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Original Research Article

Cost variation analysis of anti-epileptic drugs available in the Indian market

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ABSTRACT

Background: Epilepsy is a chronic, noncommunicable disease of the brain affecting 50 million people worldwide. Out-of-pocket expenditure (OOPE) remains a major burden for Indian households, leading to poor adherence in epilepsy treatment. Many patients discontinue therapy due to high costs, worsening disease outcomes. This study aimed to analyse price variations among different brands of anti-epileptic drugs (AEDs) available in India.
Methods: The prices in Indian rupees for all AEDs of same strength manufactured by different pharmaceutical companies in the Indian market were obtained from Current Index of Medical Specialities (CIMS) 3rd update 2024, Indian drug review (IDR) 2024 issue and National Pharmaceutical Pricing Authority (NPPA)-Pharma Sahi Daam. The cost ratio was calculated by dividing the price of the costliest brand by the price of the least costly brand. The percentage cost variation was determined by subtracting the minimum cost from the maximum cost, dividing it by the minimum cost and multiplying by 100.
Results: Analysis of 1708 brands of 23 single AEDs and 112 brands of fixed dose combinations (FDCs) in India revealed wide cost variations. Clonazepam showed highest percentage cost variation and cost ratio among single drugs, while Oxcarbazepine and Sodium valproate had the lowest percentage cost variation and cost ratio, respectively.
Conclusions: The study highlights significant cost disparities among different brands of AEDs, affecting patients' OOPEs. Clinicians should therefore consider these price variations to prescribe cost-effective treatments, improving patient compliance and disease outcomes. The findings also emphasize need for regulatory measures to promote equitable and affordable drug pricing.

Keywords: Anti-epileptic drugs, Cost variation, Indian market

INTRODUCTION

Epilepsy is a chronic, noncommunicable neurological disorder that affects people of all ages.[1] According to the Epilepsy Foundation, 50 million people worldwide suffer from epilepsy, out of which around 10-12 million people reside in India.[2] Epilepsy is a chronic disorder necessitating long term treatment, sometimes even lifelong. It has significant economic implications in terms of healthcare needs such as cost of diagnostic procedures, medications, hospital visits and emergency care for breakthrough seizures. People with epilepsy have a higher risk of premature death due to seizure-related accidents or sudden unexpected death. Frequent seizures, adverse drug reactions and social stigma makes it difficult for people with epilepsy to find work and some may experience discrimination at work or struggle to keep a steady job because of their illness.[3]

The economic burden on patients depends on the age of onset, impact on quality of life, cost of treatment, rehabilitation, risk of mortality and several other factors. With the advent of new antiepileptic drugs and implementation of surgical programs, the direct cost of epilepsy has increased by many folds. Increase in the cost of epilepsy care would be an additional strain on the already weak economics in the developing countries.[4]

Antiepileptic drugs (AEDs) are the mainstay of treatment for epilepsy. The overall goal is to completely prevent seizures without causing any harmful side effects, preferably with a single medication and a dosing schedule that is easy for the patient to follow. Worldwide, older medications such as phenytoin, valproic acid, carbamazepine, phenobarbital and ethosuximide are generally used as first line therapy for different type of seizure disorders backed by evidence and they are overall effective and are available at significantly lower cost.[5]

Several studies have reported that a large proportion of patients with epilepsy in resource-poor countries although diagnosed and initiated on treatment, soon discontinue treatment leading to decreased adherence. The high cost of treatment is one of the major reasons for decreased adherence.[6]

A substantial proportion of the current burden of epilepsy could be minimized by educating the public about regular use of AEDs and scaling up routine availability of low-cost antiepileptic drugs.[7] There is also a significant challenge for the treating physicians to deliver high-quality patient care while keeping the cost low in order to lessen the financial strain on the patient.[8]

Medicines continues to be the highest contributor of OOPE on healthcare in developing countries like India, accounting to significant financial burden on low-income individuals.[9] Drug costs are considered when adding medications to formularies and the National List of Essential Medicines (NLEM), in addition to safety and efficacy. The Indian pharmaceutical industry is expanding quickly and as a result, the country's market is crowded with branded generics produced by several companies, with costs for different brands of the same formulation varying greatly. There has also been a concerning disregard among doctors for the disparity in cost between different brands of medication.[10]

Therefore, this study was proposed to find out and compare the price variations among different brands of the same formulation of all AEDs. The understanding of the differences in prices amongst different brands of AEDs can be applied to create more cost-effective treatment plans for the treating physicians, improving patient compliance and thereby reducing the treatment gaps in epilepsy care.

