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Cost Analysis of Second Generation Antihistamines Available in Indian Market



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**Gowtham Nagarajan^{1*}, Hima Bindu Gujjaramudi²,
Uma Maheswari Nagireddy³, Solomon Raju
Kankipati⁴**

1. *2nd year postgraduate Department of Pharmacology, Government medical College, Ongole, Andhra Pradesh. India.*
2. *Assistant Professor, Department of Pharmacology, Government medical College, Ongole, Andhra Pradesh. India.*
3. *Assistant Professor, Department of Pharmacology, Government medical College, Ongole, Andhra Pradesh. India.*
4. *Professor and HOD, Department of Pharmacology, Government medical College, Ongole, Andhra Pradesh. India.*

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ABSTRACT

Background: Antihistamine drugs are extensively used to treat allergic rhinitis and other allergies. They provide relief from nasal congestion, sneezing, or hives caused by pollen and dust mites with few side effects. Various drugs with different brands and variations in prices are available in the Indian market. This study was done to find out the percentage variation of cost among different brands of antihistamine drugs available in the Indian market.

Methods: The cost of various second-generation antihistamine drugs available in the Indian market were referred from CIMS (current index of medical specialties) (March 2022) and Indian Drug Today (October 2021 to January 2022). The highest and lowest price for ten (10) tablets/capsules of each second-generation antihistamine was analyzed. The percentage cost variation and cost ratio were calculated for each drug. **Results:** A total of eleven oral Second Generation Antihistamines available in the Indian market and 566 oral tablets or capsules manufactured by different companies were identified for all the Second Generation Antihistamines. Huge variation was found in the cost of different branded preparations for the same drug (40.14% for cetirizine; INR 2.06 to INR 84.76). The most expensive cetirizine was 11.39 times costlier than the least expensive cetirizine. The least-cost variation and cost ratio saw with Bepotastine (10%) and (1.1) respectively. **Conclusion:** This study shows tremendous variation in the prices of antihistamine drugs, especially among second-generation antihistamine drugs available in India. Physicians have to select cost-effective drugs to decrease the economic burden on society.



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INTRODUCTION

Allergic rhinitis and urticaria are histamine-mediated reactions requiring management with pharmacological agents^{1,2}. Histamine is a naturally occurring compound present throughout the human body. It plays an important role in embryo development, wound healing, and regeneration through H₁histamine receptors. World Allergy Association, an international umbrella organization for regional and national allergy and clinical immunology societies, in a 2011 report states that the prevalence of allergic conditions such as rhinitis, anaphylaxis, food and medicine allergies, and urticaria are rising worldwide in both developing and developed nations^{3,4}. It is estimated that between 30-40% of the world's population suffers from an allergic condition at any given time; Worldwide, an estimated 40-50% of schoolchildren are expected to be sensitized to one or more of the common allergen^{2,3}. Allergic rhinitis affects up to 30% of adults and 40% of children worldwide^{3,5}. While considered trivial in India, 75 percent of children and 80 percent of adults with asthma reported AR². It alters a patient's quality of life by interfering in social life, sleep, academics and contributes to substantial indirect economic impact⁶. Furthermore, the worldwide prevalence of chronic idiopathic urticaria, characterized by hives, wheals, and pruritus, is estimated to be up to 0.5%, with the average duration of the disease between 3-7 years. Many chronic allergic conditions are underdiagnosed and undertreated due to lack of awareness resulting in the hampering of quality of life³. The primary target of antihistamines is the H₁ receptor involved in allergic inflammation, sleep cycles, cognition, and memory⁷⁻¹⁰. First-generation Antihistamines are widely used in adults and children for the management of allergic rhinitis¹². WHO recommends second-generation antihistamines as the preferred first-line agents for allergic rhinitis^{8,10}. Several classes of medications are used for the treatment of allergic rhinitis including antihistamines, corticosteroids, mast cell stabilizers, decongestants, nasal anticholinergics, and leukotriene-receptor agonists¹³. The Second generation Antihistamines bypass many of the side effects associated with First-generation Antihistamines due to their pharmacology. Pharmacoeconomics has been defined as the description and analysis of the cost of drug therapy to health care systems and society¹⁴. 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 outcomes^{15,16}. Although some patients with AR may require SGAs for a short duration of 3-5 days, many patients having Persistent allergic rhinitis require prolonged or even life-long use of SGAs, putting them under a 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. Various drugs with different brands and variations in prices are available in the Indian market. It is very much important for the prescribing doctors to know about the cost of drugs to reduce the price burden on the patient. So, this study was done to find out the percentage variation of cost among different brands of antihistamine drugs available in the Indian market.

