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Original Research Article

Cost variation analysis of hypolipidemic drugs currently available in Indian pharmaceutical market

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ABSTRACT

Background: Indian pharmaceutical industry is one of the growing pharmaceutical markets in the world having number of formulations available with large difference in prices. Price variations of such drugs which are used by large number of population have major economical implication. Hyperlipidemia is major risk factor for ischaemic heart diseases. So we planned this study to find out variation in cost of oral hypolipidemic drugs available in India either as a single drug or as fixed dose combination (FDCs) and to compare cost of their generic version with brands.

Methods: The prices of single and FDCs of hypolipidemic drugs were taken from “Indian Drug Review 2018” and “Current Index of Medical Specialities during October 2018 to December 2018”. Maximum and minimum prices of various hypolipidemic drugs of same strength and dosage forms manufactured by different companies were taken.

Results: Minimum cost variations are 3.62% (pravastatin 10 mg) and 3.37% (rosuvastatin 5 mg and fenofibrate 67 mg). Maximum cost variations are 500% (simvastatin 5 mg) and 500.32% (atorvastatin 10 mg and fenofibrate 160 mg). Wide variations are found in cost of brand drug with generic version of same strength components. None of the pharmaceutical companies are selling drugs cheaper than or equal to the cost of generic drugs of same strength.

Conclusions: Most of hypolipidemic drugs should come under control of Drug Price Control Order so that financial burden of healthcare services on Indian population can be reduced and by adherence to treatment will improve health status of the community.

Keywords: Cost variation, Hyperlipidemia, Statins

INTRODUCTION

Pharmaceutical industry of India is one of the growing pharmaceutical markets in the world which has number of branded and generic formulations available with large difference in selling prices. According to McKinsey and Co. Indian pharmaceutical market would have tremendous growth in recent years to become one of the top pharmaceutical markets in the world.¹

Because of availability of multiple brand/generic drugs there is lot of variation in their selling prices. This confuses the prescribers, healthcare providers as well as

consumers regarding suitable product with affordable price. Price variations of drugs which are used by large number of population regularly will have major economical implication. It also affects the compliance of the patients whose major portion of income is used for treatments.²

Cardiovascular diseases (CVD) are one of the leading causes of mortality worldwide. Among many of risk factors associated with CVD, hyperlipidemia is one of the major contributors. Although extensive clinical research is done and more efficacious therapies are available, CVDs remain the leading cause of morbidity and

mortality. India and other developing countries are also in a phase of acute rising cases of CVD.³

Hyperlipidemia (raised low density lipoproteins, triglycerides and low high density lipoproteins) is one of the major risk factor for ischaemic heart diseases. Lipid lowering agents, particularly statins have been found to reduce the risk of subsequent CHD events and non-hemorrhagic stroke in patients of dyslipidemia.⁴ Dyslipidemia treatment guidelines suggests statins as first-line lipid-lowering agents and other less commonly used second-line drugs including lipoprotein lipase activators (peroxisome proliferator-activator receptor α ctivators/fibrates), cholesterol absorption inhibitors, niacin preparations and bile acid sequestrants (resins).⁵ Recent updated 2018 guidelines on the management of blood cholesterol by the American College of Cardiology/American Heart Association, the use of statins and other drugs is expected to increase further.⁶

Indian government has issued an order named Drug Price Control Order (DPCO) with intention to control the price of medicines. Once any medicine comes under DPCO, it cannot be sold at higher price than mentioned by government. Over past many years drugs under DPCO has decreased resulting in increase in cost of medicines and thus economic burden on poor socio economic population.^{7,8} It was observed that price increase of any drug under DPCO was less than those are not under purview of DPCO.⁹

So our 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 with other hypolipidemic drug 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). Brand medicine prices will also be compared with generic medicine price.

METHODS

The study deals with the market analysis of the drug pricing of hypolipidemic drugs, and involves no clinical intervention. So the protocol is exempted from

Institutional Ethics Committee review. The study was conducted during October 2019 to November 2019.

The prices of single as well as fixed dose combinations of hypolipidemic drugs were taken from “Indian Drug Review (IDR) 2018” and “Current Index of Medical Specialities (CIMS) during October 2018 to December 2018”. The prices of drugs were calculated per 10 tablets or 10 capsules in INR. Maximum and minimum prices of various oral hypolipidemic drugs of same strength and dosage forms manufactured by different Indian pharmaceutical companies were taken. Formulations manufactured by single company and the drug preparations for which price was not disclosed in the source was excluded from analysis. Fixed drug combinations of different hypolipidemic drugs were included while combinations with other group of drugs were excluded from the study.

