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Original Research Article.

Comparative Evaluation of Metformin and Combination of Metformin and Sitagliptin in Type II Diabetic Mellitus Patients: A Hospital Based Study

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ABSTRACT

Background: Metformin, a classic drug used to treat T2DM, has been applied in clinical practice for decades. Sitagliptin, the first available dipeptidyl peptidase-4 (DPP-4) inhibitors, was approved as a treatment for T2DM and it has been widely used in clinical practice. The present hospital-based study was done to compare Metformin and Combination of Metformin and Sitagliptin in Type II Diabetic Mellitus Patients.

Materials and Methods: In the present hospital study two groups were included and each group has 30 cases & each case was having diabetic mellitus. Patients were divided to Group I and Group II. The Group I comprised of patients receiving Metformin while Group II comprised of patients receiving of combination of Metformin and Sitagliptin. Baseline Fasting (FPG) and post-prandial plasma glucose (PPPG) levels were measured. Follow up was done at 4, 8 and 12 weeks of therapy. Data were analysed by using mean ± SD & Microsoft excel.

Results: In the present study two groups were included and each group has 30 cases, means total 60 cases were included. Fasting plasma glucose in group I at 0 week was 141.34mg/dl and in group II was 167.76mg/dl, at 4 week it was 133.07mg/dl in group I and 158.65mg/dl in group II, at 8 week it was 136.45mg/dl in group I and 142.23mg/dl in group II, at 12 week it was 130.13mg/dl in group I and 116.61mg/dl in group II. Postprandial Plasma Glucose level in group I at 0 week was 201.54mg/dl and in group II was 222.21mg/dl, at 4 week it was 198.87mg/dl in group I and 219.63mg/dl in group II, at 8 week it was 197.49mg/dl in group I and 200.56mg/dl in group II, at 12 week it was 187.61mg/dl in group I and 168.23mg/dl in group II.

Conclusion: The present study concluded that the patients who were on monotherapy with metformin alone having inadequate glycaemic control while patients who were on combination therapy with metformin and Sitagliptin had effective way of maintaining glycaemic control.

Keywords: Fasting Plasma Glucose, Postprandial Plasma Glucose Level, Type II Diabetes Mellitus.

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is characterized by insulin resistance combined with progressive β-cell failure. Despite advances in the treatment of T2DM, devising an appropriate treatment strategy for patients with newly diagnosed T2DM with severe hyperglycaemia [glycosylated haemoglobin (HbA1c) >9%; fasting plasma glucose (FPG) ≥11.1 mmol/l] provides a formidable challenge to physicians. Oral drug classes such as metformin, sulphonylurea, thiazolidinedione, alpha glucosidase inhibitors and DPP IV inhibitors are available which significantly lower the HbA1c level and are routinely used in the management of diabetes. Sulphonylureas are associated with weight gain and hypoglycaemia, thiazolidinedione causes fluid retention and metformin in many patients leads to gastrointestinal irritation.[1,2] The drugs of class dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors) are equally efficacious as compared to other anti-diabetic agents and also has very limited adverse effects.[3] Sulphonylurea are associated with weight gain and hypoglycaemia, thiazolidinedione causes fluid retention and metformin in many patients leads to gastrointestinal irritation.[3] Sitagliptin which is a DPP-4 inhibitors is orally active and routinely prescribed as monotherapy or as an add on therapy. Safety and efficacy of sitagliptin is well established for the treatment of

T2DM.[4] Metformin is recommended as initial monotherapy for treatment of type 2 diabetes mellitus because it decreases the higher blood glucose by suppressing hepatic production of glucose, apart from suppression of hepatic glucose production, it also increases sensitivity of insulin, it also enhances the peripheral uptake of glucose (by inducing GLUT4 enhancer factor phosphorylation), and it also decreases the insulin-induced suppression of fatty acid oxidation. It is proved that metformin increases the peripheral utilization of glucose due to improved insulin binding to insulin receptors.[5,6] The present hospital based study was done to compare Metformin and Combination of Metformin and Sitagliptin in Type II Diabetic Mellitus Patients.

