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Original Research Article

Cost variation analysis of statins available in India

Ashika Arka Gopalakrishna¹, Noah M. Bose²*, Sharon M. Stanly²

¹Department of Pharmacy, Karavali College of Pharmacy, Mangalore, Karnataka, India ²Department of Pharmacy, Karavali College of Pharmacy, Mangalore, Karnataka, India

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***Correspondence:** Dr. Noah M. Bose, Email: nmb7bose@gmail.com

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ABSTRACT

Background: The current study aimed to find out the percentage cost variation among the various brands of statins marketed in India. Statins are HMG-CoA reductase inhibitors which are widely prescribed as blood cholesterol lowering agents and hence reduce illness and mortality in those who are at high risk of cardiovascular disease. There are numerous brands of statins are marketed in India.

Methods: Cost of a particular drug manufactured by different companies in the same strength and the dosage form was obtained from the price list provided by the pharmaceutical companies in current index of medical specialities (CIMS) (42nd year January to April 2021). The difference in the maximum and the minimum price of the same drug manufactured by different pharmaceutical companies, cost ratio and the percentage variation in price were analysed. **Results:** The percentage cost variation of statins was seen highest with tablet atorvastatin 20 mg (564.06%), followed

by combination of capsule atorvastatin 10 mg+aspirin 75 mg (325%) which was followed by combination of film coated tablet atorvastatin 10 mg+fenofibrate 160 mg (267.4%), tablet rosuvastatin 20 mg (171.1%), tablet lovastatin 10 mg (108.9%), combination of tablet rosuvastatin 10 mg+fenofibrate 160 mg (87.34%) and lowest was seen with tablet simvastatin 20 mg (6.0%).

Conclusions: There is a very wide cost variation among different brands of statins marketed in India. The percentage cost variation was found to be the highest among the moderate intensity statins.

Keywords: Brands, Cost variation, Cost ratio, Statins

INTRODUCTION

Statins are HMG-CoA reductase inhibitors. HMG-CoA reductase is a key enzyme in cholesterol biosynthesis and inhibition of this enzyme decreases the cholesterol synthesis. By inhibiting the cholesterol synthesis, statins lead to increased hepatic low density lipoprotein receptor activity as a counter regulatory mechanism and thus accelerated clearance of circulating low density lipoproteins (LDLs), resulting in a dose dependent reduction in plasma levels of low density lipoprotein cholesterol. The magnitude of LDL lowering associated with statin treatment varies widely among individuals, but once the patient is stabilized on statins, the doubling of the

statin dose produces an approximately 6% further reduction in the levels of plasma LDL cholesterol. Statins also reduce the triglycerides in a dose dependent fashion, which is roughly proportional to their LDL cholesterol lowering effects. Statins have modest high density lipoprotein (HDL) raising effect (5-10%) and is not generally dose dependent.¹

Different HMG-CoA reductase inhibitors are currently available in the market. According to the report by the American college of cardiology (ACH)/American heart association (AHA) task force on practice guidelines, statins are classified as follows.²

High intensity statin lower LDL cholesterol ≥50%	Moderate intensity statin lowers LDL cholesterol by 30- 50%	Lower intensity statin lower LDL cholesterol <30%	
Atorvastatin 40-80 mg	Atorvastatin 10-20 mg	Simvastatin 10 mg	
Rosuvastatin 20-40 mg	Rosuvastatin 5-10 mg	Pravastatin 10-20 mg	
	Simvastatin 20-40 mg	Lovastatin 20 mg	
	Pravastatin 40-80 mg	Fluvastatin 20-40 mg	
	Lovastatin 40 mg	Pilastatin 1 mg	
	Fluvastatin 80 mg		

Table 1: The ACH/AHA classification of statins.

Since statins are one of the most commonly prescribed medication, there are numerous brands of statins marketed in India and they vary widely in terms of cost, where brands of drugs are costly, generics are sold at a very less price. For a drug class such as the statins with enormous prescriptions, the price variation tend to be large even among the generics.³

Physicians often make prescriptions for drugs even though there are cheaper alternatives for the same in the hospital formulary leading to unnecessary extra financial burden on the patients.^{4,5} In a country like India where the majority of the healthcare expenses are borne out of pocket by the patients, reducing the cost of the prescription can have a large potential for improving the overall health care outcomes.⁶ About 65% of the Indian population do not have access to essential medicines.⁶ It is obvious that the cost of drugs play an important role in the long term compliance to the treatment because in India majority of the population is not covered by any insurance, leading to non-adherence and poor overall health outcomes.^{7,8} Therefore it is imperative to have an understanding of the variability in pricing among the different generics provided by the different companies in order to select the most cost effective therapy for the patient. This will have a significant impact on the long term compliance and the overall healthcare outcomes.

