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COST MINIMIZATION AND COST VARIATION ANALYSIS OF DYSLIPIDAEMIC AGENTS AVAILABLE IN INDIAN PHARMACEUTICAL MARKET

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ABSTRACT

Background: Hyperlipidemia is a condition in which there are high levels of fat particles(lipids) in the blood, including triglycerides, cholesterol, cholesterol esters and phospholipids and or plasma lipoproteins including very and low-density lipoprotein, and decreased high-density lipoprotein levels. Hyperlipidemia always arises due to other underlying diseases, so it is essential to check into the secondary causes. Ideally the doctor should consider the prices of medications while prescribing for both ethical and economic reasons as the vast differences between different brands of same drug may create confusion among both physician and patient. **Materials and Methods:** The cost of the drugs are obtained from CIMS, July to Oct, 2019, and cost range, mean cost, cost ratio and percentage cost variation for individual drug brands was calculated. The cost of 7 oral preparations available are analyzed in this study. **Results:** There is a gross variation in the prices of branded drugs of dyslipidaemic agents in India. The highest cost range (393.1) and mean cost (335.14) is for Atorvastatin 80mg. The highest cost ratio is for Atorvastatin 20mg (8.159) and percentage price variation is for Atorvastatin 20mg(735.48). **Conclusions:** There is a huge price variation between the minimum and maximum cost among the different brands of the same drug. Government, pharmaceutical companies, regulatory authorities, physicians and pharmacist need to work together towards controlling the drug pricing and helping the patients in attaining optimum healthcare economic benefits.

KEYWORDS: Dyslipidaemic agents, Cost minimization analysis, Cost ratio, Percentage cost variation, compliance.

INTRODUCTION

Chronic diseases cause increasing numbers of deaths worldwide. Cardio Vascular Diseases (CVD)s are the worlds biggest killers, accounting the leading causes of death globally and it is believed that CVDs will turn out to be the main cause of death and disability worldwide by the year 2020. Hyperlipidemia is a condition in which there are high levels of fat particles(lipids) in the blood, including triglycerides, cholesterol, cholesterol esters and phospholipids and or plasma lipoproteins including very low-density lipoprotein, and decreased high-density lipoprotein levels.[1]

Hyperlipidemia always arises due to other underlying diseases, so it is essential to check into the secondary causes.[2] Physical inactivity is corelated with increased chances of developing different types of diseases such as overweight, diabetes, hypertension, osteoporosis, and depression. Thus inactivity is asscociated with cardiovascular mortality.[3] The gap in life expectancy, still evident today, is mainly due to mortality from circulatory diseases.[4] CVD remains among the 5 diseases of unhealthy enviroment, reasons can be both societal changes and commercial influences. This causes major concern to both central and local authorities, to maintain health status of people.[5]

In health care systems, the basic services that hospitals offer are primary care, serve as referral institutes for higher-level care, and train health care workers but mostly benefits are costly.[6] In India common people do faces a lot of challenges, medicines being out- of-pocket costs include deductibles, coinsurance and copayments for covered services plus all costs for services that arent covered.[7] Affordability is always related to income but also to drug prices, unorganized sector population mainly lack social insurance.[8]

Ideally the doctor should consider the prices of medications while prescribing for both ethical and economic reasons as the vast differences between different brands of same drug may create confusion among both physician and patient. By prescribing less expensive drugs physicians can also improve the situation.[9] Economic burden which results in decreased compliance or even non-compliance is due to the increased price of medications. Thus non complaince can later lead to decreased compliance or even non-compliance which eventually

leads to morbidity. Decreased adherence to prescription medication is related to the demand of medications or its cost.[10]

The pharmaceutical sector in India is flooded with different brands of same formulation which create a full scale threat for the country's bulk drug manufacturers. The debilitating impact has not been sudden. Price variations of different brands of the same medication formulations are also widely seen in market due to loose regulations and procedures. To reduce health care costs, it is important to assure that people are able to access safe and efficacious and quality products at low costs with strict regulatory framework.[11] Here the current study aims to view the existing situation by collecting data about brand availability, cost variation and difference in pricing between various brands of dyslipidemic agents.

