# Analysis of cost variation among various statin preparations available in India

# Padmavathi Vutukuru<sup>1</sup>, Kranti Tekulapally<sup>2,\*</sup>

<sup>1</sup>Professor and Head, <sup>2</sup>Assistant Professor, Dept. of Pharmacology, Malla Reddy Medical College for Women, Suraram, Hyderabad, Telangana, India

### \*Corresponding Author: Kranti Tekulapally

Email: dr\_t\_kranti@yahoo.com

### Abstract

**Introduction:** Hyperlipidemias are recognized as one of the major risk factors for the development of Coronary Artery Disease (CAD). Statins are the most potent lipid lowering agents currently available that significantly lower the morbidity and mortality associated with CAD.

Aim: To compare the cost of various statins of different brands by calculating the percentage variation of cost.

**Materials and Methods:** Prices of different statin preparations per 10 tablets/ capsules in rupees were reviewed from Drug today April-June 2018 issue and www.drugsupdate.com for analysis. Maximum and minimum price difference of the same drug manufactured by different pharmaceutical companies was calculated. Percentage variation was calculated as per the following formula

Percentage variation In cost =  $\frac{\text{Price of most expensive brand} - \text{Price of least expensive brand}}{\times 100}$ 

#### Price of least expensive brand

Drug formulations manufactured by only one company and those whose price could not be obtained from the sources were excluded from analysis.

**Results:** Maximum companies are manufacturing single drug atorvastatin 10mg (192) and atorvastatin 5 mg + ezetimibe 10mg (40). Highest percentage variation in cost is found with atorvastatin 5 mg (900%) and in atorvastatin 10mg + amlodipine 5 mg (1488%).

**Conclusion:** There is wide variation in the cost of various statins available in India, which increases the economic burden on patients. Government of India should take more consumer friendly steps to control the cost of drugs. Physicians should maintain a P-drug list and prescribe low cost and effective drugs to improve compliance to drug therapy and ensure effective treatment of the disease.

Keywords: Statins, Cost variation, Hyperlipidemias.

# Introduction

Statins are the most effective and well-tolerated agents for dyslipidemia. These drugs are competitive inhibitors of HMG CoA reductase, an enzyme which catalysis the early, rate limiting step in Cholesterol biosynthesis. Inhibition of HMG CoA reductase enzyme leads to significant reduction in Low Density Lipoprotein Cholesterol (LDL-C) and there by decrease the development of adverse cardiovascular events. Depending on their ability to lower LDL-C levels, statins are classified into High intensity statins and Medium intensity statins. High intensity statins that includes Atorvastatin 40-80mg and Rosuvastatin 20-40mg lower the LDL-C by approximately 50% while the medium intensity statins namely Atorvastatin 10-20 mg, Rosuvastatin 5-10 mg, Simvastatin 20-40 mg and Lovastatin 40mg lower the LDL-C in the range of 30-50%. According to 2013 ACC/AHA guidelines, Medium to High intensity statins are prescribed for individuals with clinically evident atherosclerotic cardiovascular disease, LDL- C levels > 190mg/dl, individuals 40 to 70yrs of age with diabetes and LDL -C 70 to 189 mg/dl and for individuals without any clinically evident cardiovascular disease and diabetes; for whom the calculated 10yr cardiovascular disease risk is >7.5%.<sup>1</sup> The use of statins significantly lowered the risk of fatal and non-fatal CVD events, strokes and total mortality in high-risk patients such that the concept of threshold LDL-C that must be exceeded to initiate the statin therapy is abandoned bringing in more number of individuals who have to be prescribed statins for a long term.<sup>2</sup> For patients

with known cardiovascular diseases, statins may be combined with other lipid lowering agents niacin, ezetimibe and fenofibrate to meet the lipid targets. For patients with hyperlipidemias and Hypertension, antihypertensive drugs like amlodipine and ramipril are combined with statins. Statins are prescribed to diabetic patients to treat secondary hyperlipidemias. Combinations of statins with oral hypoglycemic drugs are available in the market to decrease pill burden and improve drug compliance. One important factor that will determine the compliance and the effectiveness of long-term treatment regimens for hyperlipidemias is the cost of drug therapy.<sup>3</sup>

There is an avalanche of brands of statins available in Indian pharmaceutical market leading to wide variations in the price for the same drug. Some brands are very costly while some generic drugs are available at very low cost. Improper knowledge about the cost of different brands of the same drug may lead to difficulties in prescribing most cost effective treatment regimen to the patient.

This study was therefore initiated to investigate the cost variation in different brands of statins by calculating the percentage variation in cost to ensure rational prescription by Physicians and also rational consumption by patients.

