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Research Article

COST ANALYSIS OF BRANDED VERSUS GENERIC ANTI-DIABETIC DRUGS USED FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Objectives: This study aims to assess the percentage cost variation among branded anti-diabetic drugs prescribed in a tertiary care hospital with its generic equivalent.

Methods: A cross-sectional study was performed in a tertiary care hospital among 51 diabetic patients attending the endocrinology outpatient department. Demographic data and details of anti-diabetic drugs prescribed were collected from case sheets. Costs of branded anti-diabetic drugs were obtained from the current index of medical specialties April–July 2023 and their generic equivalents from Janaushadhi price list 2023. The percentage cost variation of these drugs per prescription was determined.

Results: The mean age of the patients included in the study was 58.12, with 23 male and 28 female participants. Thirty-eight (74.5%) prescriptions contained oral hypoglycemic agent (OHA) alone, and 12 (23.54%) contained insulin and OHA. Metformin–glimepiride combination was the most common drug prescribed. The mean cost of the branded anti-diabetic drugs per prescription per day was 28.15±13.85 and the estimated mean cost of their generic equivalent was 12.10±6.68. A 135.61% cost variation was observed for the antidiabetic drug prescriptions studied.

Conclusion: In this study, it was observed that there is a significant cost variation among branded and generic anti-diabetic drugs.

Keywords: Anti-diabetic drugs, Cost analysis, Generic drugs, Branded drugs.

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INTRODUCTION

Diabetes is a rising public health issue worldwide. The latest international diabetes federation diabetes Atlas reports that 1 in 10 (10.5%) adults in the world are living with diabetes [1]. The prevalence of diabetes is expected to increase to 643 million (911.35%) by 2030 and to 783 million (12.2%) by 2045, according to the most recent data [1]. Global health expense associated with diabetes was projected to reach 1054 billion USD by 2045, up from an estimated 966 billion USD in 2021 [1,2].

Generic drugs are bioequivalent to branded drugs containing the same active pharmaceutical ingredients, which have the same pharmacological and therapeutic effect but may have different excipients [3]. Generic medicines that have received Food and Drug Administration approval function and pose the same risks and clinical benefits as their brand-name counterparts [3]. Furthermore, it is a well-known fact that branded drugs are costlier than generic ones. In India, Pradhan Mantri Bharatiya Janaushadhi Pariyojana was initiated by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers, and Government of India in 2008 with the goal of producing high-quality generic medications with affordable prices for all [4]. These medicines are made available through dedicated outlets called Jnaushdhi Kendras. In addition, they want to dispel the myth that only expensive drugs are of high quality by raising awareness of generic alternatives through public relations and education [4].

Cost-minimization analysis is a type of pharmacoeconomic analysis that provides the most economic therapeutic option when the effectiveness of two drugs comparing is similar [5]. There are only a few studies conducted on the analysis of cost variation of anti-diabetic drugs in India comparing branded drugs and their generic equivalents obtained from Janaushadhi. If a significant cost variation is identified among the branded drugs and their generic equivalent, a cost-effectiveness analysis will further help to determine the cost-effective alternative in treating type 2 diabetes mellitus (DM). This study aims at a cost analysis of branded and generic anti-diabetic drugs.

METHODS

The study was cross-sectional and conducted in the endocrinology department of Pushpagiri Medical College, Thiruvalla, Kerala, India. The study was carried out for 3 months. Prior approval from the Institutional Ethics Committee was obtained before initiating the study. We included 51 type 2 diabetes patients above 18 years of age who attended the endocrinology outpatient department in the study.

Diabetic patient's prescription information was gathered using a structured proforma following the receipt of their written informed consent. Patient's demographic and clinical details were collected using the proforma. Details of anti-diabetic medications such as brand name, dose, route, and frequency of administration were noted. The cost of the particular brand of the anti-diabetic drug was obtained from the Current Index of Medical Specialties April–July 2023 [6]. The cost of the corresponding generic drug in the same dose and dosage form was obtained from the Janaushadhi price list 2023. The cost of drugs in Indian rupee (INR) for one tablet in a particular brand and its generic equivalent were noted. The mean cost of branded anti-diabetic drugs per day and the mean cost of their generic equivalent were calculated. The percentage cost variation per prescription between the branded and generic anti-diabetic drugs was calculated from the following formulae:

$$\% \text{ cost variation} = \frac{\left(\text{Mean cost of branded drug} - \text{Mean cost of generic drug}\right) \times 100}{\text{Mean cost of generic drug}}$$

RESULTS AND DISCUSSION

Fifty-one anti-diabetic prescriptions were included in the study and all branded anti-diabetic drugs prescribed and their generic equivalent from Janaushadhi were included for analysis.

The mean age of the total 51 patients included in the study was 58.12±12.46, ranging between 30 and 80 years. Male and female participants were 23 and 28 in number, respectively. The participants in the study had an average duration of 7.8±5.89 years of diabetes treatment.

Table 1 shows the number of anti-diabetic drugs per prescription. The majority of prescriptions in the study (52.94%) included two anti-diabetic drugs followed by three anti-diabetic drugs (31.4%).

