Available online on 15.05.2015 at http://jddtonline.info
Journal of Drug Delivery and Therapeutics
Open access to Pharmaceutical and Medical research

RESEARCH ARTICLE

COMPARATIVE STUDY OF GLIMEPIRIDE AND GLICLAZIDE IN TYPE 2 DIABETES PATIENTS ON SAFETY, EFFICACY AND TOLERABILITY

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ABSTRACT:

Background and Objective: Impaired glucose tolerance and impaired fasting glycaemia are risk categories for future development of diabetes and cardiovascular disease. Apart from being the leading cause of renal failure, it also increases the risk of lower limb amputations, visual impairment and tuberculosis. Higher incidence of Diabetes Mellitus in the last decade has compelled us to conduct the present study with an objective to establish safety, efficacy and tolerability of gliclazide against glimepiride in the treatment of type 2 Diabetes Mellitus.
Methodology: The present study was single centered, prospective and observational conducted after obtaining approval from the ethics committee. A total of 40 patients who visited the outpatient block of Apollo hospital at Jubilee Hills, Hyderabad were enrolled in the study. A questionnaire was used to record the response of subjects participated in the study.
Results: A higher proportion of patients belonged to the age group of 41-50 years. Gliclazide did not result in any ADR while glimepiride caused eight ADRs. Average reduction of FBS and PPBS in gliclazide group was found to be 52.5% and 41.3% respectively. Corresponding figures for glimepiride were 56.9% and 32.3%. HbA1c reduction in gliclazide and glimepiride group was 2.44 and 1.91 respectively. Both drugs were found to be well tolerated by the patients.
Conclusion: Gliclazide was found to be superior in terms of safety and efficacy. Hence it can be concluded from the study that gliclazide is a better option in diabetes when compared to glimepiride.
Keywords: diabetes mellitus, efficacy, gliclazide, glimepiride, safety, tolerability

INTRODUCTION

Impaired glucose tolerance and impaired fasting glycaemia are risk factors for future development of diabetes and cardiovascular disease.[1] In some age groups, people with diabetes have a two-fold increase in the risk of stroke.[2] Diabetes is the leading cause of renal failure in both developed and developing countries. Lower limb amputations are at least 10 times more common in people with diabetes than in non-diabetic individuals in developed countries; more than half of all non-traumatic lower limb amputations are due to diabetes.[3] It is one of the leading causes of visual impairment and blindness in developed countries.[4]

People with diabetes require at least two to three times the health-care resources compared to people who do not have diabetes, and diabetes care may account for up to 15% of national health care budgets.[5] In addition, the risk of tuberculosis is three times higher among people with diabetes.[6]

Type 1 indicates the processes of beta–cell destruction that may ultimately lead to diabetes mellitus in which "insulin is required for survival" to prevent the development of ketoacidosis, coma and death. Type 2 is the most common form of diabetes and is characterized by disorders of insulin action and insulin secretion, either of which may be the predominant feature.[7]

Diabetes is treated either by insulin or by oral anti-diabetic drugs. Most common types of oral anti-diabetic drugs include sulphonylureas and biguanides.[8] The sulphonylureas include gliclazide, glimepiride, glibenclamide, and tolbutamide. These agents stimulate the pancreas to produce more insulin than it otherwise would at a particular blood sugar level.

METHODOLOGY

The present study was single centered, prospective and observational conducted over duration of six months with an objective to establish safety, efficacy and tolerability of gliclazide against glimepiride in the treatment of type 2 diabetes mellitus after obtaining approval from the ethics committee. A total of 40 patients who visited the outpatient block of Apollo hospital at Jubilee Hills, Hyderabad were enrolled in the study.

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 ISSN: 2250-1177 CODEN (USA): JDDTAO

Table 1: Drug brands of gliclazide and glimepiride used in the study

Drug	Name	Company
Gliclazide	Diamicron	Serdia
	Diamicron MR	Serdia
	Glimicron	Serdia
	Mylan-Gliclazide	Mylan
Glimepiride	Amaryl	Sanofi-Aventis
	Glimpid	Ranbaxy
	Glimy	Dr. Reddy's

A questionnaire was used to record the response of subjects participated in the study. Drug brands that were used in the study are depicted in table 1. Statistical mean and percentages were used to analyze the findings.

