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Pharmacology

COST VARIATION ANALYSIS OF SECOND GENERATION ANTIHISTAMINIC DRUGS (SGAS): A STUDY

Dr. Girish Joshi Professor Additional, Pharmacology Department, LTMMC & MGH, Sion, Mumbai -22

KEYWORDS :

INTRODUCTION

Allergic rhinitis (AR) is the most common form of non-infectious rhinitis most commonly affecting adults. AR affects 10% and 30% of all adults and 40% of children. Epidemiologic studies by WHO show that the prevalence of AR continues to increase worldwide and is estimated as 400 million.[1] AR can impair quality of life and through loss of work and school attendance, is responsible for as much as $2 to $4 billion in lost productivity annually.[2,3]

AR is an inflammatory, IgE-mediated disease characterized by nasal congestion, rhinorrhea (nasal drainage), sneezing and/or nasal itching. It can also be defined as inflammation of the inside lining of the nose that occurs when a person inhales something he or she is allergic to, such as animal dander or pollen; examples of the symptoms of AR are sneezing, stuffy nose, runny nose, post nasal drip, and itchy nose.[4]

AR may be classified by (1) the temporal pattern of exposure to a triggering allergen, such as *seasonal* (eg, pollens), *perennial/ year-round* (eg, dust mites), or *episodic* (environmental from exposures not normally encountered in the patient's environment, eg, visiting a home with pets); (2) frequency of symptoms; and (3) severity of symptoms. Classifying AR in this manner may assist in choosing the most appropriate treatment strategies for an individual patient.[4]

Management of patients with AR involves avoiding the allergen, if the allergen is known; and/or drug therapy. The drug therapy for patients with AR includes antihistamines, corticosteroids, sympathomimetics and mast cell stabilizers. Among these, H1 antihistamines especially the second-generation antihistamines (SGAs) are the most commonly used drugs for AR nowadays. SGAs are preferred over first generation antihistamines, as they have quicker onset of action, are highly effective on symptoms such as rhinorrhea, sneezing, and nasal pruritus, and are relatively safe in that they cause less sedation and other side effects of first generation antihistamines.[5,6]

Since the prevalence of AR is very high worldwide, the impact on health economics of the world is very large. The cost of AR in terms of money is even more than that of chronic diseases like diabetes, hypertension, coronary heart disease and depression.[7] Although some patients with AR may require SGAs for short duration of 3-5 days, many patients having persistent allergic rhinitis require prolonged or even life-long use of SGAs, putting them under great economic burden. This may lead to non-compliance to drugs and would also affect the disease management and the quality of life of the patient. The cost of medication is one of the most important determinants in compliance to the drugs, especially in developing country like India where most of the people are in the middle-income and low-income group and most do not have health insurance. Selection of low cost quality drugs would thus be helpful in this regard and may improve the patient's compliance to medication.[8]

Large number of drug formulations of various branded and generic antihistamines are flooded in the Indian market and the price also varies to a great extent. Drug prices in Indian market are kept under control by the National pharmaceutical pricing authority (NPPA), under the department of pharmaceuticals, Ministry of chemicals and fertilizers, Government of India. NPPA fixes/revises the prices of controlled drugs and formulations and is responsible to implement and enforces the prices and availability of the medicines in the country, as per the drugs prices control order, 2013, an order issued by the Indian government. It fixes the ceiling price of a drug based on essentiality of a drug. The pharmaceutical companies are then free to fix the price for their products equal to or below the ceiling price for that formulation; however, they cannot sell any medicine given in the drugs prices control order (DPCO) list at a cost higher than that fixed under this order.[9] However, only around 18% of medicines are under price control. The pharmaceutical companies can market the drugs not included in the DPCO list at a price based on their own calculations. This leads to large discrepancy in the cost of same drug manufactured by different companies in India.[10]

Pharmacoeconomics has been defined as the description and analysis of the cost of drug therapy to health care systems and society.[11] Pharmacoeconomic evaluation is called full economic evaluation when both costs and outcomes are assessed, whereas it is partial economic evaluation when only costs of two or more alternatives are assessed without regard to outcome.[12,13] Partial pharmacoeconomic evaluation will thus help to identify a preferred choice of medicine or treatment among possible alternatives based on the cost.

We are planning Partial pharmacoeconomic study to help create awareness among the doctors, pharmacists, consumers and other stakeholders regarding the range of price differences between the various generic and non-generic brands of the same SGA's being manufactured by different companies in India and thus may prove beneficial in decreasing the prescription costs.

METHOD

The costs of different branded SGA's available in Indian market were referred from the latest edition of current index of medical specialties (CIMS) September to December 2019 and the website www.medguideindia.com.[14,15] In this study, the cost of drugs in Indian rupee (INR) per ten tablets or capsules with same strength and dose of each drug and if available, cost of one injection with same strength and dose are included. The dose for each drug is taken as per WHO defined daily dose (DDD),from WHO anatomical, therapeutic and chemical (ATC) classification system for allergic rhinitis. According to WHO, "DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults".[16]

The highest and lowest price of each SGA manufactured by different pharmaceutical companies was noted. The percentage cost variation and cost ratio were then calculated for each drug. The percentage variation in the cost of the drugs was calculated using the following formula:

Percentage cost variation=(Most expensive formulation of the same SGA-Least expensive formulation of the same SGA)/(Least expensive formulation of the same SGA) x 100.[17,18]

COST RATIO FORMULA

Cost ratio=Most expensive formulation of the same SGA/Least expensive formulation of the same SGA.[17] It helps in determining how many times the most expensive formulation is costlier than the least expensive formulation of the same drug.