This study was undertaken to assess the cost variation among the different generics of statins with the same drug strength and formulation sold bv different pharmaceuticals.

METHODS

The prices of different preparations of statins (atorvastatin, lovastatin, simvastatin, rosuvastatin) marketed in India were reviewed from the CIMS 42nd year January to April 2021. The price per tablet/capsule was calculated in Indian rupee (INR). Drug formulation/s manufactured by single company and the drug preparation for which price was not mentioned were excluded from analysis. The difference in the most expensive and least expensive statin for a particular formulation sold by different companies were calculated. The percentage cost variation was calculated as per the following formula.^{9,10}

Percentage	2	cost
veriation_	(most expensive price-least expensive price)	× 100
variation_	least expensive price	× 100.

Since the study was not of a clinical nature and involved only the assessing of the market price variation of the different formulations of statins, obtaining prior ethical permission was exempted.

RESULTS

A large percentage cost variation was identified among the various formulations of statins marketed by various manufacturers. Cost variation was also high for formulations with a greater number of manufacturers.

Drug names	Dosage form	Dose (mg)	Maximum price (INR)	Minimum price (INR)	Percentage cost variation (%)	Number of manufacturers
Atorvastatin	Tab	5	9.02	1.7	429.41	7
		10	7.87	2.70	189.25	40
		20	17.00	2.56	564.06	33
		40	18.93	8.9	112.69	11
		80	32.15	17.99	78.71	5
	Fc-tab	5	5.89	1.70	246.47	9
		10	5.76	2.55	126.23	12
		20	14.70	4.98	195.18	12

Continued.

Drug names	Dosage form	Dose (mg)	Maximum price (INR)	Minimum price (INR)	Percentage cost variation (%)	Number of manufacturers
		40	20.29	7.90	156.77	10
		80	53.25	11.73	353.96	6
		5	8.5	3.2	161.53	23
	Tab	10	13.30	5.7	133.4	31
	Tab	20	26.84	9.9	171.5	23
Rosuvastatin	· · · · · · · · · · · · · · · · · · ·	40	29.20	10.99	165.69	7
Kosuvastatiii		5	8.72	5.28	65.15	4
	Fc-tab	10	15.53	8.55	81.6	4
		20	24	16.6	44.5	4
		40	44.5	43.8	1.59	2
Lovastatin	Tab	10	7.50	3.59	108.9	3
Lovastatiii	1 a0	20	12.50	7.9	58.22	3
Simvastatin	Tab	5	6.21	6.20	0.16	2
		10	10.71	9.70	10.41	2
		20	16.39	15.46	6.01	2

Tab-tablet, Fc-tab-film coated tablet.

Table 3: Price variation in drug combination with atorvastatin.

Drug names	Dosage form	Dose (mg)	Maximum price (INR)	Minimum price (INR)	Percentage cost variation (%)	Number of manufacturers
	Tab	10+10	16.59	4.94	235.82	14
Atorvastatin+ ezetimibe	Tab	20+10	23.75	14.5	67.84	2
ezetiinide	Fc-tab	10+10	18.30	7.10	157.74	5
	Tab	10+160	20.73	5.80	257.41	11
Atorvastatin+ fenofibrate	Tab (micronized fenofibrate)	10+160	33.00	20.84	58.34	2
	Fc-tab	10+160	18.34	5.00	267.40	5
	Fc-tab	10+200	14.52	8.20	77.07	2
Atorvastatin calcium+ enofibrate	Tab	10+160	9.90	6.95	42.44	2
Atorvastatin+ aspirin	Cap	10+75	8.5	2.0	325	5
Atorvastatin+	Cap	10+75+75	5.88	4	47	2
aspirin+ clopidogrel	Cap	20+75+75	7.97	5.4	47.59	2

Tab-tablet, Fc-tab-film coated tablet, Cap-capsule.

Table 4: Price variation in drug combination with rosuvastatin.

Drug names	Dosage form	Dose (mg)	Maximum price (INR)	Minimum price (INR)	Percentage cost variation (%)	Number of manufacturers
Rosuvastatin +fenofibrate	Tab	10+160	18.55	9.9	87.34	12
	Tab	10+145	14.80	11.90	24.36	5
	Tab	5+145	12.50	11.39	9.74	2
	Tab	5+67	10.75	10.40	3.36	2
	Tab	10+67	19.30	15.73	22.69	3
Rosuvastatin+ aspirin	Cap	10+75	6.90	6.00	15	2
Rosuvastatin+ vitamin D3	Tab	10+1000 IU	16.46	14.70	11.97	2

Tab-tablet, Cap-capsule.