Fig. 1 shows the distribution of fixed-dose combinations (FDCs), combination therapy, and monotherapy prescribed. Out of the total 51 prescriptions, 42 (82.4%) contained at least one FDC, 6 (11.72%) contained combination therapy without FDCs, and 3 (5.88%) were monotherapy.

Fig. 2 shows the distribution of oral hypoglycemic agents (OHA) and insulin prescribed. Thirty-eight (74.5%) prescriptions contained OHA alone, 12 (23.5%) contained insulin and OHA, and 191.96%) prescriptions contained insulin alone.

Table 1: Number of anti-diabetic drugs per prescription

Number of anti-diabetic drugs per prescription	Frequency (%) (n=51)
1	5.82
2	52.94
3	31.4
4	9.84

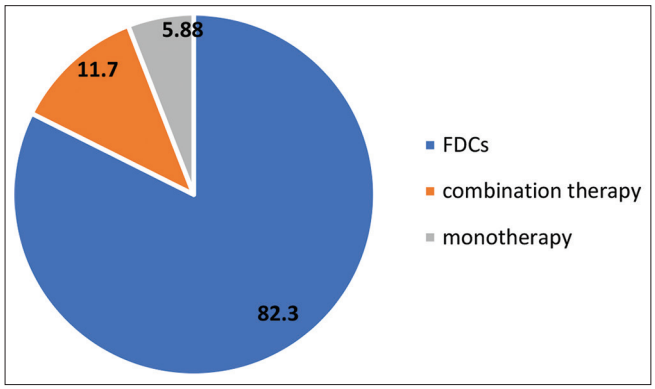

Fig. 1: Number of monotherapy and fixed-dose combinations prescribed

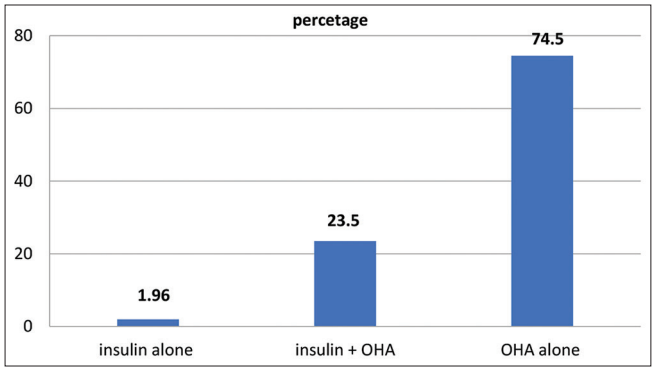

Fig. 2: Number of injections and tablets prescribed

Fig. 3 shows the prescription pattern observed in the study. Metformin–glimepiride combination (68.6%) was the most common drug prescribed followed by dapagliflozin plus vildagliptin (27.45%) and dapagliflozin alone (27.45%). Insulin was prescribed in 25.49% of prescriptions and metformin in 23.52% of prescriptions.

Table 2 shows the cost analysis of the branded and generic anti-diabetic drugs in the prescriptions. One hundred and twenty-four anti-diabetic drugs in the prescriptions were included for cost analysis. The mean cost of branded drugs per tablet was 10.48±4.47 compared to the mean cost of their generic equivalent, that is, 4.68±3.69. The mean cost of the branded anti-diabetic drugs per prescription per day was 28.51±13.85 and the estimated mean of their generic equivalent was 12.10±6.68. A statistically significant ($p<0.0001$) difference was observed between the mean cost of branded and generic anti-diabetic drugs.

About 135.61% cost variation was observed between the mean total cost per prescription of branded drugs and their generic equivalent.

In this study, 51 anti-diabetic prescriptions were analyzed. The cost of each prescription with branded anti-diabetic drugs was compared with the estimated total cost of their generic equivalents from the Janaushadhi Kendra.

The majority of the patients who were part of the study were older than 50. Type 2 DM is often referred to as a disease affecting the adult population as observed by many studies within India [7,8]. Increased incidence at this age could be brought on by stress, change in lifestyle, and inactivity [9]. Increasing age, limited physical activity, central obesity, and high body mass index were found to be the reasons for the increased prevalence of type 2 DM [9]. In this study, diabetes was more common in females (54.9%) compared to males (45.09%). Male predominance was seen in many studies [9,10] whereas similar results were observed in other studies conducted in India [10,13]. Female predominance seen in this study may be due to women being more proactive in our study group for seeking medical care.

The average number of anti-diabetic medications prescribed per prescription was 2.4, which was more than other studies conducted in India [10,11]. This may be due to comorbidities and complications associated with diabetic patients. Since the mean duration of treatment for diabetes in this study was 7.8 years, prescribing more than one drug was tented to achieve glycemic targets.