EXCLUSION CRITERIA

Fixed Dose Combinations (FDC's) with first generation antihistamines or with drugs other than SGAs, drug formulations of varying strength and drugs with no cost information. The study did not involve intervention or interactions with the patient or subjects and ethics committee approval was thus not required for this study.

STATISTICALANALYSIS

The data were entered in Microsoft excel 2016 software and percentage cost variation and cost ratio were calculated using this software.

TABLE 1

Drug name	DDD (WHO) (mg)	No. of manufacturers (brands)	Least expensive (INR)	Most expensive (INR)	Cost ratio	Cost variation (%)
Cetirizine hydrochloride	10	128	17.3	197	11.39	1039
Levocetirizine	5	169	19.8	136	6.87	587
Loratadine	10	65	19.08	101.84	5.34	434
Desloratadine	5	49	39	85	2.17	118
Fexofenadine hydrochloride	120	70	45	130	2.89	189
Ebastine	10	6	54	109.4	2.03	103
Rupatadine	10	10	52.25	132.35	2.53	153
Mizolastine	10	2	40	139.5	3.49	249

RESULTS

Table 1 shows the cost variation of different Second generation Antihistaminics. It was observed that number of brand varied for each SGA and Levocetirizine have maximum brands available and least brands are for Mizolastine. A total of eight oral SGAs used in allergic rhinitis are available in the Indian market and a total of 487 oral tablets or capsules manufactured by different companies were identified for all the SGAs.

In this study, huge variation was found in the cost of different branded preparations for the same drug (1039% for cetirizine; INR 17.3 to INR 197). Most expensive cetirizine was 11.39 times costlier than the least expensive cetirizine, levocetirizine 6.87 times costlier than the least expensive levocetirizine, and the costlier Ebastine was 2.03 times costlier than the lower priced one. From this study, maximum variation was found in Cetirizine and least variation was found in Ebastine.[19]

DISCUSSION

Pharmacoeconomics is a branch of health economics which particularly focuses upon the cost and benefit of drug therapy thereby providing a guide for decision making on resource allocation and in planning process. Government & private healthcare institutes are targeting curtailment of expenditure on drugs for saving in healthcare costs.[20]

It is very much important for the prescribing doctors to know about the cost of drugs to reduce the price burden on the patient but there are not many studies carried out on the topic. So we undertook the above study. Cost of drugs is an important determinant of compliance to treatment by the patients. In a study by Boston consulting group, 17% of patients reported noncompliance to drugs due to the high cost of medication.[21] In another study, the most common reasons for noncompliance were related to the cost of medication: 55.5% of the patients thought that the drug would cost too much, and 20.2% said that the medicines were not covered by insurance.[22]

In India, currently less than 1/5th of its medicines are under price control; the government should thus bring more drugs under the ambit of price control to ensure affordability.[10] A good example is Egypt, which has brought all its medicines under price control.[23] Government should introduce low-cost insurance schemes to increase the economic affordability and thus compliance to therapy. The Indian government and its state governments are trying to provide low cost drugs to people by establishing centers like Jan aushadhi, niramaya arvi and locost.[24-26] Indian government has recently started 293 'Jan aushadhi' generic medicine stores to provide low-cost quality medicines to people of India, although the number is quiet less in comparison to the India's large population of 1.2 billion.[24] The NPPA 2019 list of price-controlled drugs includes only one SGA cetirizine. The drugs not on the DPCO list are outside the purview of NPPA and manufacturers are free to price their drugs as per their choice.

Physicians should thus prescribe the low cost drugs and should not be influenced by pharmaceutical industries. Free lunches, free conferences, free holiday trips, gifts and other unfair practices used by pharmaceutical industries to influence prescribing should be strictly discouraged. Medical council of India is taking an initiative in this regard. The role of pharmacist is also very important in influencing the cost at which drugs are available to the patients. It has been seen that unbranded generics, although cheaper are rarely sold in private pharmacies due to lower profit margin. Also, the margin by the companies to pharmacists varies to a great extent, with the drug giving higher margin to the pharmacist being preferred. Moreover, many of the patients with allergic rhinitis buy these drugs over-the-counter and in many cases the consumer is left with no choice but has to buy the drugs as per the pharmacist's selection.

CONCLUSION

There is huge variation in price of a particular second generation antihistamine being manufactured by different companies and also between the different SGAs available in the Indian market probably because of not including Second generation antihistamines in the DPCO list except Cetrizine. Between the least expensive and the most expensive cetirizine, there is a huge cost variation of 1039%.

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