METHODS

This cross-sectional, observational study was conducted by the Department of Pharmacology at HBT Medical College and Dr RN Cooper Hospital over a period of 3 months from October to December 2024 after seeking approval from the Institutional Ethics Committee (HBTMC/IEC/6-2024/0/RP/263/24092024/2025). All single AEDs and FDCs were considered for analysis. The prices in Indian Rupees (INR) for all AEDs of different brands were obtained from Current Index of Medical Specialities (CIMS) 3rd update 2024, Indian Drug Review (IDR) 2024 issue and National Pharmaceutical Pricing Authority (NPPA)-Pharma Sahi Daam as they are readily available source of drug information and are updated regularly. Different dosage forms of all the AEDs available in the Indian market were included in this study.

The cost of each unit of the dosage form for the concerning formulation was noted. The minimum cost and the maximum cost in INR of each single AED and FDCs, manufactured by various pharmaceutical companies of the same strength was noted. The difference between maximum and minimum cost was obtained by the cost ratio, calculated by the formula,

Cost ratio=Price of costliest brand/Price of least costly brand.

Percentage cost variation was calculated by using the following formula.

Percentage cost variation=Maximum cost- Minimum cost/ Minimum cost×100.

The maximum percentage cost variation and cost ratio of a drugs were noted. Also, the minimum percentage cost variation and cost ratio of drugs were noted.

The collected data was entered in MS Excel and values were expressed in counts, percentages and ratios.

RESULTS

A total of 1708 brands of 23 single AEDs (Figure 1) and 112 brands of 2 FDCs of anti-epileptic drugs including all the dosage forms and strengths available in the Indian market were analysed.

Single drug formulations

Among single drug formulations, a total 23 drug preparations were analysed. Maximum number of brands were available for tablet clonazepam 0.5 mg (79 brands) followed by tablet levetiracetam 500 mg (71 brands). The highest percentage cost variation was found for Tablet Clonazepam 0.5 mg as 5066.66% (Figure 2).

Other significant percentage cost variations found were for injection lacosamide 10 mg (3123.38%), followed by injection levetiracetam 500 mg (2450.49%), tablet phenytoin 50 mg (1866.29%) and tablet lorazepam 1mg (1580.51%).

The highest cost ratio was found with tablet Clonazepam 0.5mg as 51.6 (Figure 3). The lowest percentage cost variation was found with tablet Oxcarbazepine extended release 600mg as 0.54% (Figure 4) and the lowest cost ratio was found with tablet sodium valproate-controlled release 200mg as 1.03 (Figure 5).

The AEDs were available in different formulations such as tablets, capsules, injections, suspensions, solutions. The oral formulations were also available in modified tablet forms such as controlled release tablets, extended-release tablets, sustained release tablets and dispersible tablets. The details regarding injectable AEDs with respect to total number of brands, their cost ratio and percentage cost variations are represented in Table 1.

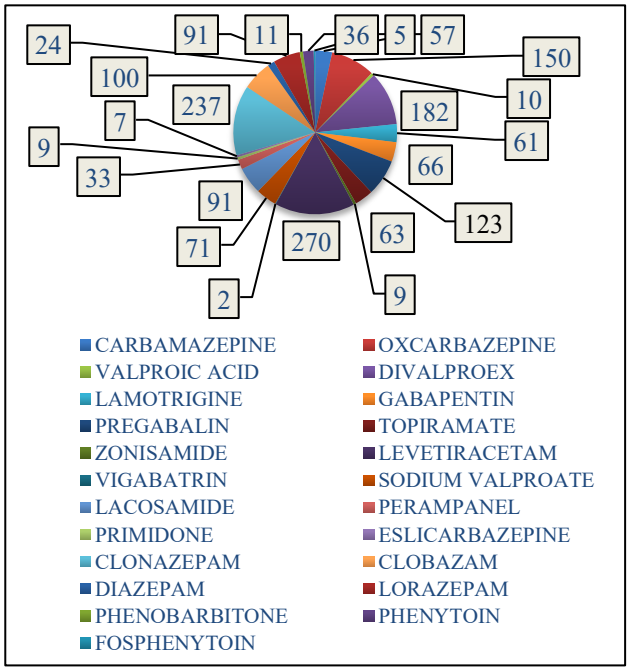

Figure 1: Total number of brands for all single AEDs (n=1708).

