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Original Research

A comparative evaluation of glimepiride plus metformin versus glibenclamide plus metformin in type 2 diabetes mellitus patients

Roohi Sharma[1], Vinay Sambyal[2], Brij Mohan Gupta[3], Mohammad Saleem Sharoo[4], Zahid Gillani[5]

[1]Demonstrator, [3]Professor, [4]Post graduate, [5]Professor & Head, Department of Pharmacology,
[2]Lecturer, Department of Medicine, Govt. Medical College, Jammu, J & K, India

***ABSTRACT*:**

Background: The present study was conducted to assess the efficacy of combination therapy in management of patients with type 2 diabetes mellitus. **Materials & Methods:** 140 patients of type 2 diabetes mellitus were divided into 2 groups of 70 patients each. Group I received combination of glimepiride plus metformin and group II received combination of glibenclamide plus metformin. Estimation of fasting plasma glucose and HbA1C before and 3 and 6 months after treatment was done. **Results:** The mean fasting blood glucose level in group I before treatment was 184.2 mg/dl and in group II was 174.6 mg/dl, after 3 months was 128.8 mg/dl in group I and 124.2 mg/dl in group II, at 6th month was 104.2 mg/dl and 112.7 mg/dl in group I and group II respectively. HbA_1C level in group I was 8.1% and in group II was 8.3%, after 3 months was 7.3% and 7.2% in group I and group II respectively. At 6th month was 6.6% in group I and 6.0% in group II respectively. The difference was significant ($P< 0.05$). **Conclusion:** Glimepiride plus metformin and glibenclamide plus metformin found to be equally effective in patients with type 2 diabetes mellitus, thus selection of patients should be done based on patient response.

Key words: Diabetes mellitus, Glimepiride, Metformin.

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Corresponding Author: Dr. Vinay Sambyal, Lecturer, Department of Medicine, Govt. Medical College, Jammu, J & K, India

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INTRODUCTION

Diabetes Mellitus (DM) is one of the most common non communicable diseases with high incidence all over the world. Diabetes is undoubtedly one of the most challenging health problems in the 21st century. DM is a spectrum of common metabolic disorders, arising from a variety of pathogenic mechanisms, all resulting in hyperglycaemia. Factors contributing to it are insufficient insulin secretion, reduced responsiveness to insulin, increased glucose production and abnormalities in carbohydrate, fat and protein metabolism.[1]

Diabetes is a chronic condition that requires continues medication and life style modification to prevent acute complication and to reduce long term complications. Blood sugar level cannot be controlled as β-cell function worsens over time, independent of whether the treatment was diet alone, sulfonyl urea, metformin, or insulin.[2]

Sulfonylureas aim to reduce diabetes associated hyperglycemia by acting on the pancreatic beta-cell channels to facilitate insulin secretion. As compared to glipizide or glimepiride, glibenclamide has a higher affinity for pancreatic beta-cell SFU receptors, greater propensity for accumulation of active metabolites and greater penetration of pancreatic tissue.[3] Glibenclamide can also increase insulin sensitivity greater than other SFUs, particularly when compared to gliclazide. Combination treatment with metformin is more effective than sulphonylureas drugs alone in improving glycaemic control in type 2 diabetes while also allowing a reduction of the dosage of each drug. Glibenclamide and metformin is the most common anti diabetic combination used in clinical practice.[4] The present study was conducted to assess the efficacy of combination therapy in management of patients with type 2 diabetes mellitus.

MATERIALS & METHODS

The present study was conducted among 140 patients of type 2 diabetes mellitus of both genders. All were informed regarding the study and written consent was obtained.

Data such as name, age, gender etc. was recorded. All were divided into 2 groups of 70 patients each. Group I received combination of glimepiride plus metformin and group II received combination of glibenclamide plus metformin. Estimation of fasting plasma glucose and HbA1C before and 3 and 6 months after treatment was done. Results were recorded. P value less than 0.05 was considered significant (P< 0.05).

RESULTS

Table I Distribution of patients

Groups	Group I	Group II
Drug	Glimepiride plus metformin	Glibenclamide plus metformin
M:F	40:30	38:32

Table I shows that in group I there were 40 males and 30 females and in group II were 38 males and 32 females.

Table II Assessment of fasting blood glucose level

Fasting blood glucose	Group I	Group II	P value
Before treatment	184.2	174.6	0.12
At 3rd month	128.8	124.2	0.05
At 6th month	104.2	112.7	0.05

Table II, graph I shows that mean fasting blood glucose level in group I before treatment was 184.2 mg/dl and in group II was 174.6 mg/dl, after 3 months was 128.8 mg/dl in group I and 124.2 mg/dl in group II, at 6th month was 104.2 mg/dl and 112.7 mg/dl in group I and group II respectively. The difference between groups was non-significant (P< 0.05).

