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LETTER TO EDITOR

Therapeutic Efficacy Of Generic Anti Diabetic Drugs

SABITHA P*,ADHIKARI PMR,KAMATH A***,SAHANA SR******

***M.D.Pharmacology (Dept of Pharmacology)**
Kasturba Medical College,Mangalore575 001(India)
****M.D.Internal Medicine (Dept of Medicine)**
Kasturba Medical College,Mangalore575 001(India)
*****M.Sc;Biostatistics,(Dept of Community Medicine)**
Kasturba Medical College,Manipal576104(India)
****M.D.Pharmacology (Dept of Pharmacology)
Kasturba Medical College,Mangalore575 001(India)
Corresponding Author:
Sabitha P
Dept of Pharmacology Kasturba Medical College, Mangalore575 001(India).
E.mail: sabitha@manipal.edu

Sir,

The cost of diabetes care has a significant influence on the access of the poor to it. One approach to improving access and reducing cost is the utilization of generic drugs[1].Generic drugs are marketed under a non-proprietary or approved name, rather than a proprietary or brand name. Generic drugs are frequently as effective as, but much cheaper than brand-name drugs. Because of their low price, generic drugs are often the only medicines that the poorest can access[2].The approval process of generic drugs by drug regulatory authorities mandate bio equivalence studies and not therapeutic equivalence studies[3].This study, which was approved by the Institutional Ethics Committee, evaluated the therapeutic efficacy of non-proprietary generic versions of oral antidiabetics.

After obtaining informed consent, we enrolled 12 patients of type 2 diabetes mellitus. Eight patients were prescribed with metformin (500 mg twice daily), and four with a fixed dose combination of metformin + glibenclamide (500mg+5mg twice daily), each preparation belonging to one particular brand, for the previous 12 weeks (Group1). Treatment with Insulin was the exclusion criterion. After recording the outcome measure ie; glycosylated haemoglobin (HbA1c) values, the patients were switched over to the respective generic substitutes of these drugs. Concomitant medications were continued as before. At the end of 12 weeks, the patients were tested for HbA1c, and the mean change in the HbA1c from that of the baseline, was calculated. This was compared with the mean change in the HbA1c values measured twice within a gap of 12 weeks, in another set of 12 diabetic patients (Group 2). This group also had eight patients treated with metformin and four with the combination, with a similar dosing schedule of the same brands as group 1 was receiving before entry into the study. No dose adjustments or addition or deletion of drugs had to be made during the 12 weeks of the treatment period, in both groups.

[Table/Fig 1] Baseline characteristics like gender, age distribution and mean HbA1c values were similar across the two groups. At the end of 12 weeks, both groups had a comparable statistically insignificant decrease in HbA1c, suggesting that the generic equivalents are at least as effective as that of their branded counterparts. Meanwhile, patients of group1 could save Rs.90-180/- in three months as a result of conversion to generic antidiabetics. No adverse events were reported in both groups during the 12 week period.

(Table/Fig 1) Patient Characteristics And Outcome Measure - Comparison Between Two Groups.

Variables		Group1(Generic) n=12	Group2 (Branded) n=12	P value
Age (Mean±SD)		64.10±8.3	65.80±8.6	0.634*
Male:Female		4:8	4:8	
HbA1c % (Mean±SD)	Baseline	7.70±1.30	8.41±1.70	0.236*
	End study	7.52±1.50	8.01±1.10	
	Change	0.16±0.87 ($p=0.542)^{\dagger}$	0.40±1.71 ($p=0.435)^{\dagger}$	0.225‡

* Baseline data compared between two groups statistically insignificant by unpaired t test ($p>0.05$).
Change in HbA1c within group† & between groups‡ statistically insignificant by repeated measures ANOVA ($p>0.05$).

Successful diabetes management depends on various factors, including access to the prescribed drug regimen[1] Prescriptions of diabetic patients usually include two or more drugs. The low socio economic status of most

of our diabetic clinic patients, demands a compelling need of a cost effective prescription. Trimming the cost of treatment may help to improve the overall therapeutic outcome of diabetes management in such patients. Barring the limitations of the study design and of small sample size, this preliminary data suggests that the cost of diabetes care can be cut down using generic antidiabetics without compromising on the efficacy. Further large - scale studies are needed to confirm this conclusion.

References

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