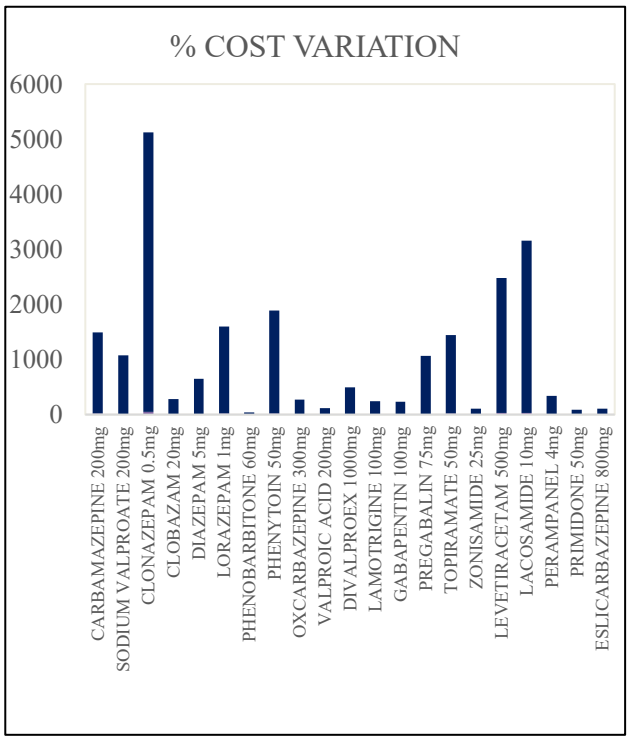

Figure 2: Maximum percentage cost variation (n=21).

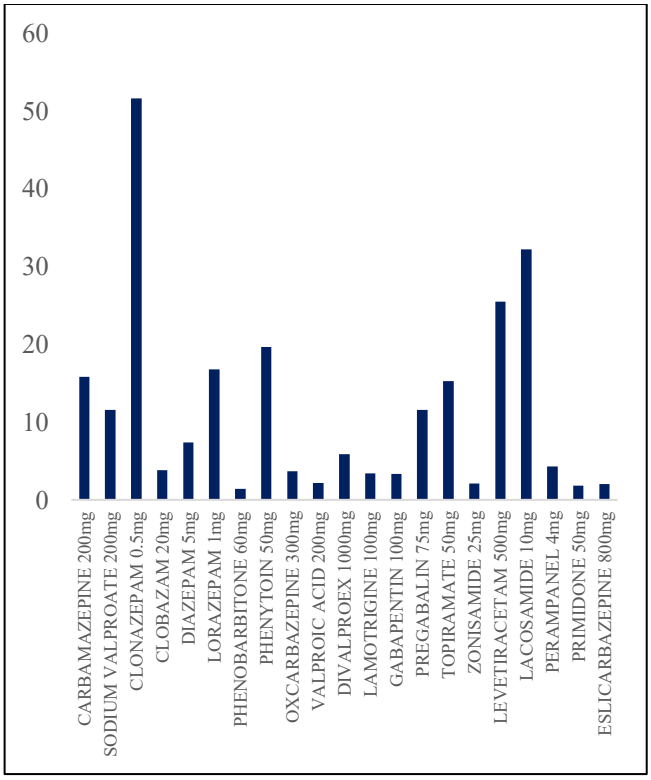

Figure 3: Maximum cost ratio (n=21).