The percentage cost variation was seen highest with tablet atorvastatin 20 mg (564.06%) which had a total number of 33 manufacturers, followed by tablet atorvastatin 5 mg (429.41%) with 7 manufacturers. For combination products, the largest percentage cost variation was for capsule atorvastatin 10 mg+aspirin 75 mg (325%) with a total of 5 manufacturers followed by film coated tablet atorvastatin 10 mg+fenofibrate 160 mg (267.40%) with 5 manufacturers. The lowest percentage cost variation was found for tablet simvastatin 5 mg (0.16%) with 2 manufacturers. The highest percentage cost variation among the rosuvastatin formulations was for tablet rosuvastatin 40 mg (165.69%) with 7 manufacturers. For simvastatin, the largest percentage cost variation was 10.47% for the 10 mg tablet with a total number of 2 manufacturers and for lovastatin, the largest percentage cost variation was 108.9% for the 10 mg tablet with a total number of 3 manufactures. Film coated atorvastatin 80 mg was the most expensive formulation marketed by a company in our analysis with a percentage cost variation of 353.96%.

DISCUSSION

Statins are the most effective, well tolerated and most commonly prescribed oral hypolipidemic drugs that lowers the blood cholesterol and hence reduces illness and mortality.¹¹ Due to the likelihood of the need for life long usage of these drugs, price consideration became an important issue. This affected not only patient's quality of life, but also imposed huge economic burden to family and society.^{12,13} As a consequence of India being one of the global generic drugs manufacturing leader, a large number of companies produced a single formulation as a result of which large cost variations can arise. Therefore, a large number of formulations were available for same drug at different prices. If the cost was too high, patient's adherence to the prescribed treatment regimen may decline.^{14,15} Statins were commonly prescribed to patients with cardiovascular disease dyslipidaemia, obesity and for people having risk factors for the development of cardiovascular diseases making it historically the drug class with the largest pharmaceutical sales.^{16,17} Cost related non adherence was a widely recognized clinical problem with serious health consequence for the patient and economic consequence for health care system.^{18,19} Previous research, mostly from the United States, had shown that such cost-related non-adherence to treatment was widespread.^{20,21} Also, in India, health insurance schemes were significantly underutilized and majority of the health care costs were afforded by the patient itself.²² Hence consideration of cost effectiveness for the majority of Indian patient while prescribing statins was highly advisable.

A study done by Shukla et al 2016 using CIMS as data source, it was observed that the highest cost variation was seen with atorvastatin 20 mg followed by atorvastatin 10 mg and atorvastatin 5 mg. In fixed dose combination, highest percentage cost variation was observed with atorvastatin 20 mg+ fenofibrate 160 mg, followed by atorvastatin 10 mg+ezetimibe 10 mg and atorvastatin 20 mg+ezetimibe 10 mg.²³

The national pharmaceutical pricing authority (NPDA) regulated the cost of drugs marketed in India.²⁴ It released a National list of essential medicines (NLEM) from time to time that was included in the drug pricing control order (DPCO), latest being in 2019. The list included ceiling prices of 847 formularies under the DPCO 2013 exclusive of goods and services tax (GST).²⁵ With respect to statins, only three formulations were included in the list (tablet atorvastatin 10 mg, 20 mg and 40 mg) with a maximum ceiling price of INR 5.37, 13.00 and 18.88 respectively. Whereas in this study atorvastatin 10 mg, 20 mg and 40 mg, have maximum prices rupees 7.87, 17.00 and 18.93 respectively. Even after accounting for the GST of 5%, the maximum price of tablet atorvastatin 10 mg and 20 mg surpassed the ceiling price set by the government.

The pricing information from DPCO and reference text such as CIMS can guide physicians and prescribers to develop their own personal drug list containing the most cost effective drugs list.²⁶ Prior experience of the prescriber and good clinical judgement should also play an important role in the creation of the drug price list along with the price.^{27,28} This when implemented in a large enough scale can have huge potential in terms of improvement of compliance and health care outcomes. Currently, only three formulations of statins have been included in the DPCO list provided by the government.²⁵ The inclusion of more formulations of statins, especially the film coated tablets, in the list would help in further regulating the pricing of these drugs and eventually have a positive impact on reducing the large cost variation.

CONCLUSION

The study showed a large amount of cost variation calculated in terms of percentage cost variation for different formulations of statins that were marketed by different companies. Although the selection of the right drug for the patient should always be the at the discretion of a qualified physician, it may be highly advisable to be aware of the variability in the cost of the same product being prescribed to the patient in order to make the most informed and cost effective prescription choice.

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