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A Comprehensive Cost Variation Analysis of Drugs Used in the Management of Type-2 Diabetes Mellitus Across India

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ABSTRACT

Background: This study aims to examine the cost variations of oral antidiabetic agents in India, highlighting the financial barriers that may impact patient adherence and treatment efficacy.

Methods: This analytical study was performed by analysing the prices of 18 oral antidiabetic drugs with 42 formulations. Data was collected from the National Pharmaceutical Pricing Authority (NPPA) platform, focusing on single-drug tablet formulations. Price variations were assessed using cost ratios and percentage cost variations. Compliance with the Drug Price Control Order (DPCO) ceiling prices were also analysed.

Results: The study revealed significant price variations among different brands of the same drug, with voglibose 0.3 mg exhibiting the highest cost ratio (1:139.92) and percentage variation (13892.30%). Additionally, a notable proportion of brands exceeded the DPCO ceiling prices, particularly metformin 1000 mg, where 9 out of 15 brands were non-compliant to the ceiling price.

Conclusion: Despite the presence of a regulatory authority, substantial price variability among oral antidiabetic agents persists in India, potentially affecting patient adherence and health outcomes. The violations of DPCO pricing regulations indicate a need for stricter enforcement and expansion of price controls to ensure the affordability of essential medications and improve overall patient care.

Keywords: Cost variation analysis, Antidiabetic agents, Drug Price Control Order, Diabetes Mellitus.

Introduction

Diabetes mellitus (DM) is a group of metabolic disorder characterized by abnormally high blood glucose levels. It includes various forms such as type 1, type 2, maturity-onset diabetes of the young (MODY), gestational diabetes, neonatal diabetes, and secondary types caused by conditions like endocrinopathies or steroid use (1). The global prevalence of diabetes has sharply increased since 1980, rising from 108 million to 422 million by 2014, particularly in low- and middle-income countries. Africa's prevalence grew from 3.1% to 7.1%, while countries like China, India, and the U.S. have the largest diabetes populations. Type 2 diabetes (T2DM) is the most common, with type 1 (T1DM) comprising about 5% of cases. In the U.S., diabetes prevalence doubled between 1980 and 2012, with many cases undiagnosed. The incidence of T2DM continues to rise globally, while T1DM incidence varies by region (2).

Diabetes places a substantial economic burden on healthcare systems, patients, and society due to its chronic nature and complications like cardiovascular disease and neuropathy, which increase healthcare costs. Both direct medical expenses and indirect costs, such as lost productivity and disability, contribute significantly. As diabetes prevalence rises globally, particularly in low- and middle-income countries, addressing this burden is essential for effective healthcare resource allocation and public health strategies (3). Effective drug therapy is essential in managing DM to control blood glucose levels and reduce the risk of complications, particularly cardiovascular disease (CVD), which is the leading cause of death in patients with type 2 diabetes. In addition to managing hyperglycemia, drug therapy plays a key role in addressing other CVD risk factors such as hypertension, dyslipidemia, and obesity (4). However, medication costs can significantly impact adherence. A US survey revealed that 11% of patients had limited their medications due to cost, and many patients do not discuss these issues with their healthcare providers, highlighting the need for improved communication and cost-conscious treatment strategies (5).

The aim of this study is to examine the cost variations of oral antidiabetic agents in India, as substantial price variations across different brands and formulations can impact patient adherence and treatment efficacy. By analysing these cost differences, the study seeks to highlight the financial barriers faced by patients and promote more cost-effective prescribing practices. This is particularly relevant in India, where the affordability of long-term diabetes management is a critical factor in improving patient outcomes and reducing the burden of diabetes complications.

Methods

This analytical study, conducted from August to September 2024, examined the prices of 18 oral antidiabetic drugs across 42 different formulations. Price data for each drug (per 10 tablets), in the same strength and dosage form but produced by various manufacturers, was gathered from "Pharma Sahi Daam", an openly accessible platform provided by the National Pharmaceutical Pricing Authority (NPPA). Ceiling prices for these medications were sourced from the NPPA's Integrated Pharmaceutical Database Management System 2.0 (IPDMS 2.0) price list for 2024, implemented under the Drug Price Control Order (DPCO). The study used unit prices for all formulations, as the DPCO regulates ceiling prices per unit in Indian Rupees (INR). Anatomical Therapeutic Chemical (ATC) classification codes were obtained from the World Health Organization's ATC/DDD Index 2024. Only single-drug tablet formulations were included, while drugs produced by a single manufacturer and fixed-dose combinations were excluded from the analysis. The minimum and maximum costs, total number of brands for each formulation were analysed. The cost ratio, which compares the highest to the lowest cost of the same drug produced by different pharmaceutical companies, was calculated by

$$Cost\ ratio = \frac{Maximum\ cost}{Minimum\ cost}$$

The percentage cost variation between the maximum and minimum prices was calculated by

$$\%\ Cost\ variation = \frac{(Maximum\ cost - Minimum\ cost)}{Minimum\ cost} \times 100$$

The percentage of brands with prices exceeding the DPCO ceiling price was calculated for each drug formulation as follows:

$$\frac{Number\ of\ brands\ having\ ceiling\ prices\ more\ than\ DPCO\ ceiling\ price}{Total\ number\ of\ brands} \times 100$$

Microsoft Excel Office 2021 was used for the statistical analysis throughout the study.

