

Branded Versus Generic Antiepileptic Drugs in Epilepsy: Weighing Clinical Impact and Cost Effectiveness

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ABSTRACT

Background: Epilepsy is a prevalent neurological disorder affecting around 50 million people globally, with a significant burden in low- and middle-income countries. The management of epilepsy requires long-term Antiepileptic Drug (AED) therapy, which can be costly, leading to concerns about patient adherence. Despite the lower costs of generic AEDs, doubts about their efficacy and safety compared to branded counterparts persist, necessitating comparative studies. **Materials and Methods:** This prospective observational study was conducted over six months at two sites in Belagavi, India, involving 62 epilepsy patients. The patients were divided into two groups: 33 receiving branded AEDs and 29 receiving generic AEDs. The study assessed Adverse Drug Reactions (ADRs), seizure frequency and severity, patient-reported improvements, and cost differences between the two drug types. Statistical analysis was conducted using descriptive data, with cost-effectiveness evaluated by comparing the cost differences between medications. **Results:** The study found that while both branded and generic AEDs were effective in managing epilepsy, branded drugs (55.7%) had slightly better outcomes in terms of seizure reduction and patient-reported improvements. However, generic drugs demonstrated significant cost savings, with some showing up to 1333.3% lower costs compared to their branded counterparts. ADRs were more frequent and severe with branded AEDs, leading to higher rates of drug withdrawal. In contrast, ADRs associated with generic AEDs were generally milder and managed symptomatically. **Conclusion:** The present study supports the use of generic AEDs as a cost-effective alternative to branded drugs, particularly in resource-limited settings, but highlights the importance of individualized treatment plans considering clinical response, side effects, and patient financial capacity. The study's findings support the use of generic drugs but highlight the need for further multi-center research to validate these results.

Keywords: Epilepsy, Antiepileptic Drugs, Cost-Effectiveness, Adverse Drug Reactions, Pharmacoeconomics.

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INTRODUCTION

Epilepsies are a disorder where cerebral functions characterized by chronic, recurrent, paroxysmal, non-synchronous discharge of cerebral neurons. Seizure is defined as an episode of neurological dysfunction. Convulsions are seizures accompanied by motor manifestations i.e. limb jerking, incontinence, etc. Seizures need not to be always convulsive; they may be manifested by other changes in neurological functions. An isolated non-recurrent seizure occurring in an otherwise healthy individual for no obvious reason should not be labeled as epilepsy (Fisher *et al.*, 2005).

Epilepsy is the most common neurological disorder and accounts for a significant proportion of the world's disease burden, affecting around 50 million people worldwide. It can occur at any age (Secretariat of ILAE/IBE/WHO Global Campaign Against Epilepsy, 2002). Globally, it is estimated that 5 million people are diagnosed with epilepsy every year wherein in high-income countries it is estimated to be 49 people per 100,000 people diagnosed each year and in low- and middle-income countries, this figure is as high as 139 per 100,000 people each year. In India, there are more than 12 million persons with epilepsy with a conservative estimate of 1% as prevalence of epilepsy, which contributes to nearly one-sixth of the global burden (Amudhan *et al.*, 2015).

To treat epilepsy, it is directed at the elimination of the cause of seizures, suppressing the expression of seizures, and dealing with psychosocial consequences. It should be clearly emphasized that this is a common disorder that affects approx. 1% of the population and control of seizures can be expected in more than



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80% of patients with drug treatment. Some of the Antiepileptic's Drugs (AED) commonly used are Sodium valproate, Phenytoin, Carbamazepine, Oxcarbamazepine, Phenobarbitone, Gabapentin, Vigabatrin, Lamotrigine, Levetiracetam, Topiramate, Zonisamide, etc., (Shih *et al.*, 2013).

The WHO defines an Adverse Drug Reaction (ADR) as 'any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis of the disease, or the modification of physiological function'. Some of the common ADRs of anti-epileptic drugs are hyperactivity, headache, confusion, drowsiness, dizziness, hypersensitivity, nephrotoxicity, slurred speech, coordination problem, hepatotoxicity, memory problems, decreased concentration, nausea and vomiting, weight gain, suicidal thoughts, etc. These adverse effects are a leading cause of treatment failure with AEDs, not only do they result in early treatment discontinuation in up to 25% of patients, but also, they preclude attainment of fully effective doses and harm patient adherence. Therefore, there is a need to assess the ADR and resolving it has been important for adhering to the treatment (Edwards & Aronson, 2000).

