Indian Journal of Pharmacy Practice., 2025; 18(4):419-424.
https://www.ijopp.org

Original Article

Prescribing Pattern of Antiepileptic Drugs and Patients Compliance to Treatment; A Prospective Study in a Tertiary Care Hospital, Bengaluru

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ABSTRACT

Background: Antiepileptic drugs are mainly used to manage epilepsy and can also be prescribed for other neurological conditions. However, usage patterns and adherence can vary based on patient demographics, comorbidities, and treatment complexity. This study evaluates AED prescribing trends, adherence levels, and the factors influencing adherence in a tertiary care hospital in Bengaluru, India. **Materials and Methods:** A prospective observational study involving 106 patients was conducted over six months. AED usage patterns and adherence levels using the Morisky Medication Adherence Scale-4 were analyzed. The correlation between variables and adherence levels was assessed using the Fisher-Freeman-Halton Exact Test in IBM SPSS statistics 29.0.2.0 software. **Results:** The study found that 58.49% of patients were male, with an average age of 56.86 years. Monotherapy was prescribed to 81.13% of patients, with levetiracetam being the most commonly used AED (64.2%). Adherence was high, with 78.3% of patients showing good adherence, though those on polytherapy had significantly lower adherence (p<0.01) consistent with. Adverse drug reactions, such as behavioral abnormalities with levetiracetam, anemia induced by phenytoin, and sedation by clobazam, were associated with poor adherence (p=0.031). The study also highlighted discrepancies between the defined daily dose and the prescribed daily dose, with drugs like levetiracetam and carbamazepine. **Conclusion:** This study emphasizes the importance of personalized AED dosing to balance efficacy and tolerability. Simplifying treatment regimens and managing ADRs are key strategies for improving adherence and optimizing treatment outcomes.

Keywords: Antiepileptic Drugs, Adherence, Prescribing Patterns, Neurology.

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Received: 27-01-2025;
Revised: 14-03-2025;
Accepted: 03-05-2025.

INTRODUCTION

With the invention of newer AEDs (Antiepileptic drugs), prescription patterns and treatment guidelines in India have shifted.[1] Therefore, analyzing these prescription trends is essential to assess their therapeutic impact, clinician preferences, and adherence to guidelines. AEDs are used to manage epilepsy and other seizure disorders by stabilizing abnormal brain electrical activity.[2] Beyond their primary use for seizures, AEDs also address conditions like bipolar disorder, nerve pain, migraine headaches, fibromyalgia, and restless leg syndrome.[3] The selection of an appropriate AED depends on the specific type of seizure and patient demographics. Approximately 80% of patients can achieve seizure control with a single AED, while the remaining 20% may require a combination of two or three AEDs.[4] Generally, monotherapy is preferred as it tends to have fewer drug interactions, reduced side effects, better tolerability, and improved patient adherence and quality of life.[5]

The ATC classification system, established by the WHO, organizes drugs based on their anatomical and therapeutic properties. For AEDs, the ATC classification is N03. It provides a standardized approach for identifying and organizing pharmaceuticals, thereby simplifying the monitoring of their utilization and impact across various healthcare environments.[6] WHO estimates that epileptic disorders affect around 50 million people globally, which can result in a reduced quality of life compared to healthy individuals due to the risks of injury during seizures and the increased mortality associated with the condition.[7]

Data indicate that 45% of AED prescriptions are for conditions beyond epilepsy. Stroke is a significant risk factor for epilepsy, with up to 50% of adult-onset epilepsy cases linked to a previous stroke.[8] Adherence is essential for achieving the best therapeutic results, reducing the frequency of seizures, and improving the overall quality of life for individuals with epilepsy. Various methods can be used to assess adherence, including self-reports, pill counts,

