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Assessing the Economic Value of Statins: A Comparison of Branded and Generic Options in India

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Introduction

Cardiovascular diseases (CVDs) are responsible for over half (52%) of all premature deaths worldwide, accounting for more than 17.5 million deaths annually[1]. Dyslipidemia is a major risk factor for cardiovascular diseases, with hypercholesterolemia being the most common form. The primary characteristic of dyslipidemia is elevated low-density lipoprotein (LDL) cholesterol, which is associated with an increased risk of cardiovascular disease, particularly in individuals with atherosclerotic cardiovascular disease (ASCVD)[2]. Consequently, one of the most widely adopted strategies in clinical practice for treating and preventing ASCVD is lowering LDL cholesterol levels[3]. Statins are currently the first-line treatment for reducing LDL cholesterol in most clinical situations[4].

Research indicates that in high-risk populations, statins can lower the likelihood of heart attacks by around 25-30%.[5] This reduction in cardiovascular events leads to improved health outcomes, including a better quality of life and fewer hospital admissions, thereby reducing the overall burden on healthcare systems.

Statins are categorized further based on their potency in reducing LDL-C levels. High-intensity statins, such as Atorvastatin at doses of 40-80 mg and Rosuvastatin at 20-40 mg, can lower LDL-C by about 50%. These are recommended for patients with a high risk of cardiovascular events, such as those with a history of heart attack, stroke, or established atherosclerotic cardiovascular disease (ASCVD). Moderate-intensity statins, including Atorvastatin 10-20 mg, Rosuvastatin 5-10 mg, Simvastatin 20-40 mg, and Lovastatin 40 mg, typically reduce LDL-C levels by 30-50%. Used in patients with moderate cardiovascular risk, including those with diabetes, certain age groups, or those who cannot tolerate high-intensity statins. Low-intensity statins, such as Simvastatin 10 mg, Pravastatin 10-20 mg and Lovastatin 20 mg, can lower LDL-C by less than 30%. Prescribed for patients with lower cardiovascular risk or those who experience side effects from higher doses.[6,7]

These drugs are competitive inhibitors of HMG CoA reductase. Statins work by inhibiting HMG-CoA reductase, an enzyme crucial for cholesterol synthesis in the liver. By reducing

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low-density lipoprotein (LDL) cholesterol levels, statins help lower the risk of atherosclerosis and subsequent cardiovascular events such as heart attacks and strokes.

The availability of multiple brand-name and generic drugs leads to significant variation in their selling prices. This creates confusion for prescribers, healthcare providers, and consumers when choosing a suitable product at an affordable price. Price variations in drugs used regularly by a large population can have significant economic implications and may affect patient compliance, especially for those whose income is heavily spent on treatment.[8]

The Indian pharmaceutical market is one of the largest and fastest-growing in the world, driven by increasing healthcare needs, a growing population, and expanding access to medicines. Despite its growth, the Indian pharmaceutical sector faces challenges, including regulatory hurdles, pricing pressures, and competition from international markets.[9]

With this background, we decided to start by collecting all the relevant information about various statins available in the market and evaluate the cost to find the ratio between the minimum and maximum value and calculate the percentage cost variation between the brands. We also compare brand-name statins versus their generic equivalents in terms of cost. This analysis will focus on identifying the price differences between the two, evaluating the potential cost savings that generics offer while maintaining similar therapeutic outcomes. The goal is to determine whether generics provide a more cost-effective option for patients and healthcare systems without compromising quality.

Methodology:

The study focuses on the market analysis of drug pricing for hypolipidemic medications and does not involve any clinical intervention. Therefore, the protocol is exempt from Institutional Ethics Committee review. The study was conducted over a period of 3 months. Cost of a particular statins and its combinations in the same strength and dosage forms being manufactured by different companies was obtained from latest “Current Index of Medical Specialties (January – April 2024), 1mg online pharmacy and janaushadhi website, as they are readily available source of drug information and are updated regularly. After going through all relevant online pharmacies, we found 1mg to have information about maximum number of brands and so we continued with that platform.