Result

This study analysed the prices of various oral antidiabetic agents marketed in India, revealing significant price variations across brands. The highest cost ratio (1:139.92) and the highest percentage cost variation (13892.30%) were observed for voglibose 0.3 mg, followed by acarbose 50 mg [(1:37.61) and (3661.75%)] and glimepiride 1mg [(1:27.28) and (2628.88%)]. Similarly, the minimal cost ratio (1:1.01) and minimal percentage price variation (1.33%) was found in bromocriptine 0.8 mg. (Table 1)

The drug with the highest number of brands available in the Indian market is found to be teneligliptin 20 mg, which has 112 brands, followed by glimepiride 1 mg which has 86 brands. Conversely, the drugs with the least number of brands, each with only 2 available formulations, are found with bromocriptine 0.8 mg, canagliflozin 300 mg, glibenclamide 2.5 mg, glipizide 2.5 mg, and miglitol in both 25 mg and 50 mg strengths. (Table 2)

The highest price violation was observed with metformin 1000 mg, where 9 out of 15 brands were sold above the DPCO recommended price, followed by glimepiride 2 mg with 40 out of 79 brands exceeding the DPCO ceiling price. (Table 3).

Discussion

The Indian pharmaceutical market is largely controlled by branded generics, with numerous companies marketing the same medication under different brand names which results in a vast selection of pharmaceutical products, estimated to range between 60,000 and 70,000, which causes considerable price differences among the drugs available in the market (6). This study highlights significant price variations among various brands of oral antidiabetic agents like voglibose 0.3 mg (13892.30%), acarbose 50 mg (3661.75%) and so on in Indian market which is similar to the findings of Thacker et al., who finds that there is a wide variation in prices between branded and generic formulations of oral antidiabetic medications (7). Cost variations significantly affect patient medication adherence, particularly in chronic conditions like diabetes. Nonadherence due to higher medication costs results in poor clinical outcomes, including increased complications, hospitalizations, and overall healthcare costs (8).

In addition to cost variations, several factors contribute to poor adherence including the financial burden of medication costs and travel expenses, complex treatment regimens, long waiting times at pharmacies, and the emotional well-being of patients (9). Studies indicate that 17.6% of patients are noncompliant, and many miss clinic appointments due to these burdens. In India, cultural beliefs also play a role, with some individuals preferring traditional remedies over prescribed medications, further contributing to nonadherence and complications such as diabetic neuropathy. Addressing these barriers by reducing medication costs can improve adherence, leading to better health outcomes and reduced healthcare expenses (10).

Understanding the factors that contribute to cost variations in pharmaceutical expenditures is crucial for addressing adherence challenges. These factors include changes in drug quantities and therapies, the introduction of new drugs, the impact of educational and managerial strategies, and the regulation of marketing practices. Other key determinants involve the therapeutic categories of medications, the release of generic drugs, and the patterns of drug diffusion (11).

Furthermore, this study found that almost all the brands violated the DPCO ceiling prices, despite the existence of a department responsible for regulating them. Additionally, a large number of drugs are not even included in the DPCO schedule. The DPCO list of price-controlled drugs initially included Glimepiride and Metformin, with Teneligliptin added later. Despite these additions, many antidiabetic agents remain unscheduled, and even for scheduled drugs, there are significant discrepancies and pricing violations. These ongoing issues highlight the challenges in effectively controlling drug prices and ensuring compliance, as numerous brands continue to exceed the established ceiling prices (12).

This study has several strengths, including a comprehensive analysis of price variations

among oral antidiabetic agents in the Indian pharmaceutical market, effectively highlighting significant cost disparities that can impact patient adherence. The inclusion of a broad sample of medications provides valuable insights into the pricing landscape. However, the study also has limitations, such as potential bias in data collection and the exclusion of fixed-dose combinations of oral antidiabetic agents.

Conclusion

In our country, despite having a regulatory body to monitor pharmaceutical pricing, there remains a considerable variation in the cost of oral antidiabetic agents across different manufacturers. Although there are strict penalties for companies that surpass the established price limits, many brands continue to violate these regulations. As a result, the efforts of the DPCO to reduce medication costs have not been fully effective. To address this, there is a need for stricter enforcement and enhanced monitoring of drug prices. It also suggests expanding price controls to cover non-scheduled drugs to make essential treatments more affordable. Further research in other therapeutic areas is crucial to uncover pricing discrepancies and promote stronger governmental oversight.

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Author contribution

The author confirms sole responsibility for the study conception, design, data collection, analysis and interpretation as well as the drafting and revision of the manuscript.

Conflict of interest

The authors confirm that the content of the article has no conflict of interest.

