Print ISSN: 2319-2003 | Online ISSN: 2279-0780

IJBCP International Journal of Basic & Clinical Pharmacology

DOI: http://dx.doi.org/10.18203/2319-2003.ijbcp20162851

Research Article

Cost variation analysis of antidyslipidemic drugs

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Received: 23 July 2016
Accepted: 06 August 2016

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ABSTRACT

Background: Dyslipidemia is the most common cause of premature coronary atherosclerosis manifesting as ischemic heart disease. Hyperlipidemia has a major role in the causation of atherosclerosis and atherosclerosis-induced conditions, such as ischemic cerebrovascular disease, coronary heart disease (CHD) and peripheral vascular disease.
Methods: The prices of 07 antidyslipidemic drugs, available in 19 different formulations marketed in 260 brands and 03 fixed dose combinations available in 11 different formulations marketed in 75 brands were analyzed. Costs of different brands of a particular generic antidyslipidemic drug being manufactured by different companies, in the same strength and dosage forms were used to calculate cost ratio and percentage cost variation.
Results: In this study, it was found that there exists a wide cost variation among the different brands of same antidyslipidemic drugs in Indian market. Among individual antidyslipidemic drugs, highest cost ratio and percent cost variation was found for atorvastatin 20 mg, followed by atorvastatin 10 mg and atorvastatin 5 mg. Among fixed dose combinations for antidyslipidemic drugs, 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. Highest number of brands of antidyslipidemic drugs available in Indian market are for atorvastatin 10 mg followed by atorvastatin 20 mg and rosuvastatin 10 mg. Highest number of brands of fixed dose combinations of antidyslipidemic drugs available in Indian market are for atorvastatin 10 mg+ezetimibe 10 mg and atorvastatin 10 mg+fenofibrate 160 mg.
Conclusions: In Indian market, there is very wide price variation of different brands of the same generic antidyslipidemic drug. Treatment of dyslipidemia has long course of treatment. For long term adherence to the treatment, cost of a drug plays an important role for successful drug treatment. Various steps are needed to reduce this wide price variation of different brands of the same generic antidyslipidemic drug.

Keywords: Cost analysis, Compliance, Adherence, Dyslipidemia, Health economics, Cost variation

INTRODUCTION

Dyslipidemia is the most common cause of premature coronary atherosclerosis manifesting as ischemic heart disease.[1] The risk of cardiovascular disease has been found to be associated with the degree of total cholesterol and LDL elevation in a graded, continuous fashion.[2] Hyperlipidemia has a major role in the causation of atherosclerosis and atherosclerosis-induced conditions, such as ischemic cerebrovascular disease, coronary heart disease (CHD), and peripheral vascular disease.[3] Raised plasma cholesterol is an important risk factor for coronary artery disease (CAD). Raised plasma TG levels or low plasma HDL-CH levels are independent high risk factors for CAD and stroke.[4] For many individuals, alterations in lifestyle have a significant role in reducing vascular disease risk and at a lower cost than drug therapy. When drug therapy is indicated, there are

multiple agents with proven efficacy. Patients with any type of dyslipidemia have higher risk of developing atherosclerosis-induced vascular disease. Statins have been found to reduce the risk of subsequent CHD events and nonhemorrhagic stroke in virtually every type of dyslipidemia. . Therefore, statins are the first line drugs among different classes of lipid-lowering agents.[3]

Lowering the level of raised LDL-CH has been found to reduce cardiovascular mortality and morbidity. Reduction in coronary and stroke events have been found to be associated with the prophylactic use of a statins in CAD/hypertensive patients even with average or lower than average CH levels. It is a standard practice to prescribe statin therapy after an acute coronary event irrespective of lipid levels. Raised LDL-CH is atherogenic while higher HDL-CH level indicates a low atherogenic state and has an protective role. The hypolipidaemic drugs prevent cardiovascular disease by retarding the atherosclerosis in hyperlipidaemic individuals.[4]