Maximum and minimum price difference of the same drug manufactured by different pharmaceutical companies was noted down. The Percentage variation was calculated as per the following formula:

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

The cost ratio (ratio between the maximum and minimum cost of the same hypolipidemic drug) was calculated as follows:

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

To compare the prices of brand drug with generic drug, <http://janaushadhi.gov.in/ProductList.aspx> (Accessed on 19th November 2019) was used as source for generic drug price.⁷

The study findings are expressed as absolute numbers and percentages in table and chart formations.

RESULTS

Table 1 shows cost ratio and cost variation (%) of mono-component and fixed dose combination (FDC) hypolipidemic drugs.

Table 1: Cost ratio and cost variation (%) of mono-component and FDC hypolipidemic drugs.

| S. no. | Drug | Dosage and formulation (quantity-10) (mg/Tablet) | No. manufacturing companies | Minimum cost | Maximum cost | Cost ratio | Cost variation % |
|--------|--------------|--|-----------------------------|--------------|--------------|------------|------------------|
| 1 | Atorvastatin | 5 | 16 | 17 | 78.6 | 4.62 | 362.35 |
| | | 10 | 56 | 25.5 | 97.5 | 3.82 | 282.35 |
| | | 20 | 43 | 41.59 | 205.8 | 4.95 | 394.83 |
| | | 40 | 18 | 79 | 294.16 | 3.72 | 272.35 |
| | | 80 | 10 | 179.9 | 484.5 | 2.69 | 169.32 |

Continued.

| S. no. | Drug | Dosage and formulation (quantity-10) (mg/Tablet) | No. manufacturing companies | Minimum cost | Maximum cost | Cost ratio | Cost variation % |
|--------|----------------------------|--|-----------------------------|--------------|--------------|------------|------------------|
| 2 | Rosuvastatin | 5 | 23 | 32.5 | 117.9 | 3.63 | 262.77 |
| | | 10 | 28 | 55 | 210 | 3.82 | 281.82 |
| | | 20 | 22 | 89 | 303 | 3.40 | 240.45 |
| | | 40 | 7 | 253 | 503 | 1.99 | 98.81 |
| 3 | Pravastatin | 10 | 2 | 99 | 102.58 | 1.04 | 3.62 |
| | | 20 | 2 | 165 | 175 | 1.06 | 6.06 |
| 4 | Simvastatin | 5 | 7 | 13 | 78 | 6.00 | 500.00 |
| | | 10 | 7 | 26.5 | 122 | 4.60 | 360.38 |
| | | 20 | 7 | 40 | 208 | 5.20 | 420.00 |
| 5 | Lovastatin | 10 | 5 | 34.75 | 120 | 3.45 | 245.32 |
| | | 20 | 5 | 63.77 | 210 | 3.29 | 229.31 |
| 6 | Fenofibrate | 160 | 3 | 87.72 | 123.5 | 1.41 | 40.79 |
| | | 200 capsule | 3 | 71.4 | 167.24 | 2.34 | 134.23 |
| 7 | Nicotinic acid | 375 | 2 | 20 | 35 | 1.75 | 75.00 |
| 8 | Ezetimibe | 10 | 2 | 72.03 | 118.2 | 1.64 | 64.10 |
| 9 | Atorvastatin + Ezetimibe | 10+10 | 18 | 32 | 168 | 5.25 | 425.00 |
| | | 20+10 | 6 | 85.25 | 244 | 2.86 | 186.22 |
| 10 | Atorvastatin + Fenofibrate | 10+160 | 19 | 50 | 300.16 | 6.00 | 500.32 |
| | | 10+200 | 3 | 69.95 | 152.7 | 2.18 | 118.30 |
| 11 | Rosuvastatin + Fenofibrate | 5+67 | 3 | 104 | 107.5 | 1.03 | 3.37 |
| | | 5+145 | 2 | 103.9 | 125 | 1.20 | 20.31 |
| | | 10+67 | 3 | 157.3 | 193 | 1.23 | 22.70 |
| | | 10+145 | 4 | 72 | 145 | 2.01 | 101.39 |
| | | 10+160 | 10 | 95 | 171 | 1.80 | 80.00 |