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Tables

Table 1: Variation in price of oral antidiabetic agents

Name of the drug	Strength	Pack size	Minimum cost	Maximum cost	Cost ratio	% cost variation
Acarbose	25 mg	10	4.9	9.8	2	100
	50 mg	10	3.19	120	37.61	3661.75
Bromocriptine	0.8 mg	10	7.5	7.6	1.01	1.33
	1.25 mg	10	7.8	14	1.79	79.48
	2.5 mg	10	11.77	27.65	2.34	134.91
Canagliflozin	100 mg	10	59	65.2	1.10	10.50
	300 mg	10	145	177	1.22	22.06
Dapagliflozin	5 mg	10	1.3	21.2	16.30	1530.76
	10 mg	10	4.4	30	6.81	581.81
Empagliflozin	10 mg	10	15	53.4	3.56	256
	25 mg	10	18	64.7	3.59	259.44
Glibenclamide	2.5 mg	10	0.57	0.74	1.29	29.82
	5 mg	10	0.41	5	12.19	1119.51
Gliclazide	40 mg	10	2.15	6.8	3.16	216.27
	80 mg	10	3	16.13	5.37	437.66
Glimepiride	1 mg	10	0.45	12.28	27.28	2628.88
	2 mg	10	1.11	15.63	14.08	1308.10
	3 mg	10	3.55	17.57	4.94	394.92
	4 mg	10	2.41	21.53	8.93	793.36
Glipizide	2.5 mg	10	0.25	0.49	1.96	96
	5 mg	10	0.46	1.3	2.82	182.60
Linagliptin	5 mg	10	2.7	30.9	11.44	1044.44
Metformin	250 mg	10	0.98	2	2.04	104.08
	500 mg	10	0.77	9	11.68	1068.83
	850 mg	10	1.49	4.39	2.94	194.63
	1000 mg	10	2.5	4.53	1.81	81.2
Miglitol	25 mg	10	4.8	12.57	2.61	161.87
	50 mg	10	10.29	20.53	1.99	99.51
Pioglitazone	7.5 mg	10	3.27	10.6	3.24	224.15
	15 mg	10	1	13.5	13.5	1250
	30 mg	10	4.4	13.3	3.02	202.27
Repaglinide	0.5 mg	10	3.81	9.75	2.55	155.90
	1 mg	10	10.45	15.94	1.52	52.53
	2 mg	10	14.9	25.46	1.70	70.87
Sitagliptin	25 mg	10	4.9	7	1.42	42.85
	50 mg	10	3.5	14	4	300
	100 mg	10	6.5	19.9	3.06	206.15
Teneligliptin	20 mg	10	3.11	18.62	5.98	498.71
Vildagliptin	50 mg	10	3.18	18	5.66	466.03
	100 mg	10	11	15	1.36	36.36
Voglibose	0.2 mg	10	1.06	25.11	23.68	2268.86
	0.3 mg	10	0.13	18.19	139.92	13892.30

Table 2: Total number of brands and formulations in oral antidiabetic agents

Oral antidiabetic agents	WHO ATC code	Formulations	Strength	No. of Brands
Acarbose	A10BF01	2	25 mg	5
			50 mg	10
Bromocriptine	G02CB01	3	0.8 mg	2
			1.25 mg	3
			2.5 mg	3
Canagliflozin	A10BK02	2	100 mg	3
			300 mg	2
Dapagliflozin	A10BK01	2	5 mg	54
			10 mg	72
Empagliflozin	A10BK03	2	10 mg	6
			25 mg	6
Glibenclamide	A10BB01	2	2.5 mg	2
			5 mg	9
Gliclazide	A10BB09	2	40 mg	11
			80 mg	24
Glimepiride	A10BB12	4	1 mg	86
			2 mg	79
			3 mg	18
			4 mg	28
Glipizide	A10BB07	2	2.5 mg	2
			5 mg	8
Linagliptin	A10BH05	1	5 mg	29
Metformin	A10BA02	4	250 mg	7
			500 mg	48
			850 mg	10
			1000 mg	15
Miglitol	A10BF02	2	25 mg	2
			50 mg	2
Pioglitazone	A10BG03	3	7.5 mg	8
			15 mg	34
			30 mg	17
Repaglinide	A10BX02	3	0.5 mg	5
			1 mg	4
			2 mg	4
Sitagliptin	A10BH01	3	25 mg	4
			50 mg	41
			100 mg	46
Teneligliptin	A10BH08	1	20 mg	112
Vildagliptin	A10BH02	2	50 mg	37
			100 mg	3
Voglibose	A10BF03	2	0.2 mg	76
			0.3 mg	82

Table 3: DPCO price variation in oral antidiabetic agents

Oral antidiabetic agents	Strength	Maximum price	DPCO price 2024	No. of Brands violating DPCO price	Brands (%) with price > DPCO
Glimepiride	1 mg	12.28	3.7	39	45.34 %
	2 mg	15.63	5.8	40	50.63 %
Metformin	500 mg	9	2.02	21	43.75 %
	1000 mg	4.53	3.49	09	60 %
Teneligliptin	20 mg	18.62	11.09	51	45.53 %

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