Branded drugs are also called as Proprietary drug, it is a drug that has a trading name and is protected by a patent (a drug that can be manufactured and sold by the innovator company). And generic drug product is referred to as a multisource pharmaceutical product that is considered to be 'essentially similar' or bioequivalent to an innovator (brand name) product. Many patients perceive generics to be less effective and less safe than their brand-name counterparts. Thus, there is a need for a study that can promote the use of the generic drug through physician and pharmacoeconomical analysis that can prove that generic drugs are less costly and cost-effective than branded drugs.

The cost of the treatment has been a concerning thing for chronic disease, because of the cost burden patients are not adhering to the therapy and are discontinuing the medications which may be cause morbidity and mortality. Hence Cost-effectiveness analysis is done for assessing the gains in health costs of different health interventions. It helps in deciding how to allocate resources and directly relates the financial and scientific implications of different interventions.

Empirical research examining the comparative outcomes of generic versus brand-name drugs in routine care is currently insufficient. Many patients and healthcare providers perceive generic medications as less effective and less safe than their brand-name counterparts. This perception underscores the necessity for studies that can advocate for the use of generic drugs through physician and pharmacoeconomic analyses, demonstrating that generics are not only less expensive but also cost-effective alternatives to branded drugs.

Observational studies that compare brand-name and generic medications often exhibit bias favoring brand-name products. Adverse Drug Reactions (ADRs) are a significant concern, particularly with antiepileptic drugs, where poor outcomes can lead to treatment discontinuation in up to 25% of patients. This discontinuation can hinder the achievement of effective dosing and negatively impact patient adherence to treatment. Therefore, assessing and addressing ADRs is crucial for maintaining adherence to therapy.

The financial burden of treatment for chronic diseases is a pressing issue, as high costs can lead to non-adherence and medication discontinuation, potentially resulting in increased morbidity and mortality. Thus, further investigation into the efficacy, safety, and economic advantages of generic drugs is essential to support their use and alleviate the cost pressures faced by patients.

OBJECTIVES

Primary objective

To compare outcomes and ADR in patients using generic vs brand drugs.

Secondary objective

To carry out the cost-effectiveness analysis for epilepsy patients substituted with generic antiepileptic drugs.

MATERIALS AND METHODS

The research was conducted at two sites in Nehru Nagar, Belagavi: KLE Dr. Prabhakar Kore Hospital and Medical Research Centre, and Pradhan Mantri Bhartiya Jan Aushadhi Kendra. The sample size consisted of 62 patients, divided into two groups: 33 receiving brand-name medications and 29 receiving generic medications. The study utilized a prospective observational design and was carried out over a six-month period following Institutional Human Ethical Clearance. (KLE/COP/943/2020/21).

Materials

The study employed a variety of materials, including data collection forms, informed consent forms, patient information sheets, patient information leaflets, adverse drug reaction reporting forms, and an epilepsy questionnaire form.

Eligibility Criteria

Inclusion criteria

- Patients suffering from epilepsy and are on anti-epileptic drugs.
- Patients with all age groups.

Exclusion Criteria

- Patients not interested to participate in study.

- A patient under antiepileptic medication with other FDA Labeled indications.

STATISTICAL ANALYSIS

All the values are expressed in percentage. The differences between the mean values were analyzed by using the descriptive data.

Cost Difference = Δ of cost between two medication

$$\% \text{ cost variation} = \frac{\Delta \text{ of cost between two medication}}{\text{Minimum cost}} \times 100$$

RESULTS

The comparison between branded and generic drugs reveals differences in demographic and expenditure variables. In terms of gender, among those who used branded medications, 60.6% were male and 39.3% were female. For those using generic medications, the distribution was slightly different, with 68.9% male and 31% female. Age-wise, those aged 5 to 25 years made up 18.1% of the branded group but had no representation in the generic group. The 26 to 45 age group had 36.3% in the branded category and 44.8% in the generic, while the 46 to 65 age group comprised 39.3% of branded users and 51.7% of generic users. The oldest group, aged 66 to 85, represented 6% of branded and 3.4% of generic users (Refer Table 1).

In terms of monthly medication expenditure, 54.5% of branded users found their medications expensive, while none in the generic group did. Additionally, 24.2% of branded users considered their costs normal, compared to only 6.8% of generic users. Conversely, 93.2% of generic users reported low expenditure, in contrast to just 12.12% in the branded group. These figures underscore the economic benefits of opting for generic drugs, particularly among older and cost-sensitive patients (Refer Table 1).

