A STUDY OF COST VARIATION ANALYSIS OF ORAL HYPOGLYCEMIC DRUGS AVAILABLE IN INDIAN PHARMACEUTICAL MARKET

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ABSTRACT

Objectives: A large number of oral hypoglycemic drugs as single or fixed dose combinations are available for the treatment of diabetes mellitus which has a wide range of price variation and becomes a constraint in the treatment for both physician and patient. However, very few studies have been done to reveal such price variations. The objective of this study was to find out the cost variation among the different brands of various classes of oral hypoglycemic drugs in similar strength and dosage forms of single therapy and fixed-dose combinations.

Methods: Cost of a particular drug being manufactured by different companies in the same strength, number, and dosage form was compared from the Current Index of Medical Specialties (CIMS) (January 2022–April 2022) and Indian Drug review 2022. The difference in the maximum and minimum price of the same drug manufactured by different pharmaceutical companies and the percentage variation in price was calculated.

Results: Among single drug therapy, Glimepiride (1 mg) shows a maximum percentage variation in price of 3450%. Among Sulfonylureas-glimepiride (1 mg) shows a maximum price variation of 3450%, in Biguanides–metformin (500 mg), in Thiazolidinediones – Pioglitazone (15 mg) shows a maximum price variation of 900%, and 300%, respectively, and among the glucosidase inhibitors, Voglibose (0.3 mg) shows maximum price variation of 571.2%. Among combination formulation, glimepiride (1 mg) + metformin SR (500 mg) shows a maximum percentage of price variation of 262.1%.

Conclusion: It is observed from our results that there is a wide variation in prices of drugs manufactured by different pharmaceutical companies. Hence, it is very necessary for regulatory authorities to regulate the wide variation in drug prices to maximize the benefits of the treatment. It is recommended that the appraisal and management of marketing drugs should be well-regulated.

Keywords: Diabetes mellitus, Cost variation, Oral hypoglycemic drugs.

INTRODUCTION

According to the International Diabetes Federation, approximately 40.9 million individuals in India are currently affected by diabetes, and this number is projected to increase to 69.9 million by the year 2025. Projections indicate that by the year 2030, the number of diabetes cases in India is expected to surpass 100 million, making it a critical health-care challenge for the nation [1].

As the prevalence of diabetes continues to rise, ensuring affordable access to essential treatments like Oral Hypoglycemic Agents (OHAs) becomes paramount. OHAs form a cornerstone in the management of diabetes, aiding patients in controlling their blood sugar levels and reducing the risk of associated complications. However, the escalating costs of healthcare, including the prices of OHAs, have raised concerns about their affordability and the potential impact on treatment adherence and health outcomes.

The Indian market boasts a vast array of more than 20,000 drug formulations, each marketed under different brand names. Notably, the Indian pharmaceuticals market ranks as the third largest market worldwide in terms of volume and holds the 13 position in terms of value [1]. However, physicians often face challenges when selecting the most suitable drug due to a lack of information on comparative drug prices. This failure to consider variations in the prices of different drug brands poses a dilemma for physicians when selecting the appropriate medication (P-Drug) for individual patients. This situation raises concerns about healthcare expenditure and patient adherence to the prescribed treatment.

Drug pricing plays a crucial role in health-care management and treatment adherence, particularly in developing countries like India. Moreover, it directly impacts the safety and efficacy of medications used for various health conditions, including diabetes [2].

Cost analysis is a form of pharmacoeconomic evaluation that involves comparing the expenses of two or more alternative medications without considering the outcomes. Percentage price variation serves as an effective tool to identify the cost differences between various brands of antidiabetic drugs [3].

The rationale behind this study stems from the pressing need to address the affordability of diabetes treatment in India. Despite the significance of OHAs in diabetes care, there remains a gap in comprehensive research on the cost variation of these agents in the Indian health-care landscape. Our findings can potentially inform health-care policies, improve accessibility to essential diabetes medications, and enhance patient outcomes.

Understanding of the variations in the costs of anti-diabetic medications can pave the way for the development of a more economically viable treatment regimen, fostering enhanced patient compliance and a reduced risk of therapy failure [4].

METHODS

In this study, the authors analyzed oral hypoglycemic drugs in single therapy and fixed-dose combinations. from Current index of medical specialities (CIMS- Jan 2022-april 2022 issue) and the Indian Drug review (issue2).