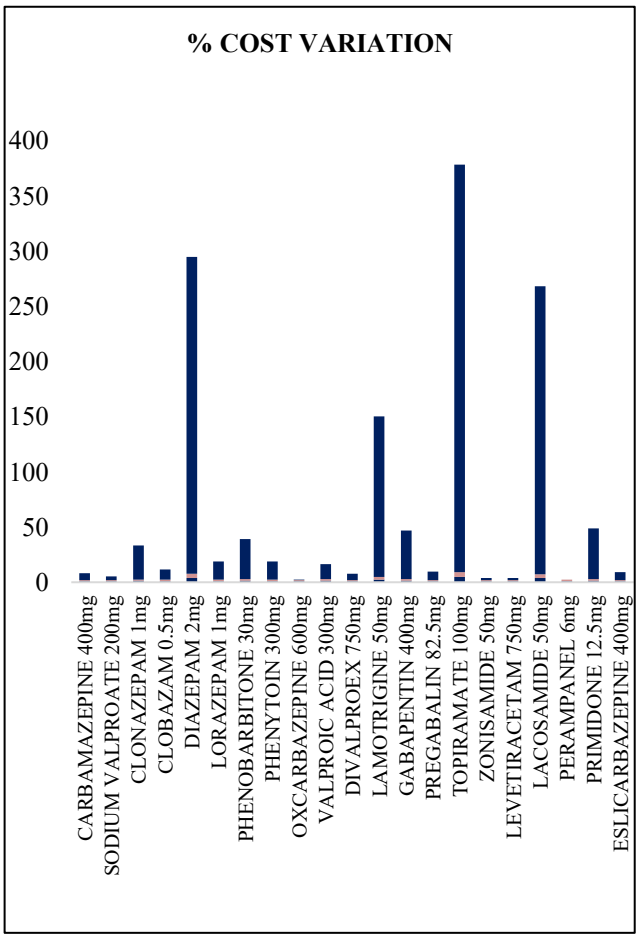

Figure 4: Minimum percentage cost variation (n=21).

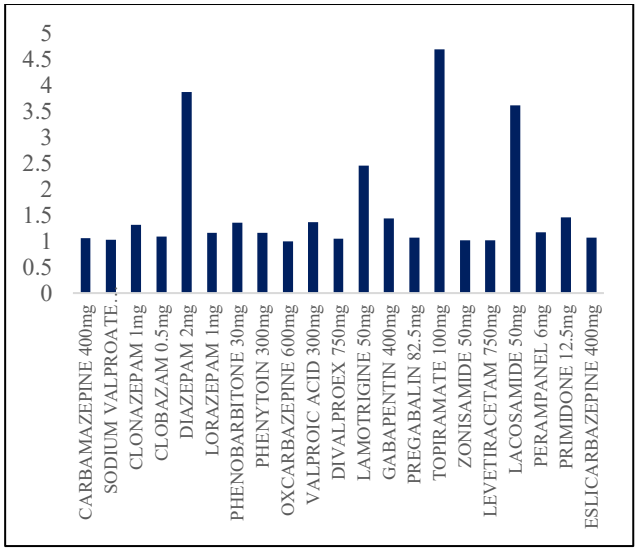

Figure 5: Minimum cost ratio (n=21).

Fixed dose combinations

Only 2 FDCs formulations were available in the resources used. Maximum number of brands were available for Tablet Sodium valproate+Valproic acid 200/85 mg (19 brands) followed by 333/145 mg of the same drug in tablet formulation. These FDCs were available in tablet and controlled release tablet dosage forms.

The highest cost variation in FDC was found for tablet sodium valproate+Valproic acid 333/145 mg controlled release (967.8%) while the lowest percentage cost variation was found in the same drug with a different strength as 400/174 mg Tablet formulation (17.44%).

The highest cost ratio was found with tablet sodium valproate+Valproic acid 333/145 mg controlled release (10.67) and lowest cost ratio was found with a different dosage formulation of the same drug as 400/174 mg tablet (1.17).

Table 1: Number of brands, cost ratio and percentage cost variation of injectable AEDs (n=8).

Drug name	Strength	Brands	Lowest price	Highest price	Cost ratio	% Cost variation
Sodium valproate	100 mg	2	7.55	7.55	1	0
Diazepam	5 mg	5	1.82	9.17	5.04	403.84
Lorazepam	2 mg	6	8	28.15	3.52	251.87
Phenobarbitone	200 mg	3	19.02	24.79	1.3	30.33
Phenytoin	50 mg	7	5.23	6.67	1.28	27.53
Fosphenytoin	150 mg	3	22.46	51.1	2.28	127.51
	75 mg	2	26.9	37.75	1.4	40.33
Levetiracetam	100 mg	22	16.27	115.16	7.08	607.8
	1000 mg	3	1.61	1.83	1.14	13.66
	500 mg	10	1.01	25.76	25.5	2450.49
Lacosamide	10 mg	9	6.67	215	32.23	3123.38

DISCUSSION

India's pharmaceutical sector has established itself as the third-largest drug producer globally by volume and the fourteenth largest by value.[11] A research conducted by the India Brand Equity Foundation revealed that India holds the top position as the main provider of generic medications, meeting over half of the worldwide demand for vaccines, 30% of the yearly needs of the United Nations International Children's Emergency Fund (UNICEF), 40% of the generic drugs used in the United States of America (USA), 25% of all medications in the United Kingdom (UK) and 60% of the global supply of anti-retroviral drugs.[11]

The Indian Pharmaceutical market is vast, with numerous pharmaceutical companies offering the same medication under various brand labels in addition to the original manufacturer. This scenario has resulted in a wide range of variation in the cost of drug available in the market.

