

ABSTRACT

TITLE:

TO COMPARE THE SAFETY AND EFFICACY OF GLIMEPIRIDE – METFORMIN WITH VILDAGLIPTIN - METFORMIN IN TYPE 2 DIABETES MELLITUS PATIENTS IN A TERTIARY CARE HOSPITAL.

STUDY BACKGROUND:

The increased prevalence of Type 2 DM leads to increased cardiovascular morbidity, dyslipidemia, etc. Failure of monotherapy over time suggests the need for combination therapy to achieve glycemic goals. Combination therapy with various agents have been implicated in great glycemic control than monotherapy with single agent.

OBJECTIVES:

TO COMPARE THE SAFETY AND EFFICACY OF GLIMEPIRIDE – METFORMIN WITH VILDAGLIPTIN - METFORMIN IN TYPE 2 DIABETES MELLITUS PATIENTS IN A TERTIARY CARE HOSPITAL.

METHODS:

In this prospective, randomised, controlled, open label comparative study, newly diagnosed Type 2 diabetic patients were assigned to receive either T.Glimepiride(1 mg) + T.Metformin (500 mg) twice daily (n=35) or T.Vildagliptin (50mg) + T.Metformin (500 mg) twice daily (n=35) for a period of 12 weeks to attain good glycemic control. FBS, PPBS at baseline, 6th week

and 12th week, HbA1c at baseline and at 12th week were compared between and within the groups at baseline and at the end of the study.

RESULTS:

All the 70 patients completed the study. At the end of the study, the mean fasting blood sugar level at baseline were 179.06mg/dl and 174.03mg/dl (P=0.43) and at the end 12 weeks were 109.80mg/dl and 104.57mg/dl (P=0.33) in Group A and Group B respectively. The mean Post prandial blood sugar levels at baseline were 270.86mg/dl and 277.94mg/dl(P=0.42) and at the end of 12th week were 159.03mg/dl and 154.45mg/dl (P=0.07) in Group A and Group B respectively. The mean HbA1c levels at baseline were 8.80 and 8.99(P=0.12) and at the end of 12 weeks were 6.47 and 6.42 (P=0.26) in Group A and Group B respectively. There was no significant difference in fasting, post prandial blood glucose & HbA1c level between the groups. The adverse effect in Group A subjects was maximum in relation to hypoglycemia. Elevated liver enzymes was seen more in Group B subjects along with diarrhoea which shows statistical significance.

CONCLUSION:

Thus from the present study we conclude that the efficacy and tolerability of Vildagliptin was similar with no significant differences, when used to treat type 2 diabetic patients with inadequate blood glucose control by dual combination of Metformin and another traditional oral hypoglycemic agent

(Glimepiride). Vildagliptin in combination with metformin also had good safety profile with low risk of hypoglycemia and weight gain.

KEYWORDS:

Type 2 Diabetes, Vildagliptin, Metformin, Glimepiride.