Table 2: Comparison of cost of brand vs generic drugs (Jana Aushadhi).

| S. no. | Drug and strength (quantity-10) | Minimum cost | Maximum cost | Generic cost |
|--------|---|--------------|--------------|--------------|
| 1 | Atorvastatin 10 mg | 25.5 | 97.5 | 7 |
| | Atorvastatin 20 mg | 41.59 | 205.8 | 10 |
| | Atorvastatin 40 mg | 79 | 294.16 | 20 |
| 2 | Rosuvastatin 5 mg | 32.5 | 117.9 | 11.2 |
| | Rosuvastatin 10 mg | 55 | 210 | 10 |
| | Rosuvastatin 20 mg | 89 | 303 | 26 |
| 3 | Simvastatin 10 mg | 26.5 | 122 | 9.05 |
| | Simvastatin 20 mg | 40 | 208 | 13 |
| 4 | Fenofibrate 160 mg | 87.72 | 123.5 | 20 |
| | Fenofibrate 200 mg | 71.4 | 167.24 | 24 |
| 5 | Atorvastatin 10 mg + Fenofibrate 160 mg | 50 | 300.16 | 16.7 |
| 6 | Rosuvastatin 10 mg + Fenofibrate 160 mg | 95 | 171 | 28 |

Among mono-component drugs; atorvastatin 10 mg tablet is manufactured by maximum fifty six (56) pharmaceutical companies followed by atorvastatin 20 mg by forty three (43). Only two (2) companies are manufacturing nicotinic acid 375 mg tablets and ezetimibe 10 mg tablets. Minimum cost variation is 3.62% (pravastatin 10 mg) and 6.06% (pravastatin 20 mg). Maximum cost variation is 500% (simvastatin 5 mg) and 420% (simvastatin 20 mg) (Figure 1-3).

Among fixed dose combinations (FDCs); atorvastatin 10 mg and fenofibrate 160 mg is manufactured by maximum nineteen (19) and atorvastatin 10 mg and ezetimibe 10 mg is manufactured by eighteen (18) pharmaceutical companies. Maximum cost variation 500.32% is observed in atorvastatin 10 mg and fenofibrate 160 mg. Minimum cost variation 3.37% is found in rosuvastatin 5 mg and fenofibrate 67 mg (Figure 4-6).

Table 2 shows comparison of prices of brand drug with generic drug. Wide variations are found in cost of brand drug with generic version of same strength components.

None of the pharmaceutical companies are selling their drugs cheaper than or equal to the cost of generic drugs of same strength.