The decision for treatment of dyslipidemia depends largely on the calculated cardiovascular risk. Adherence to the effective dietary therapy can reduce total cholesterol by up to about 25%, depending on the metabolic basis or elevated cholesterol concentrations. If dietary therapy is unsuccessful or insufficient to normalize lipid levels, pharmacotherapy is recommended. There are five well-established classes of drugs for pharmacologic modification of lipid metabolism. The inhibitors of cholesterol synthesis (i.e., HMG-CoA reductase inhibitors, also known as statins) have been found to reduce cardiovascular morbidity and mortality. However, other classes of antidyslipidemic drugs apart from statins act as important adjunctive therapies and can be the agents of choice for patients with certain specific causes of dyslipidemia.[5]

Indian pharmaceuticals market is the third largest market in terms of volume and thirteenth largest market in terms of value. Indian pharmaceuticals market is dominated by branded generics which constitutes about 70 to 80 percent of the market. India being the largest provider of generic drugs globally accounts for 20 percent of global exports in terms of volume.[6]

Indian markets have a number of branded formulations for antidyslipidemic medications with variable pricing difference between the different brands of the same formulation. The difference in cost between different brands of the same drug is variable and can be large, resulting in unfair burden on the patients.[7] It is a challenge for healthcare professionals to assure an efficient use of resources and provide quality patient care.[8]

In India, health insurance schemes are significantly underutilized and majority of the health care costs are afforded by the patients. India is one of those countries who have highest out of pocket (OOP) expenses on health care. About 65% of Indian population do not have access to essential medicines.[9]

High medical care costs are an important issue for policy makers and service providers.[10] Drug price control order (DPCO) has been brought into the action to regulate the drug prices to improve the affordability. Treatment of dyslipidemia has a long course of duration. For the successful treatment of dyslipidemia, adherence to the treatment regimen is desirable. Decreased drug cost improves adherence to the medication regimen.[11] Higher drug cost can lead to noncompliance which will lead to treatment failure. This treatment failure ultimately results in higher medical care costs. Creating awareness about pharmacoeconomics of drug therapy can play improve the chances of successful drug therapy.

This study was aimed at comparing and analysing the costs of various brands of the same generic antidyslipidemic drug, so that we can study their cost variations. Awareness of the cost variations among antidyslipidemic drugs can be applied to ensure more economical treatment regimen to improve the treatment adherence and the rate of success of therapy.

METHODS

The prices of 07 antidyslipidemic drugs, available in 19 different formulations marketed in 260 brands and 03 fixed dose combinations available in 11 different formulations marketed in 75 brands were analyzed.

- Cost of a particular drug (cost per 10 tablets), in the same strength and dosage forms being manufactured by different companies was obtained from “Current Index of Medical Specialties” (CIMS) January-April 2016
- The drugs being manufactured by only one company or being manufactured by different companies; however, in different strengths were excluded
- The cost ratio i.e. the ratio of the highest cost brand to lowest cost brand of the same generic antidyslipidemic drug was calculated. For each generic antidyslipidemic drug, we get to know that how many times costliest brand costs how many times more than the cheapest brand
- Percentage cost variation was calculated as follows;[12]

$$\text{Cost variation (\%)} = \frac{\text{Max. cost - Min. Cost}}{\text{Min. cost}} \times 100$$

RESULTS

This study shows that in Indian market, there is wide variation in the prices of different brands of same antidyslipidemic drug.

Among individual antidyslipidemic drugs, highest cost ratio (1:11.17) and percent cost variation (1017.79) was found for atorvastatin 20 mg , followed by atorvastatin 10 mg [(1:10.74) and 974.79] and atorvastatin 5 mg [(1:7.65) and 665.33] (Table 1).

Table 1: Variation in cost of antidyslipidemic drugs.