The cost of a particular oral hypoglycemic drug in the same dose and dosage forms being manufactured by different companies was compared. The difference in the maximum and minimum price of the drugs and the percentage variation in price was calculated.

Drugs that are manufactured by one company only or being manufactured by different companies, in different strengths were excluded from the study. The percentage variation in price was calculated using the following formula: Maximum Price–Minimum Price×100/Minimum Price.

The cost ratio is determined by comparing the price of the most expensive brand to the least expensive brand of the same drug. This ratio provides insight into how many times more expensive the priciest formulation is compared to the cheapest one for the same drug.

To ensure accuracy, certain exclusion criteria were applied, such as excluding drugs manufactured by only one company and those without cost information. In addition, fixed-dose combinations containing more than two antidiabetic agents were also excluded from the study. The statistical analysis involved entering the collected data into Microsoft Excel 2007. Cost ratio and percentage cost variation were then calculated and presented in the form of tables and charts.

RESULTS

In this study, we analyzed the cost of different brands of oral hypoglycemic drugs which include 20 individual drugs and 15 fixed-dose combinations of six different classes of oral anti-diabetic drugs. The percentage cost variation is higher with drugs with a greater number of brands.

Among the different classes of oral hypoglycemic drugs available in the Indian market, the maximum price variation was seen with sulfonylureas, Glimepiride (3450%), followed by Metformin (900%), Voglibose (571.2%), Pioglitazone (300%), Teneligliptin (136.4%). The lowest variation observed was with Glibinclamide 5mg (35.4%) (Fig. 1).

The price variation between sulfonylures is shown in Table 1. In this group, Glimipiride 1 mg showed a maximum price variation of 345%, while Glipizide 5 mg showed a lowest variation of 47.6%. The cost ratio ranged from 1.5 (Glipizide 5mg) to 35.5 (Glimipiride 1mg) (Table 1).

Table 2 shows price variation in Biguanides, Thiazolidiones, and Dipeptidyl peptidase 4 inhibitors group of drugs. Among these, Metformin 500 mg showed a maximum cost variation of 900%. The cost ratio of Metformin ranged from 1.8 (1000 mg SR tablet) to 10 (500 mg). The minimum cost variation was seen with Metformin SP 1000 mg (77%). The cost ratio of Pioglitazone ranged from 3.4 (30 mg) to 4 (15 mg).

Among the α-glucosidase inhibitors, Voglibose 0.3 mg showed the maximum price variation of 571.2% and Acarbose 50 mg showed a minimum price variation of 62.3% (Fig. 2). The cost ratio ranged from 4 to 6.8 for Voglibose 0.2 mg and 0.3 mg.

In the fixed dose combinations, a total of 15 preparations were analyzed. In this, the maximum variation was seen with Glimipiride+Metformin SR (1+500 mg) to be 262.1% while Pioglitazone+Glimeperide (15+2) showed the minimum variation of 6.1% (Table 3).

DISCUSSION

Diabetes, a chronic metabolic disorder, emerging as a significant public health challenge in India, which affects millions of individuals and places a substantial burden on the country's health-care system. Maintaining near-normal levels of glycated hemoglobin significantly reduces the risk of macrovascular and microvascular complications associated with diabetes [4]. Achieving and sustaining excellent metabolic control in diabetes necessitates a combination of lifestyle modifications and pharmaceutical
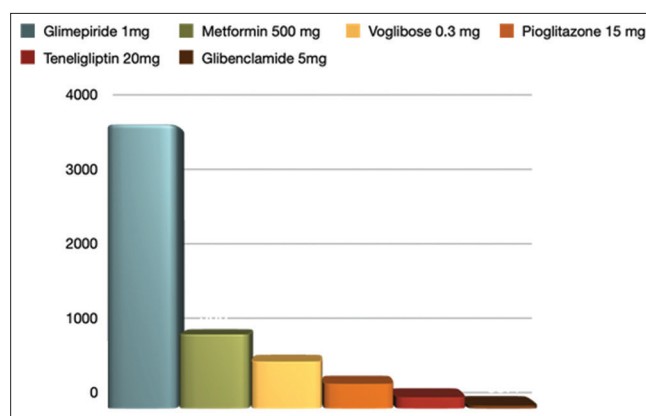