METHODS

The cost of various antihistamine drugs available in the Indian market was referred from (current index of medical specialties) CIMS (March 2022) and Indian Drug Today (October 2021 to January 2022). The highest and lowest price for ten (10) tablets/capsules of each second-generation antihistamine was analyzed. The highest and lowest price of each antihistamine 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 antihistamine - Least expensive formulation of the same antihistamine) / (Least expensive formulation of the same antihistamine) x 100^{17,18}.

Cost ratio formula

Cost ratio = Most expensive formulation of the same antihistamine / Least expensive formulation of the same antihistamine¹⁷.

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 (FDCs) with Second-generation antihistamines, drug formulations of varying strength, and drugs with no cost information.

Statistical Analysis

The data were entered in Microsoft excel 2016 software and percentage cost variation and cost ratio were calculated. Data is represented in the form of tables and charts.

RESULTS

Table 1 shows cost analysis of different Second Generation Antihistamines. It was shown that the maximum number of manufacturing brands available for Levocetirizine HCL and least was for Mizolastine. A total of eleven oral Second Generation Antihistamines available in the Indian market and a total of 566 oral tablets or capsules manufactured by different companies were identified for all the Second Generation Antihistamines.

Table No. 1: Cost analysis of Second-generation Antihistamines available in Indian Market

Drug Name	WHO (DDD) (mg)	No of Manufacturing companies (brands)	Least expensive INR	Most expensive INR	Cost ratio	Cost Variation (%)
Cetirizine dihydrochloride	10mg	132	2.06	84.76	41.14	4014
Levocetirizine Hcl	5mg	188	8.95	89.5	10	900
Loratadine	10mg	59	18.17	101.84	5.6	460
Desloratadine	5mg	34	26	93	3.57	257
Fexofenadine	120mg	88	28.5	171.82	6.02	502
Ebastine	10mg	13	44.5	98	2.2	120
Rupatadine	10mg	15	45	138.6	3.08	208
Mizolastine	10mg	3	40	153.43	3.83	283
Bilastine	20mg	15	107	130	1.21	21
Bepotastine	10mg	7	99	108.85	1.1	10
Ketotifen	2mg	12	10.5	88	8.38	738

Figure 1 and 2 shows huge variation was found in the cost of different branded preparations for the same drug (4014% for cetirizine; INR 2.06 to INR 84.76). The most expensive cetirizine was 11.39 times costlier than the least expensive cetirizine. The least-cost variation and cost ratio saw with Bepotastine (10%) and (1.1) respectively.