Graph I Assessment of fasting blood glucose level

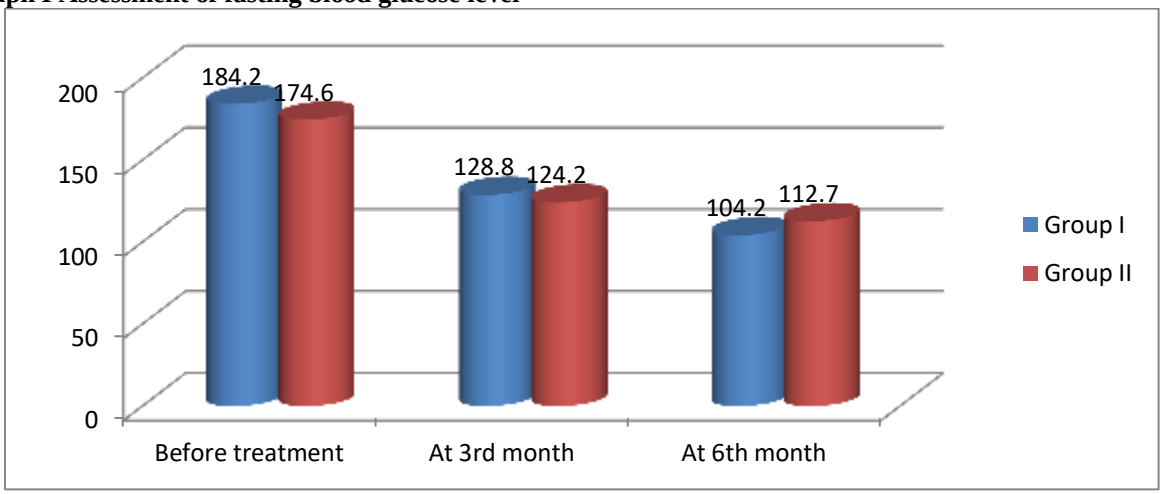
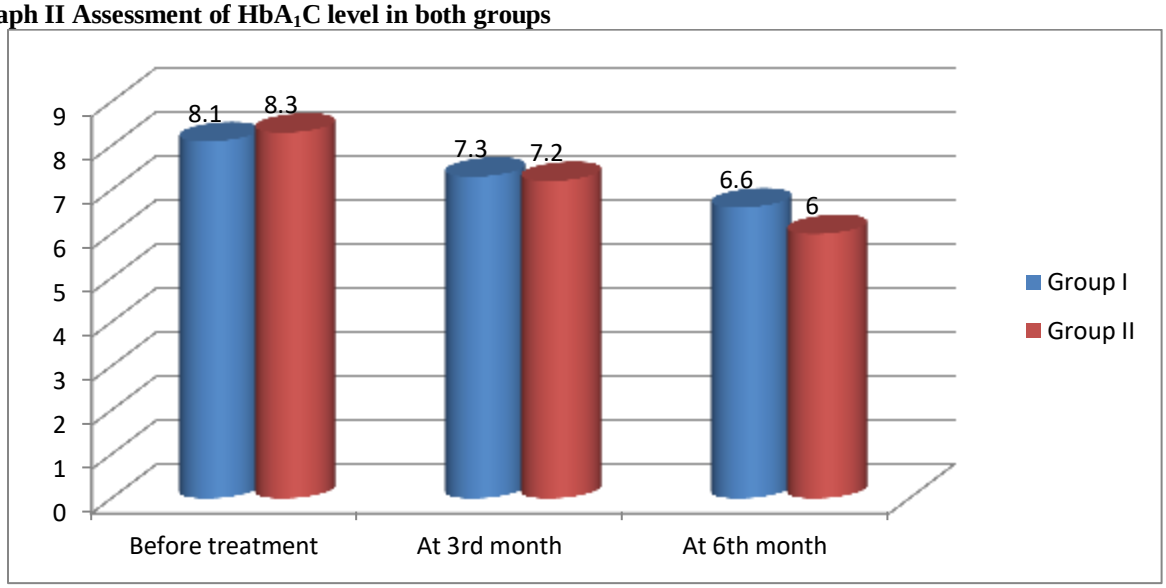


Table III Assessment of HbA_1C level in both groups

HbA_1C level	Group I	Group II	P value
Before treatment	8.1	8.3	0.05
At 3rd month	7.3	7.2	
At 6th month	6.6	6.0	

Table III, graph II shows that HbA_1C level in group I was 8.1% and in group II was 8.3%, after 3 months was 7.3% and 7.2% in group I and group II respectively. At 6th month was 6.6% in group I and 6.0% in group II respectively. The difference was significant (P< 0.05).