MATERIALS AND METHODS

In the present hospital study two groups were included and each group has 30 cases & each case was having diabetic mellitus. Before the commencement of the study ethical approval was taken from the Ethical Committee of the institute and written consent was taken from the patient after explaining the study. The study was conducted over a period of 6 months. Patients were divided to Group I and Group II. The Group I comprised of patients receiving Metformin (500 mg orally twice daily), while Group II comprised of patients receiving of combination of Metformin (500mg orally twice daily) and Sitagliptin (100mg orally once in a day). Sitagliptin was added in type II diabetic patients which were inadequately controlled with metformin alone. Baseline Fasting (FPG) and post-prandial plasma glucose (PPPG) levels were measured. Follow up was done at 4, 8 and 12 weeks of therapy. At each visit, FPG Level and PPPG level were measured. Data were analysed by using mean ± SD & Microsoft excel.

RESULTS

In the present study two groups were included and each group has 30 cases, means total 60 cases were included. Fasting plasma glucose in group I at 0 week was 141.34mg/dl and in group II was 167.76mg/dl, at 4 week it was 133.07mg/dl in group I and 158.65mg/dl in group II, at 8 week it was 136.45mg/dl in group I and 142.23mg/dl in group II, at 12 week it was 130.13mg/dl in group I and 116.61mg/dl in group II. Postprandial Plasma Glucose level in group I at 0 week was 201.54mg/dl and in group II was 222.21mg/dl, at 4 week it was 198.87mg/dl in group I and 219.63mg/dl in group II, at 8 week it was 197.49mg/dl in group I and 200.56mg/dl in group II, at 12 week it was 187.61mg/dl in group I and 168.23mg/dl in group II.

Table 1: Comparison of metformin monotherapy and combination of metformin & sitagliptin on Fasting Plasma Glucose level in mg/ dl at 0,4,8 and 12 weeks

Time interval	Group I Mean±SD	Group II Mean±SD	p-value
0 week	141.34±53.32	167.76±62.39	>0.05
4 weeks	133.07±43.23	158.65±53.23	
8 weeks	136.45±37.45	142.23±9.65	
12 weeks	130.13±28.52	116.61±33.21	

Table 2: Comparison of metformin monotherapy and combination of metformin & sitagliptin on Postprandial Plasma Glucose level in mg/dl at 0,4,8 and 12 weeks

Time interval	Group I Mean±SD	Group II Mean±SD	p-value
0 week	201.54±76.45	222.21±80.25	>0.05
4 weeks	198.87±72.34	219.63±78.89	
8 weeks	197.49±64.61	200.56±76.34	
12 weeks	187.61±60.23	168.23±52.61	

DISCUSSION

Management of T2DM has changed dramatically with the introduction of newer antidiabetic agents including dipeptidyl peptidase-4 inhibitors (DPP4i), sodium-glucose co-transporter 2 inhibitors, glucagon-like peptide-1 (GLP-1) analogs, and insulin analogs. DPP4i are a well-established class of oral agents having moderate efficacy with a good overall safety profile including low risk of hypoglycemia and weight neutrality.[7]

Fasting plasma glucose in group I at 0 week was 141.34mg/dl and in group II was 167.76mg/dl, at 4 week it was 133.07mg/dl in group I and 158.65mg/dl in group II, at 8 week it was 136.45mg/dl in group I and 142.23mg/dl in group II, at 12 week it was 130.13mg/dl in group I and 116.61mg/dl in group II. Postprandial Plasma Glucose level in group I at 0 week was 201.54mg/dl and in group II was 222.21mg/dl, at 4 week it was 198.87mg/dl in group I and 219.63mg/dl in group II, at 8 week it was 197.49mg/dl in group I and 200.56mg/dl in group II, at 12 week it was 187.61mg/dl in group I and 168.23mg/dl in group II.

Benard Charbonel et al in one of their study showed the effectiveness of addition of daily one dose of Sitagliptin 100mg with ongoing Metformin therapy in type II diabetic patients who had insignificant glycaemic control with monotherapy using Metformin.[8]

Aschner Pablo et al in their 24-week study with sitagliptin 100 mg or 200mg or placebo, reported that patient taking sitagliptin showed a significant decrease in fasting blood glucose, post prandial glucose and HbA1c levels as compared to placebo, similarly our study also reported significant decrease in these three parameters at 30 weeks.[9]

Devarajant. V et al in their 12-week study with sitagliptin 50 mg/metformin 500 mg twice daily versus glimepiride 1 or 2 mg/sustained-release metformin 1000 mg once daily concluded that at 12 weeks, both treatment groups exhibited an improvement in HbA1c, FBG, PPG from baseline, which was statistically significant (Student's t-test, P = 0.001).[10]

CONCLUSION

The present study concluded that the patients who were on monotherapy with metformin alone having inadequate glycaemic control while patients who were on combination therapy with metformin and Sitagliptin had effective way of maintaining glycaemic control.

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