Out of the 51 prescriptions analyzed, most of them (82.4%) included at least one FDC of OHA. A similar prescribing pattern of FDCs was observed in other studies which reported 56.66% and 71.06% of FDC prescriptions [14,15]. This shows a shifting prescription trend toward FDCs. Prescribing FDCs will reduce the pill burden to the patient and

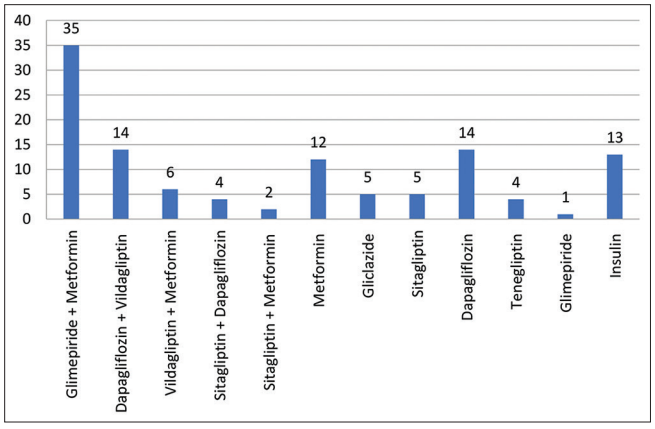

Fig. 3: Prescription pattern of anti-diabetic drugs

Table 2: Mean cost per prescription and percentage cost variation

Drug	Branded drugs	Generic drugs	p-value	Cost variation (%)
Cost per tablet (mean±SD) (n=124)	10.48±4.47	4.68±3.69	<0.0001	123.93
Cost per day (mean±SD) (n=124)	13.49±7.44	5.89±4.68	<0.0001	129.03
Mean total cost per prescription (mean±SD) (n=51)	28.51±13.85	12.10±6.68	<0.0001	135.61

SD: Standard deviation

improve adherence compared with the same combination delivered as separate pills.

In our study population, OHA alone was the commonly prescribed drug accounting for 74.5% of total prescriptions for glycemic control, followed by OHA and insulin combined which contributed 23.54%. Similar outcomes were seen in other studies as well [12,16]. In this study, the FDC of metformin and glimepiride combination (68.6%) was the most commonly prescribed OHA. This shows that most physicians preferred sulfonylureas and biguanides for treating type 2 DM. Similar results were observed in other studies with sulfonylureas and biguanides being the commonly prescribed class of anti-diabetic drugs [8,9,17,18]. The reason for this can be attributed to the effectiveness, safety, and cost-effectiveness of metformin. Metformin is advised as the first line of treatment for type 2 diabetes by several clinical guidelines, including those from the American Diabetes Association and the European Association for the Study of Diabetes [19]. Sulfonylureas are often recommended as second-line or add-on therapy. The study also documented higher prescribing frequency of newer OHA (dipeptidyl peptidase-4 inhibitors and sodium-glucose cotransporter-2 inhibitors). FDC of vildagliptin and dapagliflozin was the second most common FDC prescribed in this study. They were used in combination with other OHAs also, as FDCs, or as single drug to achieve better glycemic control. This increasing trend may be due to the additional benefits that these drugs provide beyond glycemic control, especially for patients with comorbidities.

In this study, the mean cost per prescription per day for a diabetic patient was INR 28.51±13.85. Comparing this to the cost of the generic drugs available at Janaushadhi Kendra, the average cost per prescription per day would have been INR 12.10±6.68. There is a difference in cost per day per prescription for branded and generic drugs. By selecting the most cost-effective medications, prescription cost can be decreased without sacrificing product quality [20]. The cost of prescription is an important factor in chronic illnesses such as diabetes. It can be a reason for non-adherence to therapy and inadequate glycemic control leading to morbidity and mortality.

The present study revealed a cost variation of 135.61% between branded and generic anti-diabetic drugs and hence the generic anti-diabetic drugs cost 135% less than their branded counterparts.

A study done by Yuvanesh and Geetha showed that generic antidiabetic drugs are 0–90% cheaper than branded counterparts [21]. Another study by Mohith *et al*. showed that generic drugs are 10–70% cheaper than branded drugs [22]. Generic drugs are much cheaper compared to branded drugs because they do not require the same level of investment in research and development as new drugs do. Furthermore, generic medicine manufacturers rarely spend money on advertising and marketing. However, the quality of generic medications available at lower prices should also be tested and compared with branded drugs.

CONCLUSION

In our study, it was observed that there is a significant cost variation among branded and generic anti-diabetic drugs. Prescribing generic drugs can significantly reduce the economic burden of the treatment. Physicians should be aware of the cost variation among generic and branded drugs, which may help in choosing the more affordable drug without compromising the quality. However, the effectiveness of branded drugs versus generic drugs in reducing blood sugar levels was not compared. Hence the cost-effectiveness analysis will further help to determine the cost-effective alternative in diabetes treatment.

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AUTHORS' CONTRIBUTIONS

Dr. Liya Roslin Joseph: Concepts, design, definition of intellectual content, literature search, manuscript preparation, and manuscript review. Dr. Sreelakshmi Venugopal: Data analysis, manuscript preparation, and manuscript review. Dr. Sarannya Ravi: Data collection, literature search, data analysis, statistical analysis, manuscript preparation, and manuscript review.

CONFLICTS OF INTEREST

None.

AUTHORS FUNDING

Nil.

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