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Steps for this study:

1. For this study, we searched for all the brand names and generics of specific statins and its combinations of a particular strength and dosage form.
2. Then we checked the number of brands available on the website and MIMS.
3. We checked the number of generic drugs available on the website.
4. The cost of 10 tablets/capsules was taken for our study.
5. We tabulated the number of brands/generics along with the minimum and the maximum cost that we found by sorting the data on the website.
6. The costs of individual drugs, as well as those in combination or fixed-dose combination (FDC) tablet and capsule forms, have been separately tabulated.
7. Cost ratio between the maximum and minimum cost of the same drug manufactured by different pharmaceutical companies [branded and Generics] was calculated as follows:

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

8. Percentage cost variation was calculated as follows: [branded versus Generics]

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

9. We compared cost ratio of branded versus generics.

Results:

Table 1: Maximum and Minimum cost, Cost ratio and Percentage cost variation of Branded Statins.

Drug	Doses	Formulations	Min cost (Rs)	Max cost (Rs)	Cost difference	Cost ratio	% cost variation

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Atorvastatin	5mg	5	19	72.6	53.6	3.82	282.10
	10mg	7	4	104	100	26	2500
	20mg	3	21	513	492	24.42	2342.8
	40mg	2	161	243	82	1.50	50.93
	80mg	1	246	488	242	1.98	98.37
Rosuvastatin	5mg	3	20	93.3	73.3	4.66	366.5
	10mg	4	29	194	165	6.68	568.96
	20mg	4	35	318	283	9.08	808.57
	40mg	1	60	497	437	8.28	728.33
Lovastatin	10mg	1	24.8	74.7	49.9	3.01	201.20
	20mg	1	46.5	126	79.5	2.70	170.96
Simvastatin	5mg	2	36	78	42	2.16	116.66
	10mg	1	55	118	63	2.14	114.54
	20mg	2	311	338	27	1.08	8.68
Pravastatin	10mg	2	96	107	11	1.11	11.45
Fluvastatin	40mg	1	288	288	0	1	0
	80mg	1	327	327	0	1	0
Pitavastatin	1mg	1	94	94	0	1	0
	2mg	2	199.8	292	92.2	1.46	46.14

Table 1 shows the economic comparison of branded statins, with atorvastatin 10 mg having the highest percentage cost variation at 2500%, followed by atorvastatin 20 mg at 2342%.

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Simvastatin 20 mg showed the lowest variation at 8.68%, indicating significant price differences among the statins.

Table 2: Maximum and Minimum cost, Cost ratio and Percentage cost variation of Branded Statin Combinations.

Drug	Strength	Formulations	Min cost (Rs)	Max cost (Rs)	Cost difference	Cost ratio	% cost variation
Atorvastatin +Ezetimibe	10+10 mg	2	39	258	219	6.61	561.5
Atorvastatin +Aspirin	10+75mg	4	21	78	57	3.71	271.4
Atorvastatin +Aspirin	20 + 75mg	2	31	143	112	4.61	361.2
Atorvastatin +Aspirin	20 + 150mg	2	17	77	60	4.52	352.9
Atorvastatin +Clopidogrel	10+75mg	3	38.7	196	157.3	5.06	406.4
Aspirin+ Atorvastatin +Clopidogrel	75+10 +75mg	3	65	211	146	3.24	224.6
Aspirin+ atorvastatin +Clopidogrel	75+20+75	3	71	231	160	3.25	225.35
Rosuvastatin +Aspirin	10+75mg	2	33	236	203	7.15	615.1

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Rosuvastatin +Clopidogrel	10+75mg	2	56.2	253	196.8	4.50	350.1
Rosuvastatin +Aspirin+ Clopidogrel	10+75+75 mg	2	42	154	112	3.66	266.66
Rosuvastatin +Aspirin+ Clopidogrel	20+75+75 mg	2	132	239	107	1.81	81.06

Table 2 presents an economic comparison of branded statin fixed-dose combinations (FDCs). Among the 11 FDCs analyzed,Rosuvastatin 10 mg + Aspirin 75 mg exhibited the highest percentage cost variation at 615.1%, highlighting a substantial price disparity for this combination in the market.

Table 3: Comparison between Generic price, minimum and maximum price of branded statin.