Antidyslipidemic drug	Strength (mg)	Min. cost (INR)	Max. cost (INR)	Cost ratio	% Cost variation
Atorvastatin	5	9.00	68.88	7.65	665.33
	10	12.00	128.99	10.74	974.91
	20	19.00	212.38	11.17	1017.79
	40	79.00	258.47	3.27	227.17
	80	160.00	374.50	2.34	134.06
Ezetimibe	10	56.70	79.00	1.39	39.32
Fenofibrate	145	91.80	119.00	1.29	29.62
	160	78.60	112.50	1.43	43.12
	200	76.99	138.22	1.79	79.52
Gemfibrozil	300	35.00	73.20	2.09	109.14
Lovastatin	10	45.10	75.00	1.66	66.29
	20	66.55	125.00	1.88	87.82
Rosuvastatin	5	25.00	67.00	2.68	168
	10	33.00	132.00	4.00	300
	20	60.00	400.00	6.66	566.66
	40	266.00	380.00	1.43	42.8
Simvastatin	5	35.00	89.00	2.54	154.28
	10	58.00	123.00	2.12	112.06
	20	147.50	185.00	1.25	25.42

Table 2: Price variation of fixed dose combinations of antidyslipidemic drugs.

Antidyslipidemic drug	Strength (mg)	Min. cost (INR)	Max. cost (INR)	Cost ratio	% Cost variation
Atorvastatin+ Ezetimibe	5 +10	78.74	80.00	1.02	1.60
	10+10	49.40	138.50	2.8	180.36
	20+10	85.25	198.55	2.32	132.9
Atorvastatin+Fenofibrate	10+145	99.00	120.00	1.21	21.21
	10+160	39.00	143.00	3.66	266.66
	10+200	82.00	109.70	1.33	33.78
Rosuvastatin+Fenofibrate	5+67	82.10	88.95	1.08	8.34
	5+145	85.20	125.00	1.47	46.71
	10+67	110.00	160.00	1.45	45.45
	10+145	72.00	148.00	2.05	105.55
	10+160	75.00	145.00	1.93	93.33

Table 3: Brands and formulations of antidyslipidemic drug.

AntidyslipidemicDrug	Strength	Formulations	Brands
Atorvastatin	5 mg	05	21
	10 mg		61
	20 mg		48
	40 mg		23
	80 mg		13
Ezetimibe	10 mg	01	04
Fenofibrate	145 mg	03	02
	160 mg		02
	200 mg		03
Gemfibrozil	300 mg	01	02

Lovastatin	10 mg	02	03
	20 mg		03
Rosuvastatin	5 mg	04	20
	10 mg		24
	20 mg		17
	40 mg		05
Simvastatin	5 mg	03	03
	10 mg		03
	20 mg		03

Table 4: Brands and formulations of fixed dose combinations of antidyslipidemic drugs.

AntidyslipidemicDrug	Strength	Formulations	Brands
Atorvastatin+ Ezetimibe	5+10	03	02
	10+10		21
	20+10		04
Atorvastatin+Fenofibrate	10+145	03	04
	10+160		21
	10+200		03
Rosuvastatin+Fenofibrate	5+67	05	03
	5+145		03
	10+67		03
	10+145		06
	10+160		05

In fixed dose combinations for antidyslipidemic drugs, highest cost ratio (1:3.66) and percent cost variation (266.66) was found for atorvastatin 20 mg+fenofibrate 160 mg , followed by atorvastatin 10 mg+ezetimibe 10 mg [(1:2.8) and 180.36], and atorvastatin 20 mg+ezetimibe 10 mg [(1:2.32) and 132.9] (Table 2).

Highest number of brands of antidyslipidemic drugs available in Indian market are for atorvastatin 10 mg (61) followed by atorvastatin 20 mg (48) and rosuvastatin 10 mg (24) (Table 3).

Highest number of brands of fixed dose combinations of antidyslipidemic drugs available in Indian market are for atorvastatin 10 mg+ezetimibe 10 mg (21) and atorvastatin 10 mg+fenofibrate 160 mg (21) (Table 4).