MATERIALS AND METHODS

1. Price in Indian National Rupees(INR) of dyslipidaemic agents manufactured by different pharmaceutical companies in India, in the same strength were obtained from Current Index of Medical Specialists(CIMS) July to October 2019 edition, as they are readily available source of drug information and are updated regularly.
2. The cost of 7oral dyslipidaemic agents available under different brands in Indian pharmaceutical market was analyzed.
3. Each strength in a generic group of 7 drugs are analyzed.
4. Cost range and mean cost of the drugs are calculated and cost range is the range of the drug from minimum to maximum cost and mean cost is calculated by adding the cost of all brands of the same generic drug divided by number of brands available. Cost is calculated in Indian National Rupees (INR).
5. Cost ratio gives the ratio of the cost of costliest to the cheapest brand of dyslipidaemic agents of the same strength available in the Indian market and it gives an idea about how many times the costliest brand costs more than the cheapest brand available in each generic group.

$$Costratio = \left[\frac{Maximum\ brandcost}{Minimum\ brandcost}\right]$$

6. Percentage price variation for each strength of the same generic group was calculated using the equation,

$$Percentagepricevariation = \left[\frac{Maximum\ brandcost - Minimum\ brandcost}{Minimum\ brandcost}\right] \times 100$$

7. The drug Manufactured by or a definite strength of drug manufactured by a single company are excluded.
8. The different brands of the drug whose price is not disclosed in CIMS, July to Oct 2019 are excluded.
9. Fixed dose combinations and other formulations are not analyzed.
10. The number of trades of dyslipidaemic agents in the Indian pharmaceutical market was analyzed.

RESULTS

The study shows that there are currently 192 brands of dyslipidaemic agents are available in India and Atorvastatin holds the highest number of brands 154 (80.62%), Rosuvastatin has 12 (28%), Simvastatin has 10 (5.23%) Fenofibrate has 7 (3.66%), Lovastatin has 6 (3.14%), Nicotinic Acid has 2 (1.047%) and Ezetimibe has 1 (0.52%) brands (Figure-1).

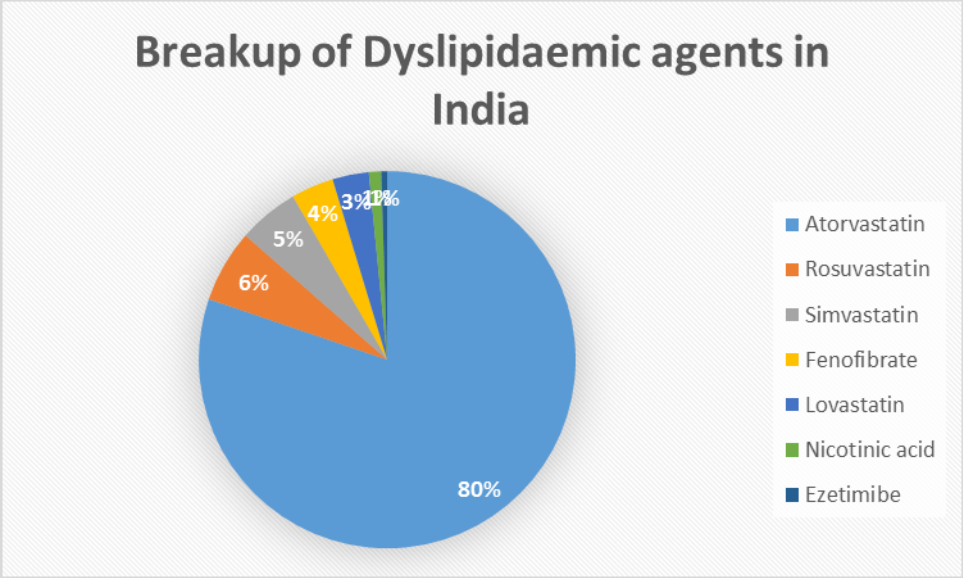

Fig 1: Breakup of Dyslipidaemic agents available in India.