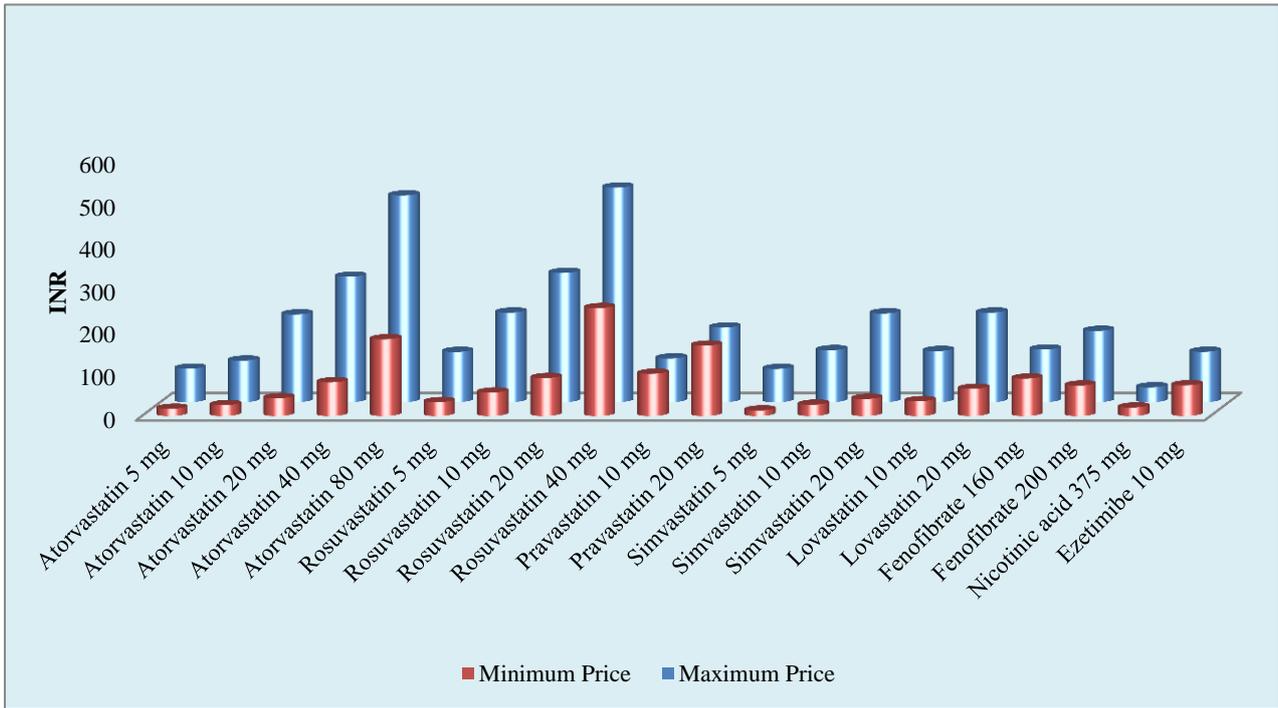


Figure 1: Comparison between maximum and minimum cost of monocomponent drugs (INR).

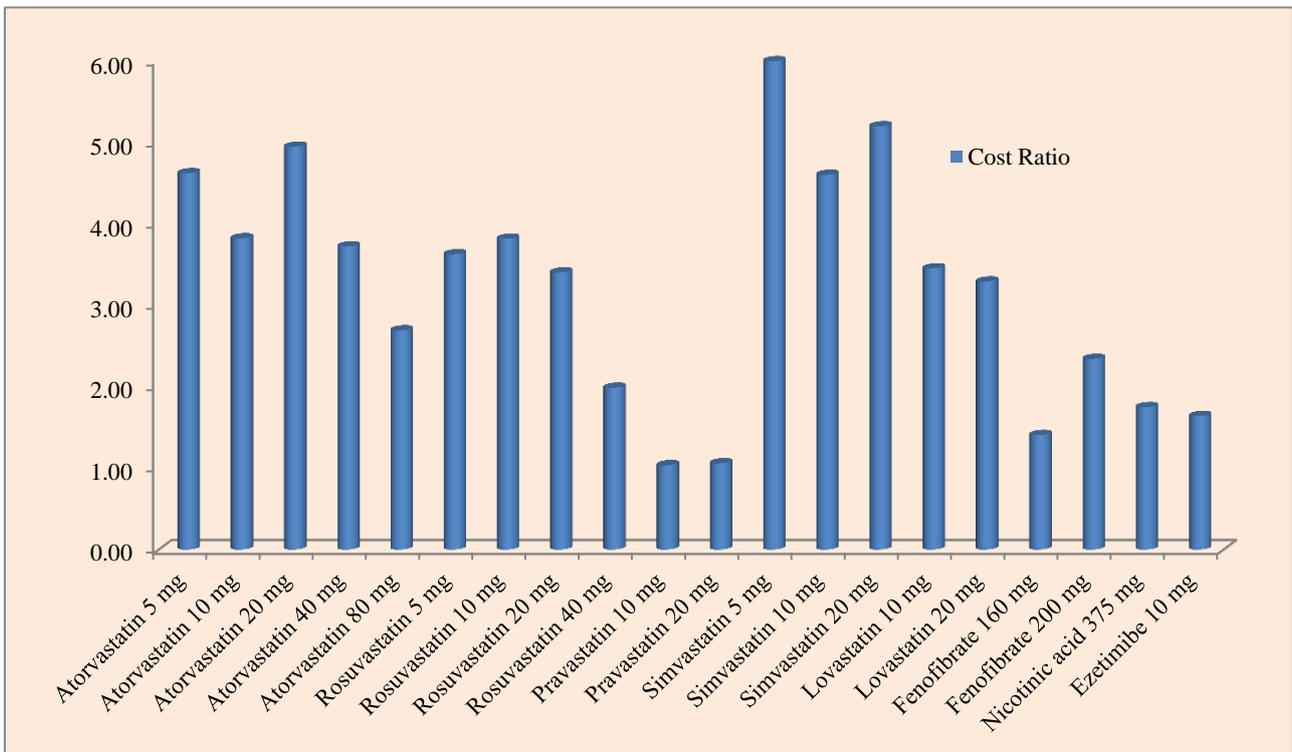


Figure 2: Cost ratios of monocomponent drugs.