Drug	Strength	Generic price [A]	Min cost (Rs)	Max cost (Rs) [B]	Cost difference [B-A]
Atorvastatin	5mg	8.4	19	72.6	64.2
	10mg	5.60	4	104	100
	20mg	9.70	21	513	492
	40mg	18.00	161	243	82
	80mg	35	246	488	242
Rosuvastatin	5mg	9.46	20	93.3	73.3
	10mg	11.20	29	194	165
	20mg	27.34	35	318	283

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	40mg	44	60	497	453
Simvastatin	10mg	9.99	55	118	63
	20mg	12.80	311	338	27

Table 3. compares the price ranges of generic statins with the minimum and maximum prices of branded statin combinations, highlighting the price disparities between generics and branded options.

Table 4: Comparison between Generic price, minimum and maximum price of branded Statin Combinations.

Drug	Strength	Generic Price [A]	Min cost (Rs)	Max cost (Rs) [B]	Cost difference [B-A]
Atorvastatin +Ezetimibe	10 + 10 mg	25	39	258	233
Atorvastatin +Aspirin	10 + 75 mg	12.75	21	78	65.25
Atorvastatin +Aspirin	20+75 mg	14.2	31	143	128.8
Atorvastatin +Aspirin	20+150 mg	16.66	17	77	60.34
Atorvastatin +Clopidogrel	10+75 mg	29.21	38.7	196	166.79
Aspirin+ Atorvastatin +Clopidogrel	75+10+75mg	39	65	211	172
Aspirin+ Atorvastatin +Clopidogrel	75+20+75mg	43	71	231	188
Rosuvastatin +Aspirin	10+75 mg	18	33	236	218

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Rosuvastatin +Clopidogrel	10+75mg	27.70	56.2	253	225.3

This table highlights the price variations between generic and branded statin combinations, comparing the cost range of branded versions with the corresponding generic alternatives.The minimum and maximum costs for branded statins are provided, along with the generic price, highlighting the potential cost savings when opting for generics.

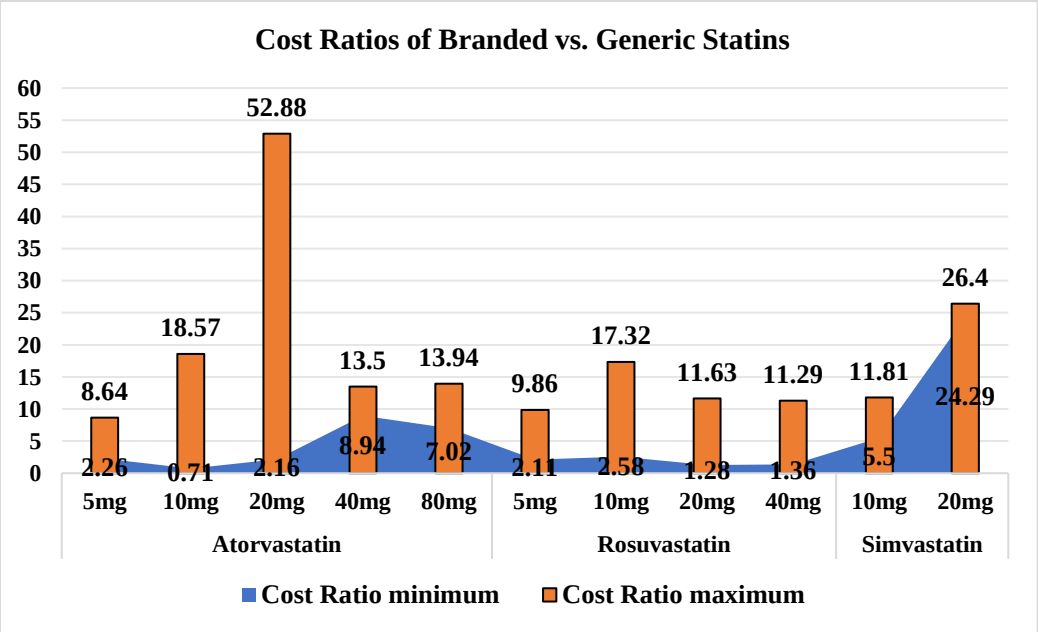

Fig 1: Compares Maximum and Minimum Cost Ratios of Branded vs. Generic Statin. Atorvastatin 20 mg has the highest maximum cost ratio of 52.88, making the branded version nearly 53 times more expensive than the generic. The minimum cost ratio for 40 mg Atorvastatin is 8.94,with the cheapest branded option being almost 9 times costlier than its generic equivalent. Rosuvastatin 10 mg exhibits a maximum ratio of 17.32, with consistently low minimum ratios across all doses. Simvastatin 20 mg shows a cost ratio range of 24.29 to 26.4, reflecting less variation compared to Atorvastatin.