DOI: 10.5530/ijopp.20250307

Medication Event Monitoring Systems (MEMS), and electronic health records. Poor adherence can result in more frequent and severe seizures, which can diminish the effectiveness of treatment and negatively affect quality of life. Additionally, non-adherence can lead to more healthcare visits, hospitalizations, and additional treatments, thus increasing healthcare costs.[9]

Due to their narrow therapeutic index and the need for long-term treatment in managing epilepsy and other neurological conditions, AEDs often lead to ADRs and drug-drug interactions. Despite the availability of a wide range of AEDs, optimal seizure control remains challenging for many patients due to issues related to drug selection, adherence, ADRs, and the complexity of treatment regimens, especially in cases requiring polytherapy. Additionally, the delayed onset of benefits, and insufficient follow-up, can discourage patients from adhering to their medication, leading to non-adherence.

This study aims to analyze the prescribing patterns of antiepileptic drugs, assess the level of patient compliance, and identify factors influencing patient compliance with antiepileptic drug treatment.

MATERIALS AND METHODS

After ethical approval (Ref ID: NCP/HEC/-CERTI-001/2024), informed consent was obtained from participants, ensuring their voluntary participation without affecting their care. A comprehensive data collection form was designed, including demographic details, seizure history, treatment, and adherence scales. Medication adherence was assessed using the MMAS-4 tool,[10] and adverse drug reactions were evaluated with the WHO Causality Assessment Scale.[11] Drug interactions were reviewed using resources like Drugs.com[12] and Stockley's Drug Interactions.[13] The sample size was determined using statistical calculations, with a final sample of 83 participants.

Study Design: Prospective observational study conducted over six months.

Study Location: The study was conducted in the Neurology and Psychiatry Departments of a tertiary care hospital in Bengaluru.

Inclusion and Exclusion Criteria

The study included male and female patients of all age groups receiving AEDs, those with a history of seizures prescribed at least one AED, and patients with or without co-morbid conditions. It also encompassed individuals experiencing seizures associated with acute causes such as post-stroke, brain trauma, or craniotomy. However, patients who were unwilling to provide informed consent were excluded from the study.

Statistical Analysis

Data analysis was conducted using IBM SPSS Statistics software. Qualitative variables were reported as percentages and frequencies, and quantitative variables were summarized as mean and standard deviation. Correlations between variables and adherence levels were analyzed using the Fisher-Freeman-Halton Exact Test.

RESULTS

The study analyzed 106 patients, as Table 1 shows a higher proportion of males (58.49%) than females (41.51%). The mean age of the participants was 56.86 years, with a standard deviation of 18.47, indicating age variability and only 11.2% of the patients had a family history of epilepsy. The lifestyle analysis revealed that 35.85% of patients consumed alcohol, while 29.24% were smokers. Stroke was the most frequently observed comorbidity, affecting 31.13% of patients, followed by craniotomy (13.21%), diabetes mellitus (10.38%), and hypertension (7.55%). Among