Among the oral formulation Atorvastatin is available at 5 mg, 10mg, 20mg, 40mg and 80mg in 17,57,52,17 and 11 brands of each strengths respectively. Ezetimibe available at 10mg as in 1 brand. Fenofibrate is available at different strengths of 145,160 and 200mg in 1, 2 and 4 brands of each strengths respectively. Lovastatin is available at 10mg and 20mg in 3 and 3brands in each strengths respectively. Nicotinic Acid is available at 375mg and 500mg in 1 and 1brands of each strengths respectively. Rosuvastatin is available at 5mg, 10mg, 20mg and 40mg in 3,5,3 and 1 brands of each strengths respectively. Simvastatin is available at 5mg, 10mg, 20mg and 40mg in 4,3,2 and 1brands of each strenghths respectively.

The cost range of oral Atorvastatin 5mg is in between 17-90 INR, 10mg is 20.40-110.20 INR, for 20mg 25.08-209.54 INR, for 40mg 79-283.50 INR and for 80mg is in between 179-573 INR. Cost range of oral Fenofibrate 160mg is in between 104.04-123.50 INR and for 200mg is 71.40-167.24 INR. Cost of oral Lovastatin 10mg ranges from 35.96-75 INR and for 20mg is 79-125 INR. Cost of oral Rosuvastatin 5mg ranges from 52.23-60.40 INR, for 10mg 99-128 INR and for 20mg is 109.90-239.50INR. Cost of oral Simvastatin 5mg ranges from 62-78 INR, for 10mg 97-122 and for 20mg is 163.90-208 INR.(Table-1).

Table-1: Dyslipidaemic Agents with their number of brands, minimum and maximum cost, cost range and mean cost of each oral formulations in India.

S.no	Drug	Dose	No.of brands	Maximum cost(INR)	Minimum cost(INR)	Cost range	Mean cost
1.	Atorvastatin	5	17	90.00	17.00	73.00	42.92
		10	57	110.20	20.40	89.6	58.11
		20	52	209.54	25.08	183.86	106.92
		40	17	283.50	79.00	204.50	168.27
		80	11	573.00	179.90	393.1	335.14
2.	Ezetimibe	10*	1	-	-	-	-
3.	Fenofibrate	145*	1	-	-	-	-
		160	2	123.50	104.04	19.1	113.77
		200	4	167.24	71.40	95.84	117.21
4.	Lovastatin	10	3	75.00	35.96	39.04	53.82
		20	3	125.00	79.00	46.00	95.30
5.	Nicotinic Acid	375*	1	-	-	-	-
		500*	1	-	-	-	-
6.	Rosuvastatin	5	3	60.40	52.23	8.17	57.21
		10	5	128.00	99.00	29.0	110.74
		20	3	239.50	109.90	129.60	181.46
		40*	1	-	-	-	-
7.	Simvastatin	5	4	78.00	62.00	16.00	160.66
		10	3	122.00	97.00	25.00	109.50
		20	2	208.00	163.90	44.1	185.95
		40*	1	-	-	-	-

*Prices are not available: hence cost range and mean cost cannot be calculated.

The current study reveals that there is a wide variation in cost of different brands of hyperlipidaemic agents in Indian pharmaceutical market. The highest cost ratio and percentage cost variation among orally available hyperlipidaemic agents was found for the drug Atorvastatin 20mg [8.159,735.48] and least for the drug Rosuvastatin 5mg [1.15,15.64]. Other significant percentage cost variations are seen with the dugs Atorvastatin 10mg [5.39,440.19], Atorvastatin 5mg[5.29,429.41] and for other hyperlipidaemic agents as described in Table- 2.

Table-2: Dyslipidaemic Agents with their number of brands, minimum and maximum cost, cost ratio and percentage cost variation available in India.

