

Cost analysis of oral hypolipidemic agents available in India

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ABSTRACT

Background: Cardiovascular diseases are the most prevalent cause of death and disability in developed and developing countries. There is a wide variation in the prices of hypolipidemic drugs marketed in India. Thus, a study was planned to find out variation in cost in the oral hypolipidemic drugs available in India either as a single drug or in combination and to evaluate the difference in cost of various brands of the same oral hypolipidemic drug by calculating percentage variation in cost in Indian rupees.

Methods: Cost of oral hypolipidemic drugs manufactured by different pharmaceutical companies, in the same strength and dosage forms was obtained from “Current Index of Medical Specialties” July-October 2014 and “Indian Drug Review” Vol. XXI, Issue No.4, 2014. The difference in the maximum and minimum price of the same drug manufactured by different pharmaceutical companies and percentage variation in cost per 10 tablets was calculated.

Results: Percentage variation in cost for hypolipidemic drugs marketed in India was found to be atorvastatin (10 mg): 1108.33%, simvastatin (5 mg): 709.09%, rosuvastatin (10 mg): 431.91%, lovastatin (10 mg): 287%, fenofibrate (200 mg): 163.58%. Among the combination therapy, variation in cost was atorvastatin + fenofibrate (10+160 mg): 233.33%, atorvastatin + ezetimibe (20+20 mg): 132.90%, rosuvastatin + fenofibrate (10+145 mg): 105.56%.

Conclusion: There is a wide difference in the cost of different brands of oral hypolipidemic drugs available in India. The clinicians prescribing these drugs should be aware of these variations in cost to reduce the cost of drug therapy.

Keywords: Hypolipidemic drugs, Variation in cost, Statins, Percentage variation

INTRODUCTION

Indian pharmaceutical industry being one of the largest pharmaceutical markets in the world has a large number of branded formulations and generic brands of the same drug with a large difference in their selling price. McKinsey and Co. have predicted that, India’s pharmaceutical market would reach a size of 20 billion USD by year 2015, which would have tremendous growth to become one of the top 10 pharmaceutical drug markets in the world.¹ The difference in cost has affected consumers, prescribers and health-care providers regarding which is the best suitable branded and generic formulation.

Variation in cost of drugs that are used very commonly in a large number of population have large economic implications. This affects the compliance of the patients who need to take these drugs regularly to maintain good health.² Furthermore, the health care providers, who prescribe these formulations need to be aware of the costs incurred by

patients. When there are hundreds of formulations available in the market of the same drug, price is one of the important factors in selecting, which formulation suits the best.

Cardiovascular disease (CVD) is the leading cause of mortality, and its prevalence is increasing worldwide. Important co-morbidities being hypertension, diabetes and smoking, hyperlipidemia is also a key contributor to CVD accounting for 55% of non-age-related risk. Despite extensive clinical research and more efficacious therapies, CVDs remain the leading cause of morbidity and mortality worldwide. In recent years, India and other developing countries have witnessed a rapidly escalating epidemic of CVD.³ Dyslipidemia is one of the risk factor for ischaemic heart diseases.⁴ It is predicted that, by 2020, coronary heart disease will be the leading cause of death in adult Indians.⁵

Previous studies estimated an average reduction of 11.5 years of life for complications arising as a consequence of CVD. This shows the importance of dyslipidemia as a risk factor,

which led to the development of hypolipidemic drugs. With the development of hypolipidemic drugs namely statins, reduction has been found in CVD and mortality.⁶⁻⁹ Lipid-lowering therapy that has a long history of drug development, with the initial CVD outcomes studies performed in the 1970s. The earliest hypolipidemic drug niacin was discovered in 1955 while the bile acid sequestrants and fibrates were developed in 1960s. These drugs have been almost completely replaced by statins. Observational studies indicate a continuous positive association between the risk of CVD and low-density lipoprotein cholesterol levels.^{10,11}

Currently available treatment guidelines consider statins as first-line lipid-lowering agents and other four classes of less commonly used second-line hypolipidemic drugs which include cholesterol absorption inhibitors, lipoprotein lipase activators (peroxisome proliferator-activator receptor α activators/fibrates), niacin preparations and bile acid sequestrants (resins).¹² With updated 2013 guidelines for the treatment of high blood cholesterol by the American College of Cardiology/American Heart Association, the use of statins and other drugs is expected to increase further.¹³

Drug Price Control Order (DPCO) is an order issued by the Indian government to fix prices of drugs. Once any medicine is brought under purview of DPCO, it cannot be dispensed at a price higher than that fixed by the government. In India over the years number of the drugs under DPCO has decreased. Due to this cost of therapy has increased tremendously and put an economic burden on the poor population of India.

As per the recent amendments, National Pharmaceutical Pricing Authority revised the prices of 418 drugs vide DPCO, April 2014. Amongst the statins only Atorvastatin has been included in the new list of essential medicines while other hypolipidemic drugs are not included in this list.¹⁴⁻¹⁶

It was noted, that percentage increase in price of drugs under DPCO was less than those drugs that are not under the purview of DPCO.¹⁷

The study was planned to find out variation in cost of oral hypolipidemic drugs like HMG Co-A reductase inhibitors (Statins), peroxisomal proliferator-activating receptor agonists (fibrates), sterol inhibitors, lipoprotein and triglyceride inhibitors available in India either as a single drug or in combination and to evaluate the difference in cost of various brands of same oral hypolipidemic drug by calculating the percentage variation in cost in Indian rupees (INR).