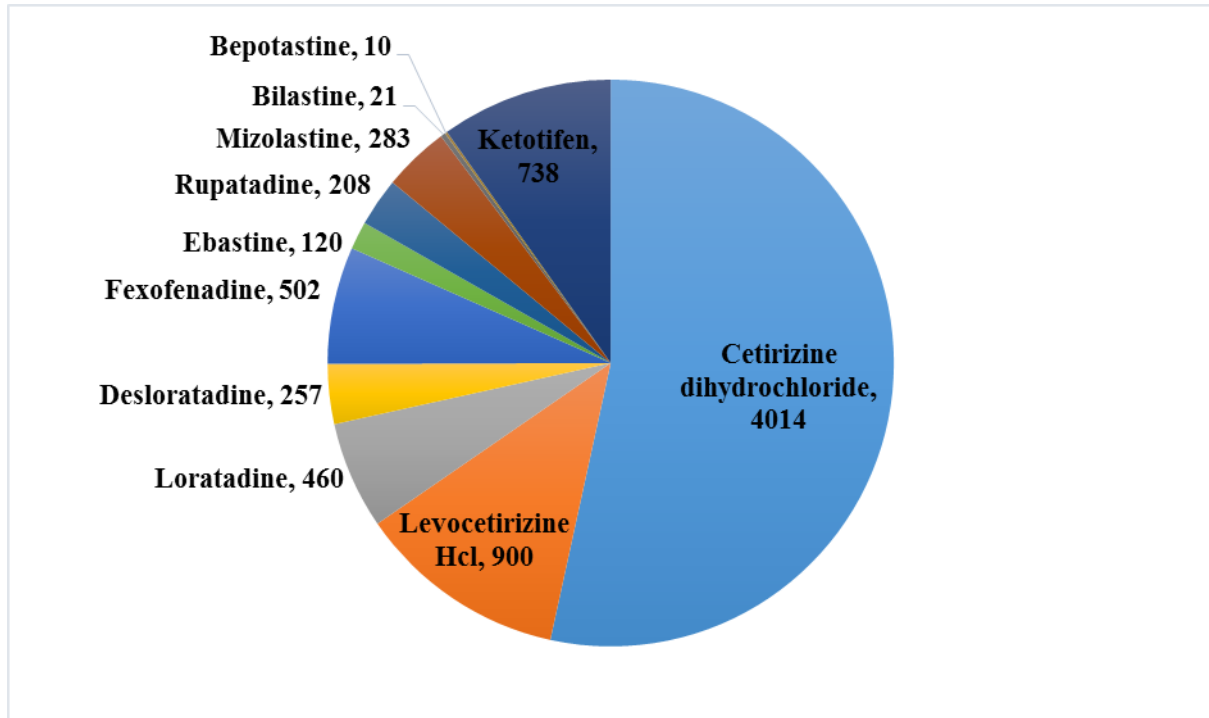


Fig. No. 1: Cost Variation (%)

