in 8.16 percent patients who were treated with Sitagliptin alone. However, no loss of weight was recorded in patients who were treated with Glimepride alone. The results of this study reveal that the Glimepride alone was more efficacious to achieve glycaemia control in comparison to Sitagliptin group. Therefore, Sitagliptin as monotherapy for control of elevated sugar level (fasting and postprandial) and HbA1c in type 2 diabetics did not result superior to Glimepride alone therapy. Time and resource constraint was the major limitation of this study therefore more short and long term studies are warranted to investigate the significance and causal relationships of the differences in the outcomes with the treatments.

CONCLUSION

The results of this study reveals that a better glycemia control was achieved by Glimepride with comparatively higher incidence of hypoglycemic episodes than Sitagliptin alone in the management of uncomplicated type-2 diabetic patients.

FIGURES AND/OR GRAPHS

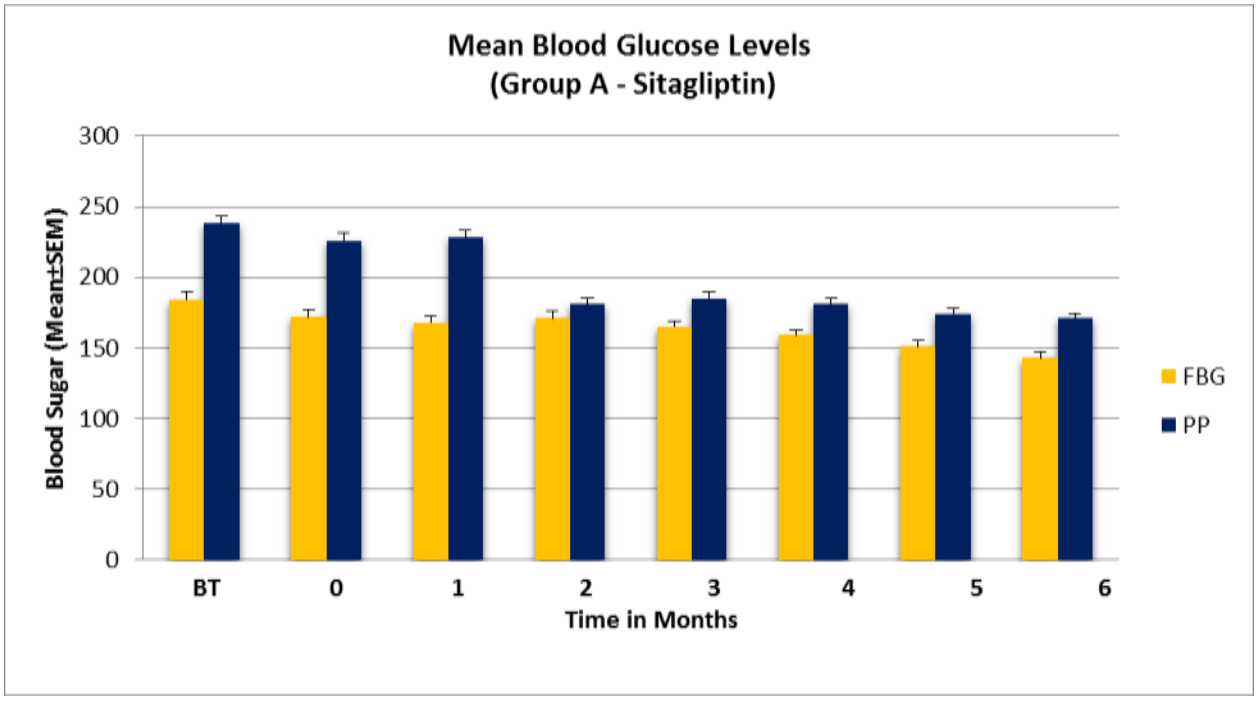

Fig.1: Comparison of mean fasting and post prandial blood glucose levels. FBG= Fasting Blood glucose, PP= Post prandial, BT= Fasting Blood Glucose Before Treatment.