S.no	Drug	Dose	No.of brands	Maximum cost(INR)	Minimum cost(INR)	Cost Ratio	Percentage Cost Variation
1.	Atorvastatin	5	17	90.00	17.00	5.29	429.41
		10	57	110.20	20.40	5.39	440.19
		20	52	209.54	25.08	8.159	735.48
		40	17	283.50	79.00	3.588	258.86
		80	11	573.00	179.90	3.201	220.11
2.	Ezetimibe	10*	1	-	-	-	-
3.	Fenofibrate	145*	1	-	-	-	-
		160	2	123.50	104.04	1.187	18.70
		200	4	167.24	71.40	2.34	134.22
4.	Lovastatin	10	3	75.00	35.96	2.085	108.56
		20	3	125.00	79.00	0.58	58.22
5.	Nicotinic Acid	375*	1	-	-	-	-
		500*	1	-	-	-	-
6.	Rosuvastatin	5	3	60.40	52.23	1.156	15.64
		10	5	128.00	99.00	1.29	29.29
		20	3	239.50	109.90	2.17	117.92
		40*	1	-	-	-	-
7.	Simvastatin	5	4	78.00	62.00	1.25	25.80
		10	3	122.00	97.00	1.25	25.77
		20	2	208.00	163.90	1.26	26.90
		40*	1	-	-	-	-

*Prices are not available: hence cost ratio and percentage cost variation cannot be calculated.

DISCUSSION

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 dyslipidaemic agents marketed in India. Thus, this study was planned observe the variation in cost of the dyslipidaemic agents available in India.

Atorvastatin holds the highest number of brands available for dyslipidaemic agents in India with 154 brands, followed by Rosuvastatin with 12 brands and Ezetimibe has the least number of marketed brands with only 1 brand. All drugs are available in oral formulation only. Among this oral formulations, Atorvastatin and Lovastatin are the cheapest preparations available in the market.

The mean cost has been calculated for all available except some preparations whose price is not mentioned in the CIMS, July to Oct, 2019 and the mean cost for oral Atorvastatin 5mg.10mg 20mg, 40mg and 80 mg is 42.92INR, 58.11 INR, 106.92 INR, 168.27 INR and

335.14 respectively. The mean cost of oral Fenofibrate 160mg and 200mg is 113.77 INR and 117.21 INR respectively. Mean cost of oral Lovastatin 10mg and 20mg is 53.82INR, 95.30 INR, respectively. Mean cost of oral Rosuvastatin 5mg, 10mg and 20mg is 57.21,110.74,181.46 INR respectively. Mean cost of oral Simvastatin 5mg, 10mg, 20mg, is 160.66INR, 109.50INR and 185.95INR respectively. The highest cost range among the oral preparation of dyslipidaemic agents is for the drug Atorvastatin 80mg and the least for the drug Rosuvastatin 5mg(393.1,8.17).

Globally ranked fourth by volume and 13th in value, the Indian pharma industry is a leading producer of high-quality, low-cost generic drug but a majority of patients are not covered under any individual or government medical insurance.[12] 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 burden on the Indian population. The physicians could play an important role to reduce the cost of the drugs prescribed if readily available information is provided.[13]

The government and regulatory agencies should frame policies for regulating the drug prices and maximum profit margin for commonly prescribed medications. Currently, very few drugs are under Drug Price Control Order. For the betterment of the healthcare of our country, government should bring majority of the drugs under the DPCO.[14] The above analysis shows that the highest cost ratio and percentage cost variation was found for the drug oral Atorvastatin 20mg [8.15,735.48] and the least for the drug Rosuvastatin 5mg[1.156, 15.64] Thus, this study highlights that there is a wide variation in cost among the Dyslipidaemic agents manufactured by different pharmaceutical companies. The Government of India should take effective measures in bringing uniformity in the cost incurred by patients.

CONCLUSION

There is a wide difference in the cost of different brands of available in India. The clinicians prescribing these drugs should be aware of these variations in cost to reduce the cost of drug therapy. Hence it is recommended that necessary measures should be taken to maximize the benefits of therapy and implications for better physician education and improved abscess are substantial.

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