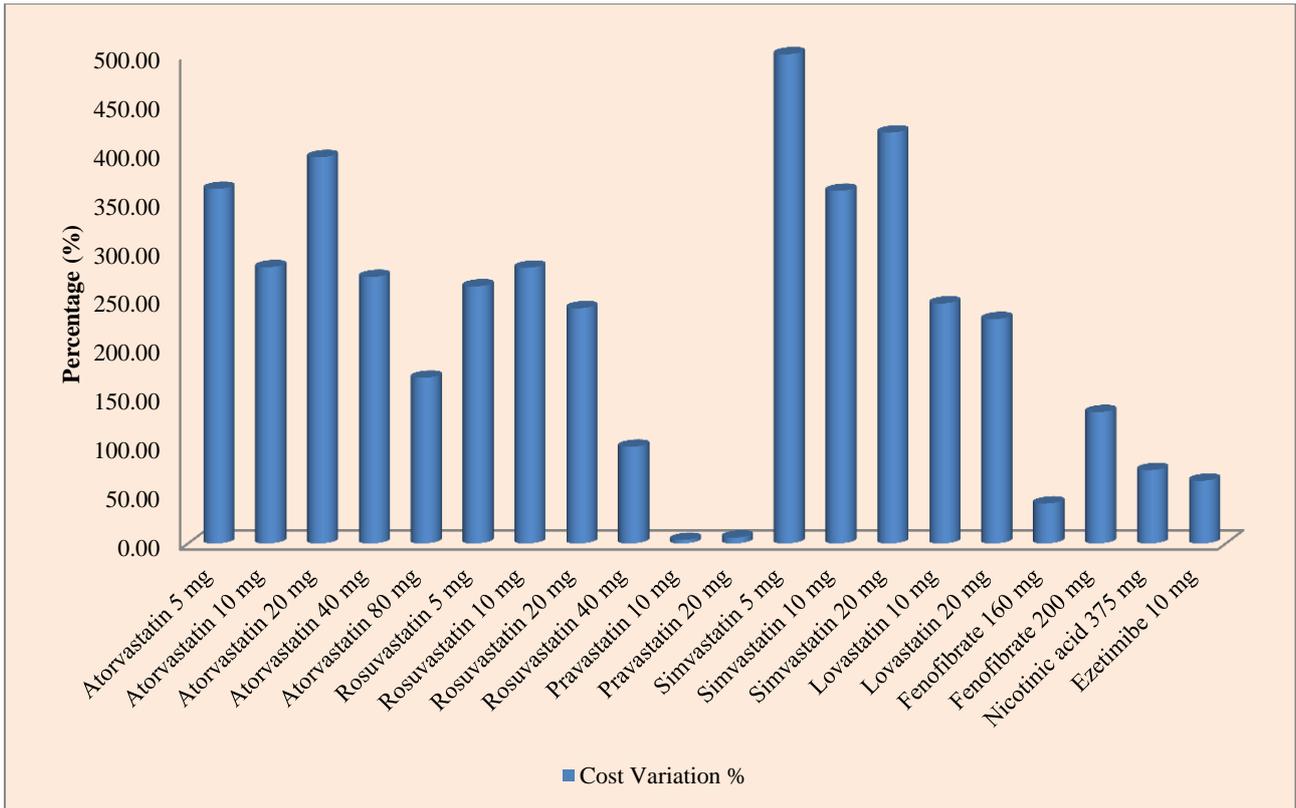


Figure 3: Cost variation (%) of monocomponent drugs.