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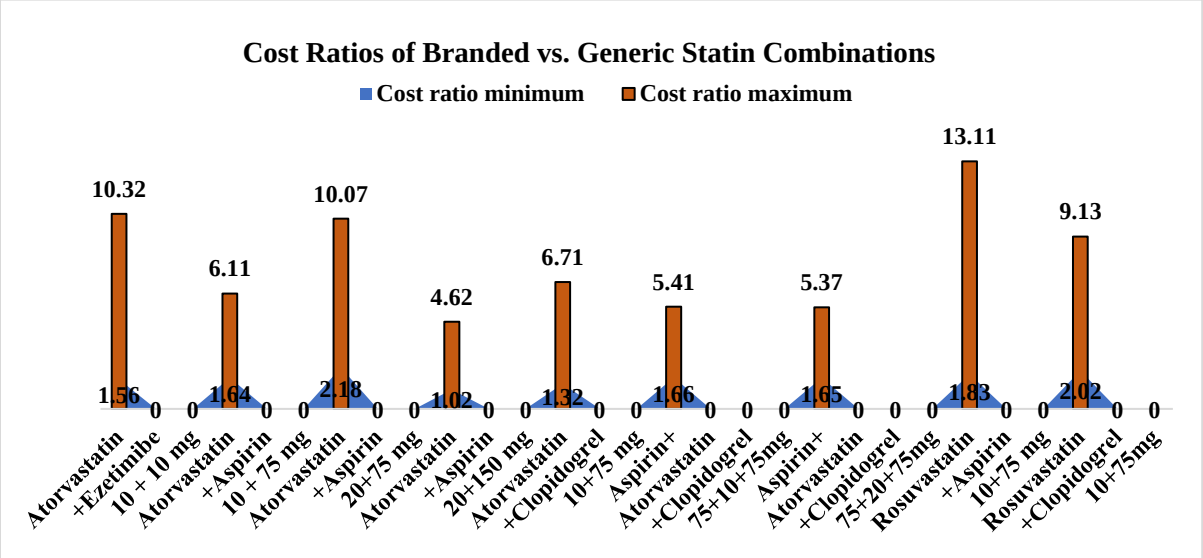

Fig 2: Compares Maximum and Minimum Cost Ratios of Branded vs. Generic Statin Combinations. Rosuvastatin combinations, particularly Rosuvastatin + Aspirin 10 mg + 75 mg, show the highest cost ratio of 13.11, while Atorvastatin + Ezetimibe has a ratio of 10.32. Atorvastatin 20mg + Aspirin 150 mg combinations at 4.62, exhibit lower cost ratios, indicating smaller price differences. Overall, Rosuvastatin combinations show the largest cost disparities.