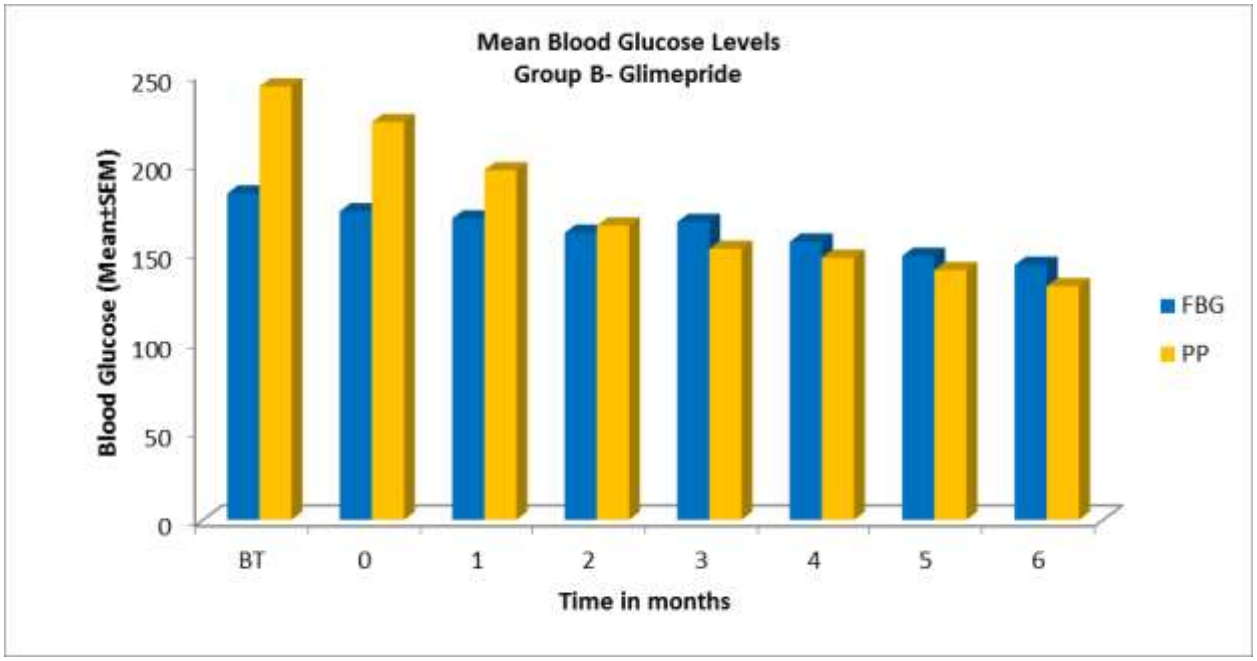

Fig.2: Comparison of mean fasting and post prandial blood glucose levels. FBG= Fasting Blood glucose, PP= Post prandial, BT= Fasting Blood Glucose Before Treatment.

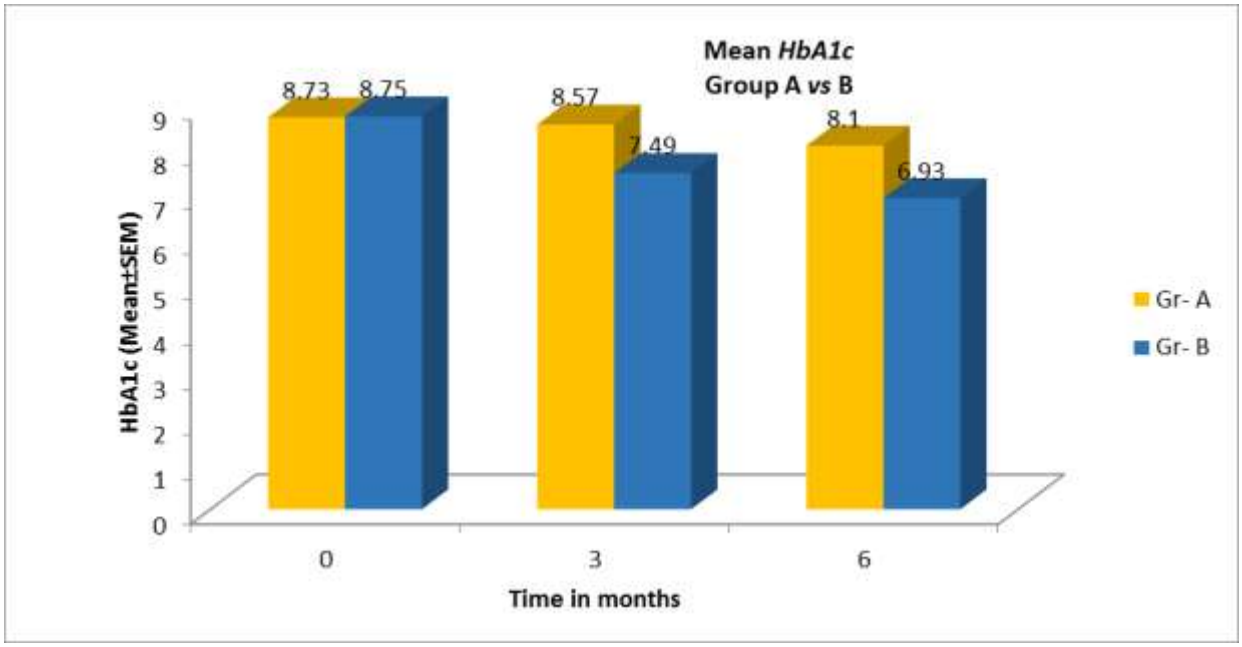

Fig-3: Comparison of *HbA1c* between group A and B. Group A= Sitagliptin, Group B= Glimepride

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