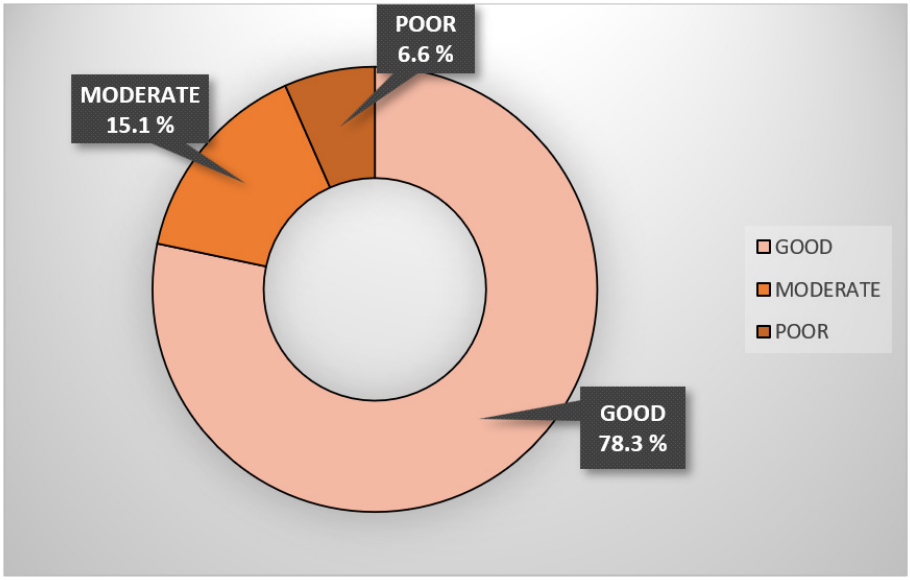

Figure 1: Distribution of Adherence Levels Among Patients.

57 patients diagnosed who were with epilepsy, generalized tonic-clonic seizures were more common (61.4%) than partial seizures (38.6%) among them. Regarding treatment patterns, monotherapy was the predominant approach (81.13%), whereas polytherapy was used in 18.87% of cases.

Table 2 indicates that the prescribed daily doses of most antiepileptic drugs were lower than their defined daily doses, highlighting variations in prescribing practices. In our study, we also analyzed drug-drug interactions using Drugs.com and Stockley's Drug Interactions as reference tools. It was noted that Levetiracetam may have reduced levels when used alongside oxcarbazepine or phenytoin. Although both interactions are classified as mild, they still warrant attention due to potential toxicity. Additionally, the effect of carbamazepine on phenytoin levels can be unpredictable, making regular drug-level monitoring essential. Furthermore, topiramate can elevate phenytoin levels, necessitating careful observation to prevent toxicity.

Several suspected Adverse Drug Reactions (ADRs) have been identified in this study, as presented in Table 3. These include behavioral abnormalities and leukopenia associated with levetiracetam, anemia linked to phenytoin, and sedation related to clobazam.

In Figure 1, it was observed that 83 patients (78.3%) demonstrated good adherence to their antiepileptic treatment, while 16 patients (15.1%) showed moderate adherence, and 7 patients (6.6%) exhibited poor adherence. This indicates that while the majority of patients adhered to their treatment plans effectively, a notable minority faced challenges in maintaining consistency in their medication regimens.

Table 4 presented an analysis of adherence, indicating that patients on monotherapy demonstrated significantly better adherence ($p<0.01$) compared to those on polytherapy. Furthermore, the occurrence of adverse drug reactions was shown to negatively affect adherence levels ($p=0.031$). This emphasizes the importance of careful drug selection and monitoring.

DISCUSSION

As usage patterns and adherence to antiepileptic drugs vary based on patient demographics, comorbidities, and treatment complexity, this study aims to evaluate AED prescribing trends, adherence levels, and the factors that influence adherence in a tertiary care hospital. The findings in this will provide insights into the utilization of AEDs, emphasizing the role of both newer and traditional AEDs in clinical practice.

Table 1: Distribution of Sociodemographic Profile of Patients.

Parameter	Category	*N*=106, n (%)
Sex	Male	62 (58.49)
	Female	44 (41.51)
Age	Mean age	56.86
	SD	18.47
Family history	Yes	12 (11.2)
	No	94 (88.68)
Alcohol	Alcoholic	38 (35.85)
	Non-alcoholic	68 (64.15)
Smoking	Smokers	31 (29.24)
	Non-smokers	75(70.76)

Table 2: Utilization Patterns of Antiepileptic Drug Dosages

Drugs	ATC Code	DDD as per ATC (gm)	PDD (g)
Levetiracetam	N03AX14	1.5	1
Brivaracetam	N03AX23	0.1	0.1
Phenobarbital	N03AA02	0.1	0.1
Lacosamide	N03AX18	0.3	0.2
Clobazam	N05BA09	20mg	10mg
Phenytoin	N03AB02	0.3	0.2
Sodium valproate	N03AG01	1.5	1
Carbamazepine	N03AF01	1	0.4
Gabapentine	N02BF01	1.8	0.2
Fosphenytoin	N03AB05	0.45	0.3
Pregabalin	N02BF02	0.3	0.3
Perampenel	N03AX22	8mg	4mg
Oxcarbamazepine	N03AF02	1	0.3
Lorazepam	N05BA09	20mg	2mg
Topiramate	N03AX11	0.3	0.1

ATC-Anatomical Therapeutic Chemical, DDD-Defined Daily Dose, PDD-Prescribed Daily Dose, g-Gram, mg-milligram.