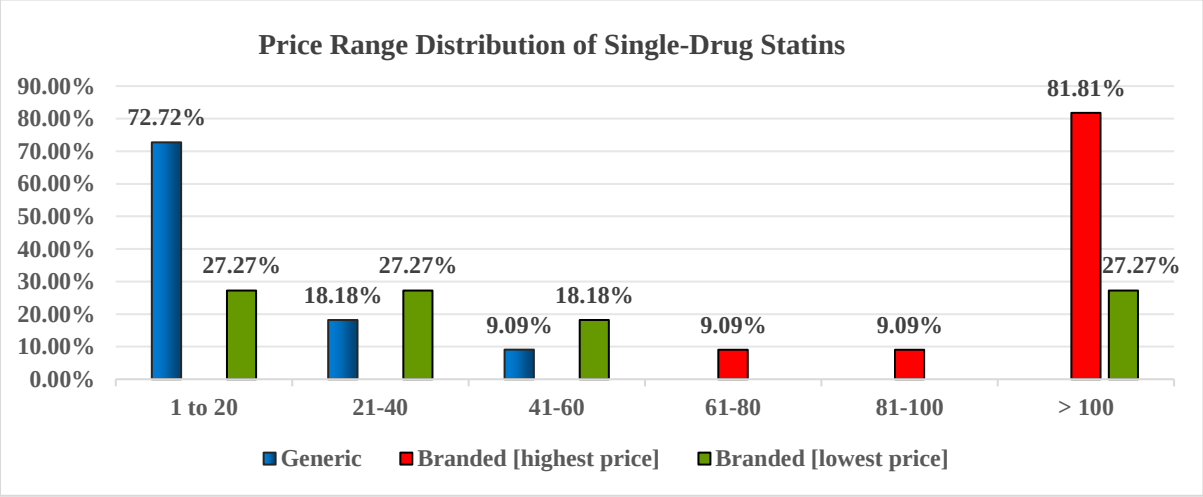

Fig.3 illustrates the price range distribution of single-drug statins. A significant majority, 72.72%, of generic statins fall within the 1 to 20 price range. In contrast, 81.81% of branded statins, particularly those at the highest price, are priced above 100, indicating a large disparity in pricing. Branded statins at the lowest price are more evenly distributed across the price ranges, with 27.27% in the 21-40 range and 9.09% in higher ranges.

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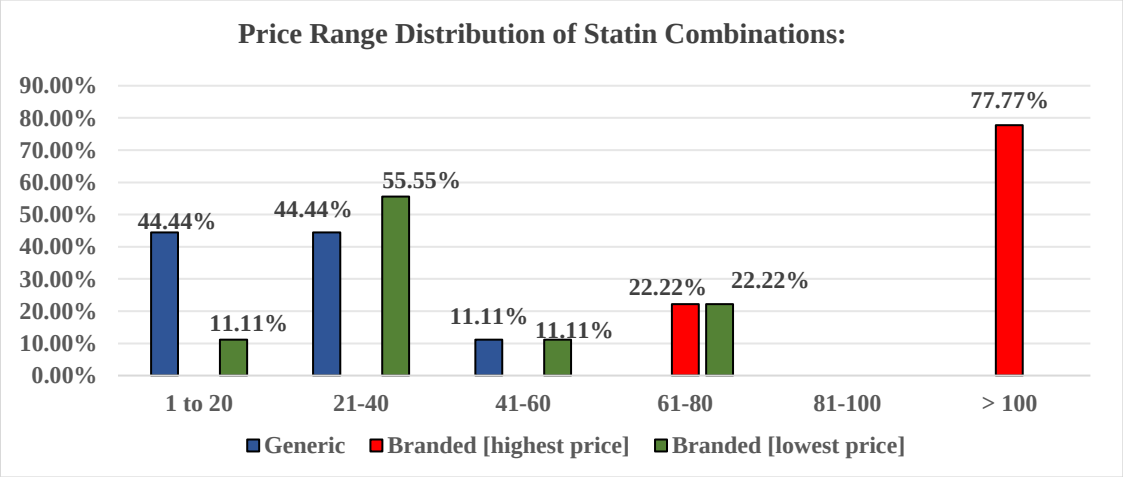

Figure 4 shows the price distribution of statin combinations. Generic statins are more evenly spread across price ranges, with 44.44% falling within the 1-40 range. In contrast, 77.77% of branded statins are priced above 100, highlighting a significant price disparity.The lowest-priced branded statins are mostly within the 21-40 range.

Discussion:

The study findings show that the average cost of branded medications was greater than that of generic medications, consistent with results from earlier research.[10]

A total of 7 single hypolipidemic drugs and 11 FDC showed a wide per cent cost variation. Our analysis showed a very high fluctuation in the minimum and maximum price of hypolipidemic drugs. The cost ratio was also observed to be high. The percentage variation in the cost was above 100% with most of the commonly used hypolipidemic drugs and also with combination form of hypolipidemic drugs.

The highest percentage of cost variation was atorvastatin 10 mg (2500%) followed by atorvastatin 20 mg (2342%), whereas Simvastatin 20 mg showed the lowest percent cost variation (8.68%). Similar results were found as per study done by Ujjawal Rawat et.al [11] and Kalita *et al.*[12] where atorvastatin 10mg (3668.50%), (3043.93%) had the highest cost variation percentage of single hypolipidemic drugs followed by atorvastatin 20mg (3293.90%), (1757.14 %). The study done by Shinde and Khushwah [13] found Atorvastatin 80mg to have the highest cost variation percentage (3284%). Minimum cost variation percentage of single hypolipidemic drugs is Atorvastatin 40mg (50.93%) in our study.[Table 1]