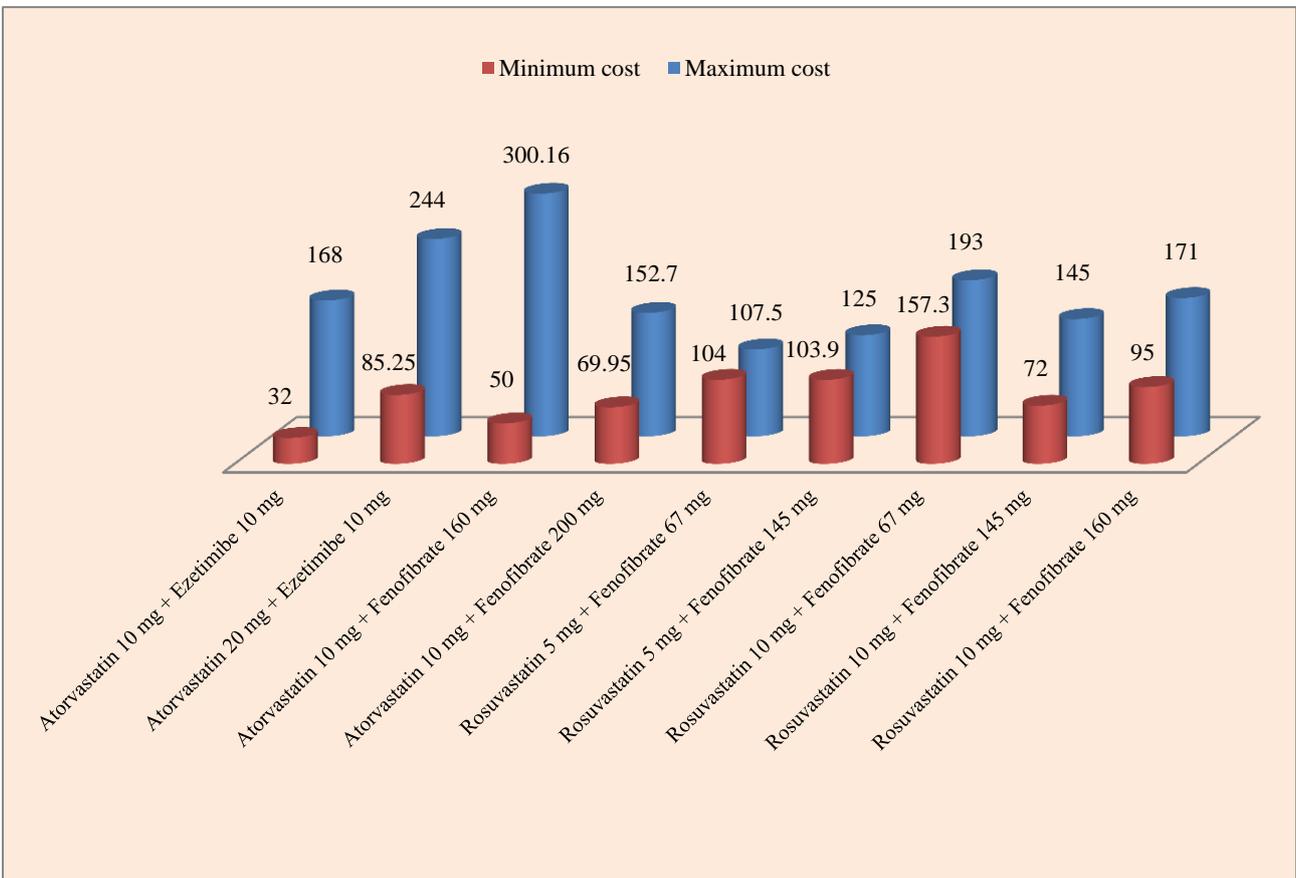


Figure 4: Comparison between maximum and minimum cost of FDCs (INR).