# Materials and Methods

The prices of different preparations of statins namely Lovastatin, Atorvastatin, Simvastatin, Pravastatin and Rosuvastatin were reviewed from Drug today (Jan – Feb 2018 issue) and www.drugsupdate.com. The price was calculated per 10 tablets/ per 10 capsules in rupees. Drug formulations manufactured only by single company and the drug preparations for which price could not be found from the source were excluded from analysis. Maximum and minimum price difference of the same drug manufactured by different pharmaceutical companies was noted. The Percentage variation was calculated as per the following formula.<sup>4</sup>

#### Percentage variation in cost =

 $\frac{\text{Price of most expensive brand} - \text{Price of least expensive brand}}{\text{Price of least expensive brand}} \times 100$ 

The results obtained are expressed in tables for each drug. Since this study deals with the market analysis of the drug pricing of statins, and involves no clinical studies, the protocol is exempted from Institutional Ethics Committee review.

#### Results

The present study shows that there is wide variation in the prices of various brands of statins available in the market.

Table 1: Price variation in different statin preparations

Maximum companies (192) are manufacturing atorvastatin 10mg followed by atorvastatin 20mg (140) and rosuvastatin 10mg (38). Highest price variation is seen with atorvastatin 5 mg (900%) followed by atorvastatin 20mg (847%) while minimum price variation is seen with atorvastatin 80mg (88%). Only two companies are manufacturing pravastatin 10mg and 20mg and there is negligible price variation in these brands (0-1%). (Table 1).

In the fixed dose combinations of statins, maximum combinations are available with atorvastatin. Highest number of companies (39) are manufacturing atorvastatin 10mg + ezetimibe 10mg. Maximum price variation is found for atorvastatin 10mg + amlodipine 5mg (1488%) followed by atorvastatin 10mg + ezetimibe 10mg (267%). (Table 2)

Among the drug combinations available with simvastatin and rosuvastatin, maximum price variation is seen with simvastatin 5mg + nicotinic acid 125mg (31%) (Table 3) and rosuvastatin 10mg + fenofibrate 160mg (165.33%) (Table 4). There were no drug combinations available with lovastatin and pravastatin.

Drug Name	Dosage form	Dose	No. of manufacturing	Minimum	Maximum	Percentage	
-	_		companies	price	price	variation	
Lovastatin	Tablets	10mg	18	25	120	380	
		20mg	22	45.25	210	364	
Atorvastatin	Tablets	5mg	45	9	90	900	
		10mg	194	15	118.50	690	
		20mg	140	19	180	847	
		40mg	32	79	280	254	
		80mg	6	169	318	88	
Simvastatin	Tablets	5mg	15	11.15	61.85	455	
		10mg	22	22.29	98.75	343	
		20 mg	19	33.45	210	528	
Pravastatin	Tablets	10mg	2	99	100	1	
		20mg	2	165	165	0	
Rosuvastatin	Tablets	5 mg	28	23	160	595	
		10 mg	38	47	259	451	
		20mg	23	99	400	304	
		40 mg	4	300	399	33	

#### Table 2: Price variation in drug combinations with Atorvastatin

Drug Combination	Dosage	Dose	No. of	Minimum	Maximum	Percentage
	from		manufacturing companies	price	price	variation
Atorvastatin + Aspirin	Capsules	10mg+ 75mg	13	17	85	100
	Tablets	10mg+ 75mg	3	17	85	100
Atorvastatin + Aspirin	Capsules	10mg+ 150 mg	4	18	25	39
Atorvastatin + fenofibrate	Tablets	10mg+160mg	23	58	171	195
Atorvastatin + Amlodipine	Tablets	10mg +5 mg	15	38.50	611.50	1488
Atorvastatin + Ezetmibe	Tablets	10mg + 10 mg	39	38.50	141.50	267
Atorvastatin + Ezetimibe	Tablets	5mg + 10mg	2	80	99	24
Atorvastatin + Clopidogrel	Capsules	10mg + 75mg	2	105	120	14
Atorvastatin + Nicotininc acid	Tablets	10mg + 500mg	3	87.50	98	12
Atorvastatin + Ramipril + Aspirin	Capsules	10mg + 5 mg+ 75 mg	4	28	95	240
Atorvastatin + Glimepride + Metformin	Tablets	10  mg + 2  mg + 500  mg	2	69	83.50	21

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Drug Combination	Dosage from	Dose	No. of manufacturing companies	Minimum price	Maximum price	Percentage variation
Simvastatin + Ezetimibe	Tablets	10mg+ 10mg	4	57	68	19
Simvastatin + Nicotinic acid	Tablets	5mg + 125mg	3	45	59	31