METHODS

1. Price in INR of oral hypolipidemic drugs manufactured by different pharmaceutical companies in India, in the same strength was obtained from "Current Index of Medical Specialties" July-October 2014 and "Indian

Drug Review" Vol. XXI, Issue No.4, 2014.

2. The drug formulation being manufactured by only one company or being manufactured by different companies; however, in different strengths were excluded.
3. Cost of the oral hypolipidemic drug formulation was calculated for an average of 10 tablets as the number of tablets available per strip varied.
4. Difference in the maximum and minimum price of the same drug formulation manufactured by different pharmaceutical companies and percentage variation in price was calculated.
5. Percentage cost variation was calculated as follows:

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

RESULTS

The prices of 13 oral hypolipidemic drugs (8 single and 5 combinations), available in 28 different formulations were analyzed.

Table 1 shows, variation in cost of oral hypolipidemic drugs used as a single drug therapy. Percentage variation in cost was found to be atorvastatin (10 mg): 1108.33%, simvastatin (5 mg): 709.09%, rosuvastatin (10 mg): 431.91%, lovastatin (10 mg): 287%, fenofibrate (200 mg): 163.58%.

Table 2 shows, variation in cost of oral hypolipidemic drugs used in combination. Percentage variation in cost was found to be atorvastatin + fenofibrate (10+160 mg): 233.33%, atorvastatin + ezetimibe (20+20 mg): 132.90%, rosuvastatin + fenofibrate (10+145 mg): 105.56%.

DISCUSSION

In India, more than one pharmaceutical company sells a particular drug under different brand names along with the innovator company. Hence, a large number of formulations for the same drug are available at different prices.

Studies lack in India comparing the cost of the same drug sold under different brand names by different pharmaceutical companies. Therefore, this study was conducted to compare the cost of different brands of the same oral hypolipidemic drug. The drug prices available in CIMS and IDR were compared as they are one of the available sources of drug information that are updated on a regular basis. Drugs used in the management of dyslipidemias (Hypolipidemic agents) were selected as they affect the morbidity and mortality in patients with CVD and these drugs are used continuously on a long term basis for the treatment of dyslipidemias.

The findings in our study show a percentage variation in cost above 100% for the available oral hypolipidemic drugs in India. These percentage variations in cost cannot be accepted in a developing country like India. Out of 13 commonly prescribed drugs which were studied, there was a

Table 1: Variation in cost of single drug therapy.

Drug	Formulations (n)	Dose (mg)	Minimum cost (INR)	Maximum cost (INR)	% variation in cost
Statins					
Atorvastatin	5	5	9	101.40	1026.67
		10	12	145	1108.33
		20	19	198	942.10
		40	79	253.50	220.88
		80	160	292	82.50
Simvastatin	3	5	11	89	709.09
		10	22	123	459.09
		20	33	185	460.61
Rosuvastatin	4	5	27	69	155.55
		10	47	250	431.91
		20	120	400	233.33
		40	285	399	40
Lovastatin	2	10	31	120	287
		20	55	210	281.81
Fibrates					
Fenofibrate	2	160	70	102.35	46.21
		200	76	200	163.58
Gemfibrozil	1	300	70	130.50	86.43
Sterol absorption inhibitors					
Ezetimibe	1	10	56.70	125	120.46
Lipoprotein and triglyceride synthesis inhibitors					
Niacin	2	375	16.50	29.85	80.91
		500	20.90	44.15	111.24

INR: Indian rupees

Table 2: Variation in cost of combination therapy.

Drug combination	Formulations (n)	Dose (mg)	Minimum cost (INR)	Maximum cost (INR)	% variation in cost
Atorvastatin+Ezetimibe	2	10+10	65	124	90.77
		20+20	85.25	198.55	132.90
Atorvastatin+Fenofibrate	2	10+160	39	138	233.33
		10+200	72.08	105	45.67
Rosuvastatin+Fenofibrate	2	5+145	104	125	20.19
		10+145	72	148	105.56
Simvastatin+Ezetimibe	1	10+10	68	80	17.65
Simvastatin+Nicotinic acid	1	5+125	55	59	7.27

wide percentage variation in cost leading to an unnecessary economic burden on Indian population.

In India, a large number of patients are not covered under any individual or government medical insurance. Hence, the patients have to purchase the prescribed drugs by themselves. These wide variations in the prices of different formulations of the same drug have severe economic implications on the Indian Population. The decision to

prescribe any companies brand is taken by the physician without taking into consideration the socioeconomic condition of the patient. Thus, patient does not have any say in the type of brand prescribed by their physicians. The physicians could play an important role to reduce the cost of the drugs prescribed if such type of information about drug prices were readily available. Different studies have shown that if a comparative manual of drug prices is available to the physicians, it will reduce the cost of

therapy tremendously.¹⁸ Health care providers are using this information in allocating their limited health care resources.¹⁹

Currently, prices of few drugs are under government control through DPCO. Hence the physician should always remember that he should not avoid treating the patient with a particular drug because it is expensive and should rather balance his therapeutic decisions in prescribing a particular drug by considering the patient's socioeconomic status. Hence, we need to draw attention to the prices of various drug formulation brands available to reduce the cost of therapy.²⁰

Hence, there is a need on the part of the government to bring all life-saving and essential medicines under DPCO. Furthermore, the combination therapy of oral hypolipidemic drugs should be included in National List of Essential Medicines to provide economic benefits to a large population.¹⁶ Thus, this study highlights that there is a wide variation in cost among the oral hypolipidemic drugs manufactured by different pharmaceutical companies. The Government of India should take effective measures in bringing uniformity in the cost incurred by patients.

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