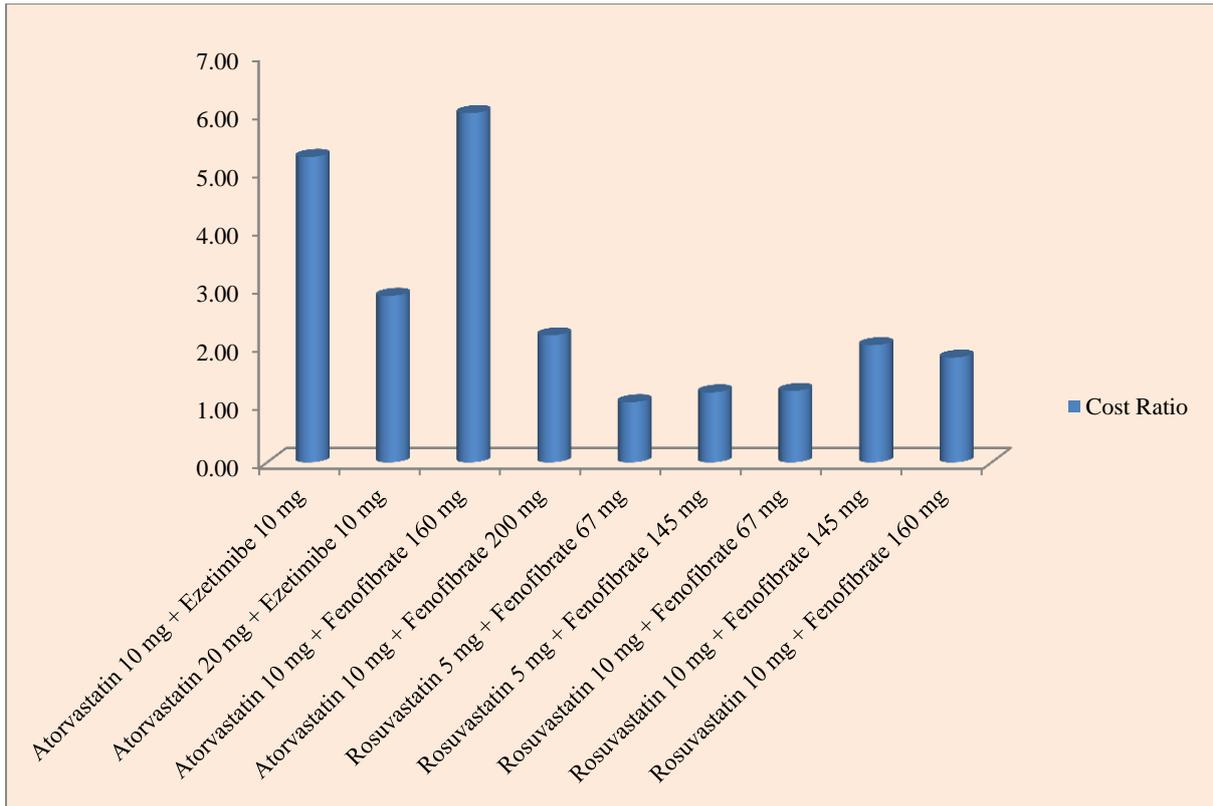


Figure 5: Cost ratios of FDCs.