DISCUSSION

In this study, it was found that there exists a wide cost variation among the different brands of same antidyslipidemic drugs in Indian market. Among individual antidyslipidemic drugs, highest cost ratio and percent cost variation was found for atorvastatin 20 mg, followed by atorvastatin 10 mg and atorvastatin 5 mg. In fixed dose combinations for antidyslipidemic drugs, 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. Highest number of brands of antidyslipidemic drugs available in Indian market are for atorvastatin 10 mg followed by atorvastatin 20 mg and rosuvastatin 10 mg. Highest number of brands of fixed dose combinations of antidyslipidemic drugs available in Indian market are for atorvastatin 10 mg+ezetimibe 10 mg and atorvastatin 10 mg+fenofibrate 160 mg.

The cost of drugs included in National list of essential medicines (NLEM) is regulated by Drug price control order 2013.There are 376 medicines which have been included in NLEM 2015 while in NLEM 2011, there were only 348 medicines.[13,14]

Among the antidyslipidemic drugs in NLEM 2015 issued by government of India, atorvastatin 10 mg, 20 mg and 40 mg have been included.[13]

In NLEM 2011, among the antidyslipidemic drugs, only atorvastatin 5mg and 10 mg were included.[14] Therefore, this increase in the number of formulations of antidyslipidemic drug will facilitate the reduction of cost and thus will reduce the cross variation.

The treatment of dyslipidemia follows a long course of treatment. In India, more than 80% of health financing is borne by patients.[15] A major part of health expenditure is out of pocket and significant portion of this expenditure is on medicines. In Indian scenario, the health insurance schemes are underutilized. The most vulnerable groups of the society are dependent on the out of pocket spending for purchase of medicines. The NLEM may act as a

guidance document for governments to frame strategy in this regard.[14]

Higher medication costs are an important factor for medication nonadherence.[16] Quality of medicines has no correlation with their corresponding prices. The price of medicines have been found to be linked with their marketing strategies.[17] There is lack of awareness among the doctors about the degree of cost variation of drugs. This unawareness among doctors results in increased overall drug expenditures.[18] Availability of drug manual with comparative drug prices among doctors can play an important role in circumventing this lack of awareness about cost variations. This will play an important role in reducing patient's drug expense.[19] Wide variations has been found among the costs of different brands of the antiepileptic agents and antidepressant drugs.[20,21]

Pharmacoeconomics should be an integral part of undergraduate and postgraduate medical education. This will foster their ability to appreciate the efficient usage of the resources without compromising the quality of health care. Very few antidyslipidemic medications are covered under drug prices control order (DPCO). This is an important factor responsible for wide cost variation among their different brands. Hence, it is high time that the government should bring more dyslipidemic drugs under price control.

Provision of drug manual of comparative prices, sensitization about the pharmacoeconomic aspects of drug therapy, increasing the number of antidyslipidemic drugs covered under DPCO and improving the awareness among doctors can play an important role in reducing cost variation of drugs used in the treatment of dyslipidemia.

CONCLUSION

In Indian market, there is very wide price variation of different brands of the same generic antidyslipidemic drug. Treatment of dyslipidemia has long course of treatment. For long term adherence to the treatment, cost of a drug plays an important role for successful drug treatment. Various steps are needed to reduce this wide price variation of different brands of the same generic antidyslipidemic drug.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: Not required