Table 3: Adverse Drug Reactions Along with Causality Assessment

Suspected drug	Adr	Incidence	Causality assessment	Management
Tab. Levetiracetam	Behavioural abnormality	1	Possible	Drug withdrawal
	Leukopenia	1	Probable	Reducing the dose
Tab. Phenytoin	Anemia	1	Probable	Adding vitamin b Reducing the dose
Tab. Clobazam	Sedation	1	Probable	Reduce the dose

ADR-Adverse Drug Reaction.

Table 4: Correlation of Variables with Adherence Levels.

Variables	Good adherence, n (%)	Moderate adherence, n (%)	Poor adherence, n (%)	Exact significance value
Age				
≤ 18 years	3	0	0	O.124
s18-60 years	41	4	1	
≥ 60 years	39	12	6	
Gender				
Male	45	12	5	0.259
Female	38	4	2	
Alcohol				
Yes	26	9	3	0.171
No	57	7	4	
Smoking				
Yes	22	7	2	0.377
No	61	9	5	
Co-Morbidity				
Yes	79	15	7	1.00
No	4	1	0	
Complexity of Treatment				
Monotherapy	79	6	1	< 0.01*
Polytherapy	4	10	6	
ADRs				
Yes	1	2	1	0.031*
No	82	14	6	

*Indicates statistically significant.

In the study population, males (58.49%) outnumbered females, with a mean age of 56.86 years, Table 1 similar to findings by Dave and Trivedi.[14] The high prevalence of stroke (31.13%) and post-craniotomy cases (13.21%) among patients supports the need for individualized AED therapy, particularly for post-stroke epilepsy, as noted by Loikas *et al.*[15]

Levetiracetam was the most commonly prescribed AED, with 61.63% of patients receiving monotherapy. This shift towards newer AEDs can be attributed to their favorable safety profile and lower incidence of adverse effects, consistent with findings from Khoshdel *et al.*,[16] and Rehman *et al.*,[17] Despite this trend, traditional AEDs such as sodium valproate and phenytoin remain in use, especially in combination therapy (18.87%), due to their proven efficacy and cost-effectiveness, as highlighted by Nimesh *et al.*[18]

The study underscores the broader application of AEDs beyond epilepsy management, particularly in urban tertiary care settings where access to newer AEDs is feasible. This contrasts with findings from Patel *et al.*,[19] who reported a higher reliance on older AEDs, such as sodium valproate and carbamazepine, in rural settings due to economic constraints and limited drug

availability. These disparities highlight the impact of healthcare access and socioeconomic factors on prescribing practices.

In terms of dosage utilization, the study found that levetiracetam and carbamazepine were prescribed at lower doses than the Defined Daily Dose (DDD), Table 2 while phenobarbital and brivaracetam were closer to standard dosing recommendations. This pattern aligns with the findings of Mandal *et al.*,[20] who reported dose adjustments, particularly among elderly and comorbid patients, to minimize side effects.

Adherence to AED therapy was observed in 78.3% of patients, Figure 1 which is significantly higher than the 30-50% non-adherence rates reported by Ejeliogu *et al.*[21] The improved adherence in this study may be attributed to simplified treatment regimens and better patient education. However, polytherapy was associated with significantly lower adherence ($p<0.01$), Table 4 consistent with Raj *et al.*,[22] who noted that complex treatment regimens increase non-adherence due to adverse effects and drug interactions. Simplifying therapy and patient counseling may help improve adherence levels.