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Among 11 FDCs studied, cost variation was highest for Rosuvastatin 10mg + Aspirin 75mg (615.1%) which is in consistent with findings of Kalita et al.[12](561.341%). Maximum cost variation of FDCs in studies done by Shinde et al. was atorvastatin 10mg + ezetimibe 10 mg (484%). [Table 2]

In our study we found that minimum price of branded formulation of Atorvastatin 10 mg (4 INR) is less than the generic price (5.60 INR). On the other hand, the minimum generic price of atorvastatin 5mg was observed by Kushwah and Shinde et.al.[13] to be greater than the minimum branded price by 60.7%.

When we compared the generic prices of various hypolipidemics with their maximum branded price, it was found that the maximum cost difference was seen in Atorvastatin 20 mg (492). These findings are consistent with those reported by Kalita et al.[12] [Table 3]

We found that minimum price of branded formulation of Atorvastatin +Aspirin 20mg+150 mg (17 INR) is almost equal to the generic price (16.66 INR). When we compared the generic prices of various FDC's of hypolipidemics with their maximum branded price, it was found that the maximum cost difference was seen in Atorvastatin +Ezetimibe 10 + 10 mg (233). [Table 4] Moreover, single atorvastatin and its combination with ezetimibe, is also being produced by highest number of pharmaceutical companies. This finding may be due to the fact that atorvastatin is one of the most widely prescribed hypolipidemic drug and earlier studies have also demonstrated highest cost effectiveness of atorvastatin over other statins.[14]

Atorvastatin has the highest cost disparity between branded and generic versions, with a ratio of up to 52.88. In comparison, Rosuvastatin and Simvastatin show more moderate cost differences. Rosuvastatin combinations have the highest cost disparity, while Atorvastatin combinations show smaller variations. [Fig1.]

72.72% of generic statins are priced between 1 to 20, while 81.81% of branded statins at the highest price are over 100. Branded statins at the lowest price are more evenly distributed across various price ranges.[Fig3.] Generic statins combinations are broadly distributed across price ranges, with 44.44% falling in the 1-40 range. In contrast, 77.77% of branded statins combinations exceed 100, while the least expensive branded options are primarily priced between 21-40. [Fig 4]

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Generic drugs are essentially copies of brand-name medications that contain the same active ingredients, dosage forms, and strength. They undergo rigorous testing to ensure they meet the same quality standards as the branded counterparts, including bioequivalence, meaning they work in the body in the same way and provide the same clinical benefit. [15]

The lower price of generics is largely due to the fact that manufacturers do not have to invest in the costly research and development or marketing that is required for brand-name drugs.[16] Despite these benefits, many physicians hesitate to prescribe generics due to concerns about variability in inactive ingredients, which may affect tolerability, and the perception that a lower price equates to lower quality. [17] Additionally, patients may express doubts or experience confusion when transitioning from a well-known brand to a less familiar generic version, especially for long-term medications like those used for chronic conditions.[18,19]

Expensive medications remain competitive despite cheaper generic alternatives due to brand loyalty and perceived superiority in efficacy or safety. Patients and physicians often trust established brands, while pharmaceutical companies reinforce this through strong marketing and relationships with healthcare providers. These factors influence prescribing patterns, allowing branded drugs to retain market share, even when generics offer similar therapeutic benefits.

The Drug Price Control Order (DPCO) regulates drug prices in India, ensuring they don't exceed set limits. However, only a few hypolipidemic drugs are included, causing price variations between brands. More hypolipidemic drugs should be added to the DPCO to reduce cost differences.

Physicians often lack awareness of drug price variations. By considering patients' financial situations and prescribing more affordable generics, doctors can offer better care. A study by Frazior et al.[20] showed that providing a manual of comparative drug prices improves prescribing practices.

CONCLUSION

Our study suggests that more hypolipidemic drugs should be included under the DPCO to ease the financial burden on patients. Promoting generics, which offer the same efficacy at lower costs, can enhance treatment adherence and improve overall health outcomes. Achieving the WHO’s "Health for All" goal requires collaboration among healthcare

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providers, pharmaceutical companies, the government, and the public. Cost analysis studies like ours can guide physicians in making informed therapeutic decisions and promoting rational, generic prescribing.

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