In this study, the highest percentage cost variation and cost ratio was found with Clonazepam, the lowest percentage cost variation was found with Oxcarbazepine and the lowest cost ratio was found with Sodium valproate. The results were similar to the study conducted by Banerjee et al and Kumar et al, where Clonazepam showed highest cost ratio and percentage cost variation, whereas the lowest cost ratio and percentage cost variation was found with Carbamazepine.[12]

Similar study by Kumar et al has mentioned clonazepam exhibited highest cost ratio and percentage cost variation, which aligned with the result of this study and carbamazepine showed lowest cost ratio and percentage cost variation.[13] In a study conducted by Sai et al, the highest cost ratio and percentage cost variation were shown by carbamazepine and the lowest percentage cost variation was shown by Oxcarbazepine which is in agreement with the result of this study.[14] As observed in the present study, these wide variations in the prices of different brands of the

same drug have severe economic implications in India, as more than 80% of health-related expenses in India is borne by patients in contrast to those in developed countries.[15]

Patients financial burden is increased when a costly brand is prescribed as they must pay extra for the same medication available at low cost in the market. This can be avoided by informing the public about the several health insurance options available, enabling them to receive high-quality and affordable healthcare services.[16] A study conducted by Eaddy et al, on cost sharing trends affecting the adherence and outcomes has concluded that 85% of the studies which showed an increasing patient share of medication costs was significantly associated with a decrease in adherence.[6]

This finding has highlighted that giving doctors access to a handbook of comparable medication costs along with illustrative prescription recommendations can assist in lowering patient medication costs, particularly for those suffering from chronic disorders requiring long-term treatment.[17]

The practice of prescribing generic medications rather than branded ones is being encouraged these days and is well recognized in many countries; however, it is still not widely accepted in India.[18] To increase the availability of generic medicines to the population, the Government of India launched the Jan Aushadhi Scheme (JAS) in 2008. Prices of the Jan Aushadhi medicines are 50%-80% less than that of branded medicine's prices available in the open market and these medicines are procured only from World Health Organization Good Manufacturing Practices (WHO-GMP) certified manufacturers for ensuring the quality of the products with each batch of drug is tested at laboratories accredited by 'National Accreditation Board for Testing and Calibration Laboratories' (NABL) for ensuring best quality.[19]

In India, the drug prices are regulated by the National Pharmaceutical Pricing Authority (NPPA) of the Government of India. It fixes the ceiling price of a particular drug based on its essentiality. It also safeguards the interest of both the manufacturer and the consumers by ensuring that the essential medicines are available at affordable prices. Essential medicines are those that satisfy the priority health care needs of the population. They are selected with regard to public health relevance, evidence on efficacy and safety and comparative cost-effectiveness.

This prevents pharmaceutical companies from selling medicines at a price which is higher than the ceiling price.[20] NPPA deserves recognition for their crucial role in ensuring availability of affordable healthcare in India. Including all AEDS in the National List of Essential Medicines (NLEM) 2022 and bringing them under the Drug Pricing Control Order (DPCO) for ceiling price regulation, is praiseworthy. It ensures that essential, lifesaving medications remain accessible to those who need them most, helping to manage and control epilepsy more effectively across the country.

CONCLUSION

This study revealed significant price variations among different brands of the same anti-epileptic drugs available in the Indian market. The findings of this study if used appropriately can significantly reduce the economic burden of patient, improve patient adherence to treatment and thereby improve the disease outcome. Scaling up the accessibility to cost-effective treatment, encouraging generic prescribing, changing government laws and regulations and creating awareness about the cost variations among the physicians with the knowledge of the need to prescribe cost-effective therapies, may reduce financial stress on the patients and aid in addressing the existing treatment gaps.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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