RESULTS

Equal distribution of patients was done between two groups in the study, however variation was found according to gender. Majority (45%) of patients were from the age group of 41-50 years, while just 2.5% were from 71-80 years as shown in table 2. In terms of safety, gliclazide did not show any adverse drug reaction within the six months study period of treatment but glimepiride group evidenced few ADRs as seen in table 3. However, the subjects continued the treatment as the symptoms were not severe. Fasting blood sugar (FBS) and post-prandial blood sugar (PPBS) levels of both groups were analyzed every month during the study.

Table 2: Distribution of patients based on gender and age

Age group	Glimepiride		Gliclazide		Total
	Male	**Female**	**Male**	**Female**	
21-30	2	1	-	1	4 (10.0%)
31-40	2	1	1	2	6 (15.0%)
41-50	3	3	4	4	14 (45.0%)
51-60	1	4	2	3	10 (25.0%)
61-70	1	1	1	2	5 (12.5%)
71-80	-	1	-	-	1 (2.5%)
Total	9 (22.5%)	11 (27.5%)	8 (20.0%)	12 (30.0%)	40 (100%)

Table 3: Tabular representation of Safety in both the groups i.e. Gliclazide and Glimepiride

Drug	Adverse Drug Reaction			Total ADRs
	Diarrhoea	Gastric Irritation	Weight Gain	
Gliclazide	0	0	0	0
Glimepiride	4	1	3	8

Table 4: Tabular representation of values showing average FBS and PPBS levels (mg/dL) in gliclazide and glimepiride groups during six months study period

Months	Gliclazide		Glimepiride	
	FBS	**PPBS**	**FBS**	**PPBS**
Month 1	206.3	330.6	212.1	315.4
Month 2	185.4	308.4	198.3	296.6
Month 3	165.7	286.5	179.1	277.4
Month 4	139.9	250.7	156.4	255.7
Month 5	120.0	219.1	135.9	228.5
Month 6	108.3	194.0	120.6	210.8
Average reduction*	**98.0 (52.5%)**	**136.6 (41.3%)**	**91.5 (56.9%)**	**104.6 (33.2%)**

**Average reduction is from month one to month six*

Average reduction of FBS and PPBS in gliclazide group was found to be 52.5% and 41.3% respectively. Corresponding figures for glimepiride were 56.9% and 32.3% as shown in table 4.

The data of HbA1c levels of both groups Gliclazide group and Glimepiride group were collected, tabulated, analyzed and compared during total study period of both groups. Table 5 shows the tri-monthly average HbA1C levels of gliclazide and glimepiride group during the total study period which shows better control of diabetes in gliclazide group compared to glimepiride group. At the end of the study, HbA1c reduction in gliclazide and glimepiride group was 2.44 and 1.91 respectively.

 ISSN: 2250-1177 CODEN (USA): JDDTAO

Table 5: HbA1c levels of both groups

Month	Gliclazide	Glimepiride
Month 1	8.82	8.71
Month 4	6.38	6.80
Reduction	**2.44**	**1.91**

The data of tolerability of both groups was collected, tabulated and compared. It was found that both groups were showing well tolerance towards their respective drug during the study period.

DISCUSSION

Safety of gliclazide was better than glimepiride in the present study, which coincides with a previous study where 50% fewer hypoglycemic episodes were reported in gliclazide group than glimepiride users.[9] Gliclazide was found to be better in terms of efficacy in the present study. Similar observations were reported by a study conducted on 870 type 2 diabetes patients of India and Malaysia.[10] Both drugs were found to be well tolerated by the subjects during the study.

CONCLUSION

Gliclazide was found to be superior in terms of safety and efficacy. Hence it can be concluded from the study that gliclazide is a better option in diabetes when compared to glimepiride.

CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest.

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 ISSN: 2250-1177 CODEN (USA): JDDTAO