The study also assessed the diagnosis status, reduction in seizure episodes, severity of seizure attacks, and the timing of the last seizure episodes among users of branded and generic medications. Regarding diagnosis, 39.3% of those on branded medications were newly diagnosed, while 60.6% had recurrent conditions. In contrast, 24.1% of generic medication users were newly diagnosed, and 72.4% had recurrent conditions. When assessing seizure reduction, 39.3% of branded users experienced a reduction, compared to 24.1% of generic users. However, 60.6% of branded users and 72.4% of generic users did not see a reduction in seizure episodes (Refer Table 2).

In terms of seizure severity, 48.4% of branded users experienced severe seizures compared to 62.1% of generic users. Mild seizures were reported by 51.5% of branded users and 37.9% of generic users. Notably, no patients in either group reported very severe or very mild seizures. Lastly, 93.9% of branded users and 89.6% of generic users had their last seizure episode within one year, while

6% of branded and 10.3% of generic users had seizures more than a year ago. These figures suggest varying levels of efficacy and seizure control between branded and generic drug users (Refer Table 2).

The comparison between branded and generic drugs in terms of improvement after taking the medicine reveals notable differences in patient outcomes. Among those who reported improvement, 57.5% were using branded drugs, while 44.8% were using generics. Conversely, 42.4% of branded drug users did not experience improvement, compared to a higher 65.5% of generic drug users who reported no improvement. This suggests that a higher percentage of patients on branded medications reported positive outcomes compared to those on generics (Refer Table 2).

Several Adverse Drug Reactions (ADRs) were observed in patients taking branded antiepileptic drugs. Gardenal (Phenobarbitone) caused pancytopenia, which was managed symptomatically. Eptoin (Phenytoin) was linked to two severe reactions: Stevens-Johnson syndrome and diffuse erythema, both requiring drug withdrawal. Dizziness was reported with both Lacoset (Lacosamide) and Lopez (Lorazepam). Valparin Chrono (Sodium Valproate) led to hyperammonemia, necessitating drug withdrawal, while Frisium (Clobazam) caused ataxia, also leading to drug withdrawal. Levipil (Levetiracetam) was associated with three ADRs: excessive somnolence, tremor, and cough. The excessive somnolence and tremor required drug withdrawal, while the cough was managed symptomatically. Overall, the WHO causality assessment categorized seven of the ADRs associated with branded antiepileptic drugs as "Probable" and three as "Possible" (Refer Table 3).

Fewer ADRs were observed in patients taking generic antiepileptic drugs. Sodium Valproate caused vomiting, which was managed symptomatically, and the patient recovered. Phenobarbitone led to a loss of appetite, also treated symptomatically. Levetiracetam was associated with decreased appetite and somnolence, necessitating drug withdrawal; Lacosamide induced vomiting, Phenytoin caused excessive somnolence, Clobazam was linked to nausea and vomiting, all were managed symptomatically, and the patients recovered. Overall, the WHO Causality Assessment for ADRs associated with generic antiepileptic drugs predominantly rated the causality as Probable (6), with only one case (Clobazam) assessed as Possible (Refer Table 4).

The cost comparison between branded and generic drugs reveals notable differences. For instance, Gardenal 60 mg is priced at Rs 4.3 per unit, while its generic version, phenobarbitone 60 mg, costs only Rs 0.3, resulting in a 1333.3% cost difference. Pirament 800 mg, at Rs 21, is significantly more expensive than its generic counterpart, Piracetam, which is priced at Rs 1.7, showing a 1135.3% variation. Eptoin 100 mg costs Rs 6.4, while Phenytoin 100 mg is just Rs 0.5, leading to an 1180% difference. Similarly, Frisium 5 mg, at Rs 15, compared to clobazam at Rs 1.3, results

in a 1053.8% cost variation. Other drugs, such as Lopez 2 mg/mL, Valparin Chrono 300 mg, and Ocotol 150 mg, also show substantial savings with their generic equivalents, underscoring the potential for significant reductions in healthcare costs by opting for generics (Refer Table 5).

DISCUSSION

The present study aimed to investigate whether the difference does exist in the pharmacotherapy of epilepsy with generic drugs vs branded drugs with the consideration of efficacy and safety. In this regard, a total of 62 patients were enrolled, with data collected from KLES Dr. Prabhakar Kore Hospital and Medical Research Center and Pradhan Mantri Bhartiya Jan Aushadhi Kendra Nehru Nagar, Belagavi. Previously multiple investigators have been made to investigate the comparison of branded and generic drugs for multiple diseases. Building on these findings,

this study assessed the effectiveness and safety of these two drug categories in the treatment of epilepsy.