Table 3: Price variation in drug combinations with Simvastatin

### Table 4: Price variation in drug combinations with rosuvastatin

Drug Combination	Dosage from	Dose	No. of manufacturing companies	Minimum price	Maximum price	Percentage variation
Rosuvastatin + Ezetimibe	Tablets	10mg+ 10mg	3	123	170	38.21
Rosuvastatin + Fenofibrate	Tablets	10 mg+ 67mg	3	110	142.30	29.36
	Tablets	10mg + 145 mg	6	120	160	33.33
	Tablets	5 mg + 145 mg	3	89	110	23.6
	Tablets	10 mg + 160 mg	9	75	199	165.33
	Tablets	5 mg + 160 mg	3	75	104	39
	Tablets	5 mg + 134 mg	2	85	98.50	16

# Discussion

Statins are the most commonly prescribed hypolipidemic drugs that characteristically decrease the incidence of adverse cardiovascular events. In India, more than one pharmaceutical company sell statins under different brand names along with the innovator company. Hence, a large number of formulations are available for same drug at different prices. It is irrational to prescribe expensive drugs when cheaper drugs are available.

Patient adherence to treatment is often determined by the cost of drugs. According to WHO, 'Rational use of medicines requires that the patients receive medications appropriate to their clinical needs in doses that meet their own individual requirements for an adequate period of time, and at lowest cost to them and to their community'.<sup>5</sup> If the cost is too high, patients may not adhere to prescribed medications particularly people with chronic illnesses, low incomes and those who do not have insurance.<sup>6</sup>

In the light of above facts, we initiated this study to assess the cost variation amongst various brands of statins available in India. The results of the present study revealed that most of the pharmaceutical companies are manufacturing atorvastatin (5 mg and 20 mg) with maximum price variation. Among the drug combinations, maximum price variation is seen with Atorvastatin 10 mg and amlodipine 5 mg, whereas most of the companies are manufacturing Atorvastatin 5 mg and ezetimibe 10 mg. However, the results of such cost variation studies usually vary from time to time.

A study done by Shukla et al (2016) using Current Index of Medical Specialties (CIMS) as data source reported highest cost variation with atorvastatin 20 mg followed by atorvastatin 10 mg and atorvastatin 5 mg. In fixed dose combinations, highest cost ratio and percent cost variation

was found for atorvastatin 20 mg+ fenofibrate 160 mg, followed by atorvastatin 10 mg + ezetimibe 10 mg, and atorvastatin 20 mg + ezetimibe 10 mg.<sup>7</sup>

The main reason for such price variation in India is the pricing policy for medicines.<sup>8</sup> The National Pharmaceutical Pricing Authority (NPPA) regulates the cost of drugs marketed in India. It releases a National List of Essential Medicines (NLEM) from time to time that is included in the Drug Pricing Control Order (DPCO); latest being in 2015.9 This list contains 348 medications and 841 formulations. Among the statins, only three namely atorvastatin 10 mg, atorvastatin 20 mg and atorvastatin 40 mg are included with maximum ceiling price of Rs.5.15, 12.47 and 18.11 per tablet respectively.<sup>10</sup> Inclusion of more statins in the NLEM will help to regulate their prices and reduce the cost variation. Also, there is need to develop more consumer friendly policies to regulate the cost of the branded- generics marketed making them more affordable to the people of India.

Physicians are required to be aware of the drug cost through medical literature and drug advertisements, which will enable them to prepare their personal drug (P-drug) list, with a set of drugs for regular use in practice. One of the important criteria to select a P drug is the cost of the medication or treatment<sup>11</sup> and independent of who pays for it - state or insurance companies or by the patient themselves. For patients who are on polypharmacy and for treatment of chronic diseases, affordability determines the adherence to drug therapy. Non-adherence to the prescribed treatment regimen leads to poor clinical outcomes, which then increase acute health care service utilization and overall health care costs.<sup>12</sup> We therefore suggest that every physician need to select his preferred/personal drug (Pdrug) keeping in mind the cost of statins. This would ensure the rule of rights for rational use of drug- the right drug, to the right patient, in right dosage and at a right cost.

# Conclusion

The present study shows that there is a wide variation in the cost of statin preparations available in Indian market. There is a need to develop more policies to regulate the cost of the branded- generics marketed making them more affordable to the people of India. Physicians should prescribe the drugs keeping cost in mind so that patients adhere to the prescribed drug therapy.

# Conflict of Interest: None.

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