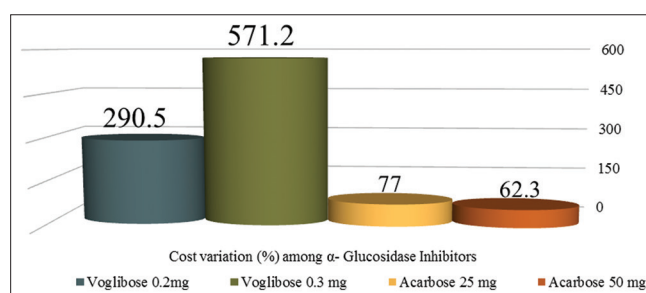**Fig. 1: Cost variation among different oral hypoglycaemic drugs**

Fig. 2: Cost variation among α- Glucosidase Inhibitors

therapy [4]. The objective of the study was to assess the cost and percentage price variation among the various brands of oral hypoglycemic drugs available in the Indian market, prescribing a cost-effective drug will reduce the economic burden on the patient and the healthcare.

The study's findings indicated a substantial disparity in the prices of oral anti-diabetic drugs produced by various companies across different brands, displaying significant variation between the lowest and highest price points. In our study, Glimepiride 1 mg showed maximum price variation of 3450%, followed by Metformin (900%), Voglibose (571.2%), Pioglitazone (300%), and Teneligliptin (136.4%). The lowest variation observed was with Glibenclamide 5 mg (35.4%) among all the 6 classes of OHAs.

However, Hussain found that glipizide 5 mg exhibited the most significant price variation at 780%, followed closely by glimepiride 2 mg at 682% [5]. In another study, Jadhav *et al.* reported that glimepiride 1 mg had the highest price variation, approximately 650% [6]. In addition, Mehani and Sharma revealed that glimepiride 2 mg had the maximum price variation at 562%, with metformin 500 mg following closely at 492% [1]. Shyam and Mahanthegowda found that Glimipiride 1 mg showed a maximum price variation of 1366% followed by Glimipiride 3 mg at 998% [7].

In our study, the maximum price variation was seen with sulfonylureas, Glimepiride 1 mg (3450%), followed by Metformin 500 mg (900%).

In one study, Hussain observed that the combination of glimepiride 1 mg and metformin 500 mg displayed the highest price variation, reaching 533%, compared to all other fixed-dose combinations [5]. In a separate study, Jadhav *et al.* reported that the combination of glipizide 2.5 mg and metformin 400 mg showed the highest price variation, approximately 400% [6]. In our study, the maximum variation was seen with Glimipiride+Metformin SR (1+500 mg) to be 262.1% which is similar to the study by Hussain. The variation in cost analysis results among these different studies can be attributed to the frequent entry of newer brands into the market, often offering distinct formulations.

Table 1: Cost variation among Sulfonylureas

Drug	Formulation	Strength in mg	Least expensive price/tablet (INR)	Most expensive price/tablet (INR)	Cost ratio	Cost variation (%)	No. of brands
Glibenclamide	Tab	5	0.51	1.34	2.7	162.8	6
Glicazide	Tab	30	1.82	8.14	4.5	347.3	4
	Tab	40	1.3	4.1	3.2	215.4	8
	Tab	80	3	8	2.7	166.7	12
Glimepiride	Tab	1	0.6	21.3	35.5	3450	40
	Tab	2	1.08	6.4	6	492.6	42
	Tab	3	4.8	14.1	3	193.8	7
	Tab	4	4.4	16.2	3.7	268.2	13
Glipizide	Tab	5	0.5	0.738	1.5	47.6	4

Table 2: Cost variation among Biguanides, Thiazolidinediones, and DPP-4 inhibitors

Drug	Formulation	Strength in mg	Least expensive price (INR)	Most Expensive Price (INR)	Cost Ratio	Cost variation (%)	No. of brands
Metformin 500 mg	Tab	500 mg	0.4	4	10	900	20
Metformin 1000 mg	Tab	1000 mg	2.95	6.1	2.1	106.8	9
Metformin SR 500 mg	SR	500 mg	1.3	2.5	2	92.4	12
Metformin SR 1000 mg	SR	1000 mg	2.6	4.6	1.8	77	8
Pioglitazone 15 mg	Tab	15 mg	1.5	6	4	300	13
Pioglitazone 30 mg	Tab	30 mg	2.7	9.1	3.4	237.1	12
Teneligliptin 20 mg	Tab	20 mg	5.5	13	2.4	136.4	15