REFERENCES

1. Talbert RL. Dyslipidemia. Dipiro JT, Lamber RL, Yee GC, Matzke GR, Wells BG, Posey LM. Pharmacotherapy: a Pathophysiologic Approach. 19th edition. New York, NY: McGraw-Hill; 2011:365-84.
2. Menotti A, Lanti M, Nedeljkovic S, Nissinen A, Kafatos A, Kromhout D. The relationship of age, blood pressure, serum cholesterol and smoking habits with the risk of typical and atypical coronary heart disease death in the European cohorts of the seven countries study. Int J Cardiology. 2006;106:157-63.
3. Bersot TP. Drug therapy for hypercholesterolemia and dyslipidemia. In: Brunton LB, Chabner BA, Knollman BC, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics.12th ed. New York, NY:Mcgraw-Hill;2011:877-904.
4. Tripathi KD. Essentials of Medical Pharmacology.7th edition. New Delhi: Jaypee Brothers Medical Publishers Pvt. Limited; 2013.
5. Krisko TI, Armstrong EJ, Cohen DE. Pharmacology of cholesterol and lipoprotein metabolism. In: Golan DE, Tashjian Jr. AH, Armstrong EJ, Armstrong AW eds. Principles of pharmacology: the pathophysiologic basis of drug therapy. 4th ed.Philadelphia : Wolters Kluwer Health/Lippincott Williams and Wilkins, 2017:336-55.
6. India in business. Ministry of External affairs, Govt. of India. Investment and Technology Promotion Division. Available at http: //indiainbusiness.nic.in /newdesign/index.php?param=industryservices_landing/347/1. Accessed on 31July 2016.
7. Das SC, Mandal M, Mandal SC. A critical study on availability and price variation between different brands: Impact on access to medicines. Indian J Pharm Sci. 2007;69(1):160-3.
8. Pharmacoeconomics: Principles, Methods, and Applications. Dipiro JT, Lamber RL, Yee GC, Matzke GR, Wells BG, Posey LM. Pharmacotherapy: a Pathophysiologic Approach. 19e. New York, NY: McGraw-Hill;2011:01.
9. Operational Guidelines on Free drug service Initiative. National Health Mission. Available from: https://mpphscl.in/Files/PDF/b731acad-eded-43b6-b2869aea308b1fb_0_Free_Drugs_Service_Intitiative.pdf. Accessed on 31 July 2016.
10. Gupta SK. Proposed Pharmacoeconomics Guidelines for India (PEG-I). IPSOR India. 2013;79:100.
11. Shrank WH, Hoang T, Ettner SL. The implications of choice: prescribing generic or preferred pharmaceuticals improves medication adherence for chronic conditions. Arch Intern Med. 2006;166(3):332-7.
12. Akila L, Rani RJ. Cost analysis of different brands of antianginal drugs available in India. Int J Basic Clin Pharmacol. 2015;4:860-3.
13. National list of essential medicines 2015. Available from: http://www.drugscontrol.org/pdf/NLEM-2015.pdf. Accessed on 22 July 2016.
14. National List of Essential Medicines, 2011. Available at: http: //www.who.int /selection_medicines/country_lists /India_ NLEM _2011. pdf. Accessed on 31 July 2016.
15. Creese A, Kotwani A, Kutzin J, Pillay A. Evauating pharmaceuticals for health policy in low and middle income country settings. In: Freemantle N, Hill S,

editors. Evaluating pharmaceuticals for health policy and reimbursement. Massachusetts, USA: Blackwell Publication; (in collaboration with WHO Geneva); 2004:227-43.
16. Ho PM, Bryson CL, Rumsfeld JS. Medication Adherence: Its Importance in Cardiovascular Outcomes. Circulation. 2009;119:3028-35.
17. Singal GL, Nanda A, Kotwani A. A comparative evaluation of price and quality of some branded versus branded-generic medicines of the same manufacturer in India. Indian J Pharmacol. 2011;43:131-6.
18. Allan GM, Lexchin J, Wiebe N. Physician awareness of drug cost: a systematic review. PLoS Med. 2007;4(9):283.
19. Frazier LM, Brown JT, Divine GW, Fleming GR, Philips NM, Siegal WC, et al. Can physician education lower the cost of prescription drugs? A prospective, controlled trial. Ann Intern Med. 1991;115(2):116-21.
20. Shukla AK, Mehani R. Cost analysis of antiepileptic drugs available in India. Int J Basic Clin Pharmacol. 2016;5:1636-40.
21. Shukla AK, Sharma P. Cost variation study of antidepressant drugs. Int J Basic Clin Pharmacol. doi:10.18203/2319-2003.ijbcp20162695.

Cite this article as: Shukla AK, Sharma P. Cost variation analysis of antidyslipidemic drugs. Int J Basic Clin Pharmacol 2016;5:1850-5.