The present study had a total of 62 sample sizes in which the majority of male patients utilized both branded and generic formulations i.e. 60.6% and 68.9% respectively. Similarly, the total age groups were from 5 to 85 years old from which subjects from 46-65 years of old were having major utilization of antiepileptic drugs where the majority of subjects preferred generic drugs over branded one i.e. 51.7%.

Cost-effectiveness is a major consideration in long-term treatment, particularly for chronic conditions like epilepsy. Patient compliance with therapy is directly concerned with the cost of drugs; hence, we assess the cost-effectiveness among the both drugs; cost of low medications was high with generic i.e. 93.1% whereas the cost-effectiveness for branded was low i.e. 6%. Assessment of the outcome of treatment can be influenced by the

Table 1: Comparison of brand and generic group in terms of demographics.

Sl. No.	Variables	Variables	Brand		Generic	
			Frequency	Percentage (%)	Frequency	Percentage (%)
1	Gender	Male	20	60.6	20	68.9
2		Female	13	39.3	9	31
1	Age in years	5 to 25	5	18.1	0	0
2		26 to 45	6	36.3	13	44.8
3		46 to 65	10	39.3	15	51.7
4		66 to 85	2	6	1	3.4
1	Monthly expenditure on medications	Too expensive	3	9.1	0	0
2		Expensive	18	54.5	0	0
3		Normal	8	24.2	2	6.8
4		Low	4	12.12	27	93.2

Table 2: Comparative Analysis of Patient Characteristics and Seizure Outcomes in Branded versus Generic Anti-Epileptic Drug Groups.

Sl. No.	Variables	Components	Brand		Generic	
			Frequency	Percentage (%)	Frequency	Percentage (%)
1	Diagnosis	Newly diagnosed	9	39.3	7	24.1
2		Recurrent	20	60.6	21	72.4
1	Reduction in seizure episodes	Yes	13	39.3	7	24.1
2		No	20	60.6	21	72.4
1	Seizure attacks	Very severe	0	0	0	0
2		Severe	16	48.4	18	62.1
3		Mild	17	51.5	11	37.9
4		Very mild	0	0	0	0
1	Last seizure episodes	Within one year	31	93.9	26	89.6
2		More than one year	2	6	3	10.3
1	Improvement and effect after taking the medicine.	Yes	19	57.5	13	44.8
2		No	14	42.4	19	65.5

Table 3: Adverse Drug Reactions associated with Branded Antiepileptic Drugs.

Sl. No.	Brand name	ADR Caused	Treatment given	Outcomes	WHO Causality Assessment
1	Gardenal	Pancytopenia	Symptomatic	Recovered	Possible
2	Eptoin	Stevens Johnson syndrome	Specific -Withdrawn	Recovered	Probable
3	Eptoin	Erythema diffuse	Specific -Withdrawn	Recovered	Probable
4	Lacoset	Dizziness	No any treatment given	Recovered	Probable
5	Valparin Chrono	Hyperammonemia	Specific -Withdrawn	Recovered	Probable
6	Frisium	Ataxia	Specific -Withdrawn	Recovered	Probable
7	Lopez	Dizziness	No any treatment given	Recovered	Probable
8	Levipil	Excessive Somnolence	Specific -Withdrawn	Recovered	Possible
9	Levipil	Tremor	Specific -Withdrawn	Recovered	Probable
10	Levipil	Cough	Symptomatic	Recovered	Possible

Table 4: Adverse Drug Reactions associated with Generic Antiepileptic Drugs.

Sl. No.	Generic name	ADR Caused	Treatment given	Outcomes	WHO Causality Assessment
1	Sodium Valproate	Vomiting	Symptomatic	Recovered	Probable
2	Phenobarbitone	Loss of Appetite	Symptomatic	Recovered	Probable
4	Levetiracetam	Decreased appetite, Somnolence	Specific -Withdrawn	Recovered	Probable
5	Lacosamide	Vomiting	Symptomatic	Recovered	Probable
6	Phenytoin	Somnolence excessive	Symptomatic	Recovered	Probable
7	Clobazam	Nausea & Vomiting	Symptomatic	Recovered	Possible

Table 5: Comparison of Cost difference and % cost variation of branded and generic drugs.