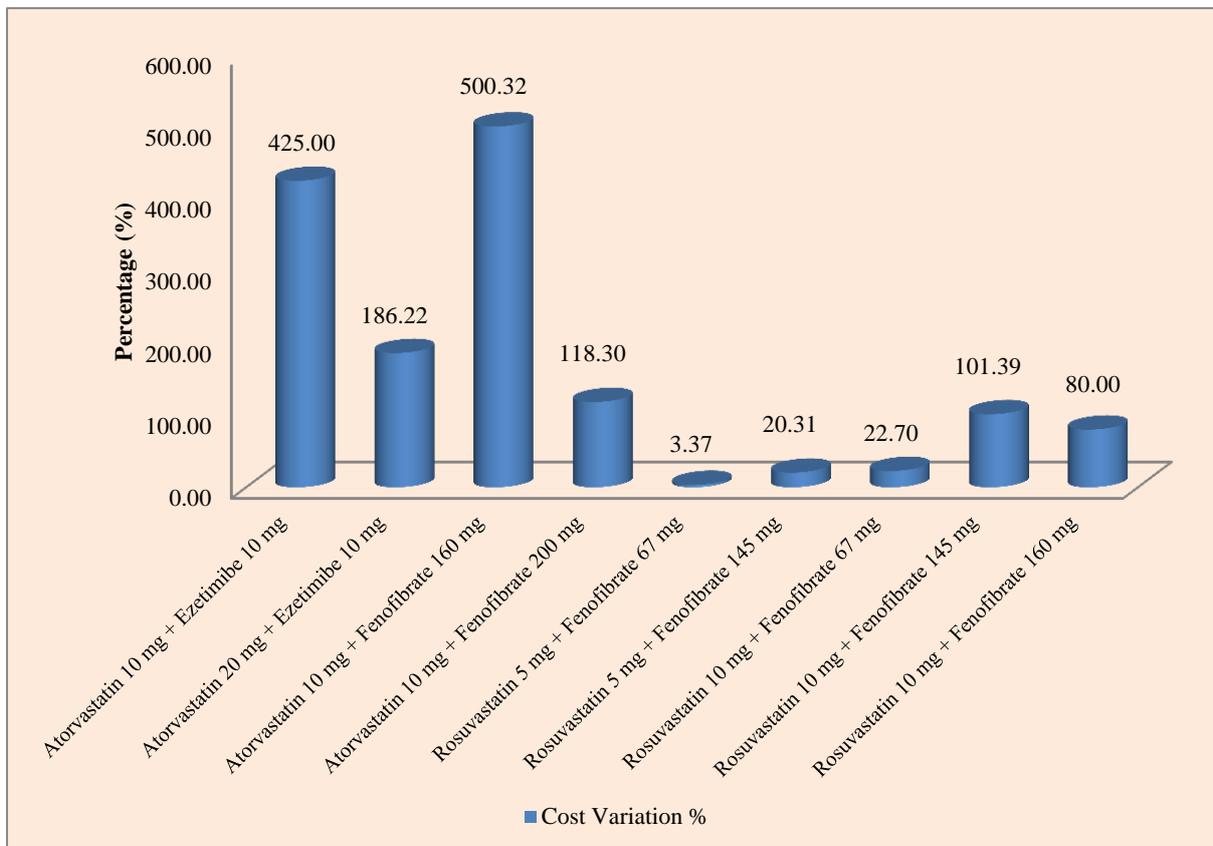


Figure 6: Cost variation of FDCs (%).

DISCUSSION

Most of the drugs are manufactured under different brand names in Indian pharmaceutical market which leads to substantial variability in drug cost to the patients.¹⁰ Dyslipidemia is one of the major risk factor for developing and progression of CVDs, majority of physicians prescribe statins for correction of dyslipidemia.¹¹ In most cases higher drug cost is responsible for non-adherence to the treatment. This leads to progression of CVDs and increase in morbidity and mortality of the patients.

In our study more than 100 % variation in the drug cost of majority hypolipidemic monocomponent and FDCs is seen. This is in accordance with previous analytic studies done by Mamatha et al and Bhandari.^{12,13} From our study we came to notice that minimum cost of brand hypolipidemic drugs available in India are approximately three (03) times more than their generics. Thus average Indian patients have to spend three times more money to procure their medicines.

In developed countries like USA majority of health care expenses are paid by the medical insurance companies. In contrast, developing countries like India medical expenses are paid by patient themselves. This results in higher economic burden on Indian population. Almost all of the Indian Health insurance companies cover hospitalization and not the out-patient and day care.¹³ Out-patient medicine spending in India has increased by approximately fifty percent in the last 10 years. Majority of prescribers write brand names in prescriptions which are far costlier than their available generics. Generic prescription imparts flexibility to the patient in choosing the brand that they can easily afford as generics are in no way subsidiary to the costly branded equivalent. Thus, there is an immense need to create awareness to the health care professionals about wide cost variation and their related consequences.

Indian government for fixing prices of drug issues DPCO. Drug cannot be given above the price set by DPCO. DPCO is an important aid to restrict drug prices in India. Very few hypolipidemic drugs are under DPCO. This is the reason behind cost variation between different brands of hypolipidemic drugs. Hence more and more hypolipidemic drugs should come under DPCO.^{14,15}

Some doctors are not aware about cost variation. Before prescribing any medicine physician must consider financial condition of the patient and prescribe more generic drugs. So if information regarding drug prices is readily made available to physicians, they can provide better healthcare services to their patients at the cost patients can afford. Study done by Frazier et al have shown that giving manual of comparative drug prices expound with prescribing advice to physician reduce their patient's drug expenses.¹⁶

Our study has some constraint as we used only CIMS and IDR for brand medicine prices. However there are other sources also like online website for drug marketing where other brand drugs are marketed. So we have confined number of brand drugs in our study.

CONCLUSION

From our study we came to conclusion that most of hypolipidemic drugs should come under control of DPCO so that financial burden of healthcare services on Indian population can be reduced and by adherence to treatment will improve health status of the community. Goal of WHO "Health for all" will only be achieved by combined efforts from health care practitioners, pharmaceutical companies, government and general population.

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