Graph II Assessment of HbA_1C level in both groups



DISCUSSION

Diabetes mellitus is a chronic condition and is characterized by hyperglycemia resulting from defect in insulin secretion, insulin action or both. Due to this the amount of glucose in the blood increases and leads to hyperglycemia. It is of type 1 and type 2. Type 2 diabetes mellitus is the most common form of diabetes comprising of 90% to 95% of all diabetes cases.[5]

Metformin is the first-line treatment for type 2 diabetes mellitus patients. The mechanism of action of metformin and other biguanides is not completely understood, but recent in vitro and in vivo studies suggest that metformin may act in part by both increasing the binding of insulin to its receptor and potentiating insulin action.[6] Glimepride is very effective in to stimulate insulin action through extrapancreatic effects that affect insulin-receptor binding and enhance tissue responsiveness to insulin; to favorably influence the principal pathophysiologic abnormalities, defective secretory dynamics, and target-cell resistance to insulin observed in noninsulin-dependent diabetes.[7] Glibenclamide is one of the sulfonylureas widely used in the management of diabetes mellitus. It acts by stimulating insulin secretion by pancrease. In present study, we compared the efficacy of glimepiride plus metformin versus glibenclamide plus metformin in patients with type 2 diabetes mellitus patients.[8] The present study was conducted to assess the efficacy of combination therapy in management of patients with type 2 diabetes mellitus.

We observed that the mean blood glucose level (mg/dl) in group I before treatment was 180.4 and in group II was 176.2, after 3 months was 130.8 in group I and 128.4 in group II, at 6th month was 106.2 and 110.2 in group I and group II respectively. This is in agreement with Raju et al.[9]

In present study, we found that in group I there were 40 males and 30 females and in group II were 38 males and 32 females. Sivakumar et al[10], in their study, 96 type 2 diabetic patients in which 52 patients were taking glimepiride plus metformin (group A) and 44 patients were taking glibenclamide plus metformin (group B). After 6 months of treatment the HbA1C value decreased more significantly in group A (1.6%) than group B (1.29%), PPBS and cholesterol level also reduced more significantly in group A patients. But FBS value was more significantly reduced in group B patients. Glimepiride plus metformin combination therapy can be considered as the best combination in patients with increased glycaemic control as compared to glibenclamide plus metformin therapy.

We found that mean fasting blood glucose level in group I before treatment was 184.2 mg/dl and in group II was 174.6 mg/dl, after 3 months was 128.8 mg/dl in group I and 124.2 mg/dl in group II, at 6th month was 104.2 mg/dl and 112.7 mg/dl in group I and group II respectively. Gawali et al[11] conducted a study in which patients with type 2 diabetes mellitus were randomized into two groups to receive combination of metformin plus glimepiride (1000mg+2mg) and metformin plus glibenclamide (1000mg+10mg) for 12 weeks. Primary efficacy end points were changes in fasting blood sugar (FBS) and postprandial blood sugar (PPBS) from baseline to 4 weeks, 8 weeks and 12 weeks and changes in HbA1C from baseline to final assessment i.e. at 12 weeks. The secondary efficacy end point included changes in lipid profile from baseline to final assessment. At the end of 12 weeks difference in reduction in fasting blood sugar(FBS) and Glycosylated haemoglobin between the treatment groups was not statistically significant ($p>0.05$). But reduction in postprandial blood sugar (PPBS) was

statistically more significant in glimepiride and metformin group.

We found that HbA_1C level in group I was 8.1% and in group II was 8.3%, after 3 months was 7.3% and 7.2% in group I and group II respectively. At 6th month was 6.6% in group I and 6.0% in group II respectively. Shimpi et al[12] in glimepiride and metformin combination treatment found significant reductions in TC, TG, and LDL-C while there was increase in the HDL-C throughout the study while in glibenclamide and metformin combination group it caused reductions in TC, TGs, but not the extent of glimepiride and metformin combination group and there were no changes in LDL-C and HDL-C.

CONCLUSION

Authors found that glimepiride plus metformin and glibenclamide plus metformin found to be equally effective in patients with type 2 diabetes mellitus, thus selection of patients should be done based on patient response.

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