Table 3: Cost variation among fixed dose combinations

Drug	Formulation	Strength in mg	Least expensive price (INR)	Most Expensive Price (INR)	Cost Ratio	Cost variation (%)	no.of brands
Glibenclamide+Metformin (5+500 mg)	Tab	5+500	1.5	5	3.4	233.4	15
Glicazide+Metformin (80+500 mg)	Tab	80+500	4.5	11.6	2.6	157.8	20
Glicazide+Metformin SR (80+500 mg)	SR	80 mg+500	7.5	10.2	1.4	36	2
Glimepiride+Metformin (1+500 mg)	Tab	1+500	2.64	8.1	3.1	206.9	9
Glimepiride+Metformin (2+500 mg)	Tab	2+500	4.7	10.2	2.2	117.1	12
Glimepiride+Metformin (2+1000 mg)	Tab	2+1000	8.6	11.83	1.4	37.6	4
Glimepiride+Metformin SR (1+500 mg)	SR	1+500	2.4	8.69	3.7	262.1	30
Glimepiride+Metformin SR (2+500 mg)	SR	2+500	4.5	15.73	3.5	249.6	31
Glipizide+Metformin (5+500 mg)	Tab	5+500	1.16	1.7	1.5	46.6	5
Pioglitazone+Metformin (15+500 mg)	Tab	15+500	3.64	8.4	2.4	130.8	6
Pioglitazone+Metformin SR (15+500 mg)	SR	15+500	4	8.34	2.1	108.5	4
Pioglitazone+Metformin SR (30+500)	SR	30+500	5.8	8.62	1.5	48.7	4
Pioglitazone+Glimepiride (15+2)		15+2	6.6	7	1.1	6.1	3
Voglibose+Metformin (0.2+500 mg)	Tab	0.2+500	5	7.24	1.5	44.8	5
Voglibose+Metformin (0.3+500)	Tab	0.3+500	6.6	11.9	1.9	80.4	5

The National Pharmaceutical Pricing Authority, under the Government of India, regulates drug prices in the Indian market. It determines the maximum price (ceiling price) of a drug based on its essentiality, and pharmaceutical companies are required to set the prices of their products at or below this ceiling price for the respective formulations. However, any medicine listed under the drugs prices control order cannot be sold at a cost higher than the price fixed under this order [8].

Pharmaceutical companies are enticing physicians with lucrative incentives while promoting their brands [9]. In India, the majority of physicians prescribe drugs using brand names and often lack awareness of alternative brands and the significant price variations that exist among them [10]. Regulating the prices of these commonly used drugs is an urgent necessity that falls on the government's shoulders [11-13].

Furthermore, providing physicians with a comprehensive drug manual containing details about the different available brands and their respective prices would be beneficial. Such a resource would be helpful in increasing awareness among physicians and enabling them to make more informed prescribing decisions.

Non-compliance is a prevalent issue among patients, as the cost of medications often becomes a hindrance, leading them to stop taking their prescribed drugs. This aspect significantly impacts the patient's health, contributing to higher morbidity and mortality rates. Encouraging the prescription of cost-effective drugs can help enhance treatment adherence, ultimately leading to better patient outcomes [14].

This study's strength lies in its use of information from both CIMS and IDR, encompassing both single and combination therapies for oral anti-diabetic drugs. However, a notable limitation is that the analysis did not include certain miscellaneous oral anti-diabetic drugs and Insulin.

CONCLUSION

Our study showed a high price variation among OHAs by different brands available in the Indian market. As diabetes is a chronic debilitating illness; compliance with the treatment of a condition that demands lifelong management can be influenced by several factors. Among them, the cost of medication assumes a crucial role in determining long-term adherence.

Creating awareness among physicians, pharmaceutical companies, and regulatory bodies about the significant price variation is imperative

to reduce drug costs and make medications more affordable for the general population.

AUTHORS CONTRIBUTION

Conceptualization and drafting were done by: Dr. Florance Joy and Dr. Stephen Nand. Editing done by: Dr. J. L. Marko.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare. All coauthors have seen and agree with the contents of the manuscript and there is no financial interest to report.

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