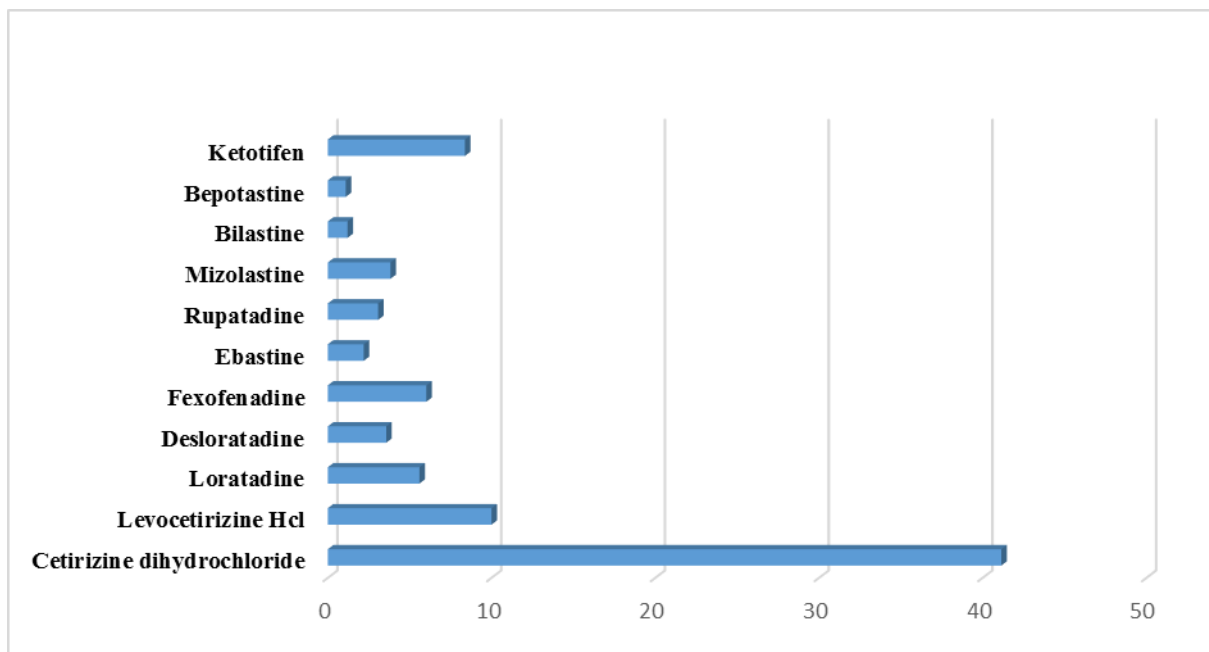


Fig. No. 2: Cost Ratio

DISCUSSION

Pharmacoeconomics is a branch of health economics that particularly focuses upon the cost and benefit of drug therapy thereby providing a guide for decision making on resource allocation and in the planning process. Government & private healthcare institutes are targeting curtailment of expenditure on drugs for saving in healthcare costs¹⁹. The 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 medication²⁰. 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 insurance²¹. Drug prices in the 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 enforce the prices and availability of the medicines in the country, as per the prices of the drugs control order, 2013, an order issued by the Indian government. It fixes the ceiling price of a drug based on the 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 prices of the drugs control order (DPCO) list at a cost higher than that fixed under this order²². 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 a large discrepancy in the cost of the same drug manufactured by different companies in India²³. In this study, huge variation was found in the cost of different preparations for the same drug, especially with Levocetirizine. Out of 373 manufacturing companies, the most expensive levocetirizine costs INR 125.35 with the least cost of INR 7 resulting in the highest cost variation (1690 %) and cost ratio (17.90) among all second-generation antihistamines. On the contrary, Rupatadine showed the least cost variation (7.7%) and cost ratio (1.07) among all antihistamines agents. In India, 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 like Egypt, which has brought all its medicines under price control²⁴. The Indian government and its state governments are trying to provide low-cost drugs to people by establishing centers like Jan aushadhi, niramayaarvi and locost²⁵⁻²⁷. 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 quite less in comparison to India's large population of 1.2 billion ³¹. The NPPA 2019 list of price-controlled drugs includes only one second-generation antihistamine 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. The pharmacist plays a pivotal role in influencing the cost as 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. Policymakers to make healthcare affordable should be easy accessibility of consumers to quality, low-priced drugs to reduce the cost of treatment, which in turn would help increase the compliance and quality of life of patients.

CONCLUSION:

This study shows tremendous variation in the prices of antihistamine drugs, especially among second-generation antihistamine drugs available in India. Healthcare professionals have to select cost-effective drugs decreasing the economic burden on society.

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	<p>Gowtham Nagarajan– Corresponding Author Second year postgraduate, Department of Pharmacology, Government medical College, Ongole, Andhra Pradesh Institute Address: Government Medical college, Ramnagar, Ongole, Andhra Pradesh,523001</p>
	<p>Hima Bindu Gujjarlamudi Assistant Professor, Department of Pharmacology, Government medical College, Ongole, Andhra Pradesh Institute Address: Government Medical college, Ramnagar, Ongole, Andhra Pradesh,523001</p>
	<p>Uma Maheswari Nagireddy Assistant Professor, Department of Pharmacology, Government medical College, Ongole, Andhra Pradesh Institute Address: Government Medical college, Ramnagar, Ongole, Andhra Pradesh,523001</p>
	<p>Solomon Raju Kankipati Professor and HOD, Department of Pharmacology, Government medical College, Ongole, Andhra Pradesh Institute Address: Government Medical college, Ramnagar, Ongole, Andhra Pradesh,523001</p>