ADRs significantly impacted adherence ($p=0.031$), with patients experiencing adverse effects more likely to discontinue or modify therapy, consistent with Maqbool *et al.*[23] The most frequently reported ADRs included behavioral abnormalities and leukopenia with levetiracetam, as well as anemia with phenytoin. Table 3 these findings emphasize the importance of monitoring and managing ADRs to enhance adherence and therapeutic outcomes.

The study's short duration of six months and its limited sample size pose challenges for the generalizability of the findings. Moreover, reliance on self-reported measures of adherence may lead to an overestimation of actual treatment outcomes. To enhance understanding of AED utilization across various populations, future research should pursue larger, multicenter trials that provide a more comprehensive view. Lastly, implementing patient education programs and simplifying treatment regimens may significantly improve adherence rates, exploring safer polytherapy options that can effectively minimize adverse effects while ensuring optimal seizure control which remains an essential area for further investigation.

CONCLUSION

This study offers important insights into the sociodemographic profile, comorbidities, seizure types, antiepileptic drug prescribing patterns, and adherence rates among patients in a tertiary care hospital. It highlights the application of AEDs in critical areas, particularly for patients with complex comorbidities. The study emphasizes the need for monotherapy in cases with fewer complications to enhance adherence and improve patient outcomes. Furthermore, the broader use of AEDs beyond epilepsy illustrates their effectiveness in managing various neurological and psychiatric conditions. However, the presence of additional medical conditions may complicate treatment, increasing the risks of adverse drug reactions and drug-drug interactions. Therefore, a personalized approach that takes these factors into account is crucial for optimizing AED therapy and improving patient outcomes. Additionally, the study indicates that adherence is a significant issue, with only 78.3% of patients demonstrating good adherence. A notable percentage still struggles with moderate or poor adherence, especially those on polytherapy regimens. Overall, simplifying treatment regimens and prioritizing patient education and management of adverse drug reactions are vital for optimizing AED therapy, enhancing treatment outcomes, and ultimately improving the quality of life for patients.

ACKNOWLEDGEMENT

We would like to extend our sincere gratitude to our guide, Dr. Priyanka N, Assistant Professor, Department of Pharmacy Practice, Nargund College of Pharmacy, whose invaluable guidance and expertise were instrumental throughout this study. We are deeply thankful for her mentorship and commitment to our academic development.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

AEDs: Antiepileptic drugs; **WHO:** World Health Organization; **MEMS:** Medication event monitoring systems; **ADR:** Adverse drug reactions.

ETHICAL APPROVAL

The ethical approval was provided by the institutional ethics committee of Nargund College of Pharmacy, Bangalore (Ref ID: NCP/HEC/-CERTI-001/2024) after a thorough discussion and review of the study protocol.

CONSENT TO PARTICIPATE

The informed consent form in this study was designed to ensure clarity and comprehension of its purpose. Participants received the form and provided their consent before taking part in the study, with a focus on ensuring their understanding and voluntary involvement.

SUMMARY

The study was conducted over six months with 106 patients, the research found that the majority of patients were male with an average age of 56.86 years, and 81.13% were prescribed monotherapy, predominantly levetiracetam. Overall, 78.3% of patients displayed good adherence, although those on polytherapy had significantly lower adherence rates. Adverse drug

reactions were linked to poorer adherence, while discrepancies existed between prescribed and defined daily doses. The study underscores the need for personalized AED dosing and simplified treatment regimens to enhance adherence and optimize outcomes for patients with epilepsy and related conditions.

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Cite this article: Bhavana, Sutanu Lal, Ankitha, Priyanka. Prescribing Pattern of Antiepileptic Drugs and Patients Compliance to Treatment; A Prospective Study in a Tertiary Care Hospital, Bengaluru. Indian J Pharmacy Practice. 2025;18(4):419-24.