Sl. No.	Branded Drugs	Cost/Unit (Rs)	Generic Drugs	Cost/Unit (Rs)	Cost Difference	%Cost Variation
1	Gardenal 60 mg	4.3	Phenobarbitone 60 mg	0.3	4	1333.333
2	Pirament 800 mg	21	Piracetam	1.7	19.3	1135.294
3	Eptoin 100 mg	6.4	Phenytoin 100 mg	0.5	5.9	1180.00
4	Frisium 5 mg	15	Clobazam	1.3	13.7	1053.846
5	Lopez 2 mg/mL	3	Lorazepam 2 mg	0.65	2.3	353.846
6	Valparin Chrono 300 mg	6	Sodium valproate	1.7	4.3	252.941
7	Ocetol 150 mg	6.7	Oxcarbamazepine	2	4.7	235.00
8	EVIC-SR 400 mg	3.3	Carbamazepine 400 mg	1.3	2	153.846
9	Levipil 500 mg	13.2	Levetiracetam 500 mg	6.2	7	112.903
10	Clonax-Plus	4	Clonazepam (0.5 mg) + Propranolol (10 mg)	5	1.8	81.818
11	Lacoset 50 mg	13.6	Lacosamide 100 mg	-	-	

formulation type and its category which can be assessed by the evaluation of seizure episodes.

Concerns still persist among patients and physicians that generic drugs may be clinically inferior to brand-name drugs (Leclerc *et al.*, 2017). Although generic drugs must demonstrate bioequivalence to their branded counterparts, some physicians and patients worry about differences in efficacy, safety, and side effects. These concerns can stem from variations in inactive ingredients, absorption rates, or even physicians or patient perception, leading to hesitancy in prescribing or using generic drugs.

Further, diagnosis of epileptic subjects with recurrent epilepsy were also the major variables to contrast the efficacy of branded vs generic drugs in which the present study identified recurrent epilepsy for the branded drug was found to be 60.6%, however, for the generic, it was 72.4%. Also, the present study found that among patients using branded drugs, 48.4% experienced severe seizure attacks, while 51.5% had mild attacks. In comparison, for those on generic drugs, 62.1% experienced severe seizures, and 37.9% had mild attack, also it was observed that the occurrence of seizure within one year of pharmacotherapy with branded drugs was found to be 93.9% however with generic formulations 89.6%, it was comparatively low. However, the improvement in seizure episodes was identified to be better in branded drugs i.e. 57.5%.

Overall, in terms of ADR the analysis suggests that while both generic (7) and branded (10) antiepileptic drugs can cause ADRs, those associated with branded drugs were found higher and more severe and often required specific interventions or drug withdrawal. In contrast, ADRs from generic drugs were generally milder and more frequently managed with symptomatic treatment.

Despite these differences, it is important to recognize that both generic and branded drugs play essential roles in epilepsy management. Generic drugs provide a cost-effective alternative, making treatment accessible to a larger population. However, the choice between generic and branded AEDs should be individualized, taking into account the patient's clinical response, potential side effects, and financial situation.

CONCLUSION

The present study compared the efficacy of anti-epileptic generic drugs with brand which showed the efficacy and safety of generic drug to be same as branded one. Further, the generic drugs were found to be cost effective compared to brand. The study's limitations include the relatively small sample size and the single-center design, which may limit the generalizability of the findings. Future research should involve larger, multi-center studies to validate these results and further explore the factors influencing the clinical outcomes of generic versus branded AEDs.

The comparative analysis of patient characteristics and seizure outcomes between brand-name and generic anti-epileptic drugs reveals important insights into their efficacy and patient experiences. The data indicate that a higher percentage of patients in the brand-name group reported recurrent diagnoses and a reduction in seizure episodes compared to their generic counterparts. Additionally, while both groups exhibited similar patterns in the severity of seizure attacks, the brand-name group had a greater proportion of patients experiencing severe seizures.

Overall, these results underscore the need for further research to explore the factors influencing patient perceptions and outcomes associated with brand-name and generic anti-epileptic drugs. Addressing these perceptions may help improve adherence to treatment and optimize therapeutic outcomes for patients with epilepsy.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of Interest.

ETHICAL STATEMENT

This study was approved by the Human Institutional Ethics Committee of KLE College of Pharmacy, Belagavi (Ref No. KLE/COP/943/2020/21). Participant confidentiality was strictly maintained.

ABBREVIATIONS

AEDs: Antiepileptic Drugs; **ADRs:** Adverse Drug Reactions; **QOL:** Quality of Life; **OPD:** Outpatient Department; **IPD:** Inpatient Department; **CNS:** Central Nervous System; **ICF:** Informed Consent Form; **PIL:** Patient Information Leaflet.

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