

DOI: <https://dx.doi.org/10.18203/2319-2003.ijbcp20262779>

Original Research Article

Evaluation of drug utilization pattern of antiepileptic drugs and adherence to treatment in outdoor patients of neurology department at a tertiary care teaching hospital

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Received: 15 July 2026

Accepted: 30 July 2026

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ABSTRACT

Background: Epilepsy is a chronic condition characterized by recurrent seizures. Adherence to antiepileptic drugs (AEDs) is crucial for treatment success, reducing relapses and improving patient outcomes. Aim and objectives of this study were to evaluate the drug utilization pattern of AEDs, identifying the extent of polypharmacy and percentage of adherence to treatment in patients with epilepsy attending neurology OPD.

Methods: A cross-sectional observational study was conducted over 12 months at RNT Medical College, M.B. Hospital, Udaipur after IEC approval. Inclusion criteria include patients age ≥ 18 years with confirmed diagnosis of epilepsy prescribed at least one AED. Exclusion criteria include patients with status epilepticus or admitted. Data collection included patient demographics, treatment details and adherence assessment through the Medication Adherence Rating Scale (MARS-10) questionnaire.

Results: We evaluated 144 epilepsy patients. Demography showed 59% (n=85) males and 41% (n=59) females; mean age of 32.88 ± 13.30 years. Patients diagnosed with generalized seizure was 93.8% than focal seizure 6.3%. Mean age of onset of seizure was 24.13 ± 13.58 years. Monotherapy was given in 49.3% (n=71) patients while 50.7% (n=73) treated with polytherapy. Most commonly prescribed AED was valproic acid (63.3%) followed by levetiracetam (37.5%) and clobazam (23.6%). Total 71.53% (n=103) patients were adherent to treatment.

Conclusions: Among 144 epilepsy patients, 93.8% had generalized seizures; Sodium valproate and Levetiracetam was most commonly used AEDs and total 71.53% patients was adhered to treatment.

Keywords: Adherence, Antiepileptic, Drug utilization, Epilepsy, Seizure

INTRODUCTION

The WHO defines drug utilization study as “The marketing, distribution, prescription and use of the drug in a society, with special emphasis on the resulting medical, social and economic consequences”.¹ According to International league against epilepsy (ILAE) “Epilepsy is a chronic neurological disorder characterized by a predisposition to recurrent, unprovoked seizures, at least two unprovoked seizures occurring more than 24 hours apart.” “An epileptic seizure is a transient occurrence of

signs and/or symptoms due to abnormal excessive or synchronous neuronal activity in the brain.”² ILAE revised classification of epilepsy and seizure in 2017 and 2025, In this revised classification, seizures are classified based on three features: -Origin of the seizure in the brain, degree of awareness during the seizure, level of body movement. Based upon these features seizures are classified into three types, focal onset seizures, which are further subsided into three subtypes retained awareness/impaired awareness, motor/non-motor onset, focal to bilateral tonic-clonic, generalized onset seizures, which further classified in

motor or non-motor (absence) onset seizures, unknown onset seizures can be divided in motor/non-motor or unclassified seizure. Further according to type of seizures, types of epilepsies are classified.^{3,4} The overall goal of antiepileptic therapy is to control and prevent recurrence of seizures. At the initiation of treatment, monotherapy should be employed and use the lowest effective dose of AED to minimize side effects. If seizures remain uncontrolled with the highest attainable drug levels and good adherence to treatment, then patient may be switched on another AED of different mechanism of action from previous drug. If further patient doesn't respond then after combination therapy of AED with different mechanism of action. These type of combination of AEDs acting by different mechanisms may improve efficacy.^{5,6}

In epilepsy, adherence to treatment is of critical consequence because it is typically a chronic condition and because uncontrolled seizures pose serious risks of recurrent seizure episodes, treatment resistance further it can become life threatening.⁷ Very few studies were found regarding the pattern of prescription of antiepileptic drugs along with assessment of adherence in outdoor patients in India. No local data was found regarding this in our population, so this study has been planned.

The aim and objectives of study were assessment of drug utilization pattern of antiepileptic drugs in the outdoor patient in the neurology department as per WHO core drugs prescribing indicators, to classify AEDs according to anatomical therapeutic chemical (ATC) classification, to compare PDD (prescribed daily dose) defined daily dose (DDD), to evaluate the most commonly prescribed drugs in different type of seizure disorder, to identify the extent of polypharmacy and to find prevalence of adherence to AEDs treatment using medication adherence rating scale 9 (MARS-10) questionnaire.⁸

METHODS

This study was a hospital based cross-sectional observational study conducted in the Pharmacology and Neurology OPD of RNT Medical College, Udaipur after getting approval from IEC (RNT/ACAD./IEC/2023/818) for duration of 1 year January 2024 to December 2024. Total 144 patients were evaluated in 01 year of duration. Inclusion criteria include patients of age ≥ 18 years with confirmed diagnosis of epilepsy and prescribed at least one AED. Exclusion criteria include patients with status epilepticus or acute seizures associated with any acute emergency condition like traumatic brain injury, stroke who subsequently admitted to hospital. Informed consent was taken from all the patients prior to enrolment in study. Data collection included patient demographics, treatment details and adherence assessment was done through the MARS-10 questionnaire. In MARS-10 questionnaire scale 10 questions were asked to the patient in 'Yes' or 'No' format. In question no. 1 to 6, 9 and 10 the answer 'No' was considered as '1' score; in question number 7 and 8 answer 'Yes' was considered as '1' score. The total score

was calculated. If score was ≤ 5 considered as non-adherent to treatment. Total number or percentage of adherent and non-adherent was calculated.⁹

Statistical analysis

All data was collected in study proforma and entered in Microsoft excel and statistical analysis was done. Quantitative variables were summarized as mean and standard deviation (SD). Qualitative variables were expressed as proportion.

RESULTS

We evaluated 144 patients with epilepsy. Demography showed 59% (n=85) males and 41% (n=59) females. Mean age of the participants was 32.88 ± 13.30 years; out of all patients maximum 50.70% were of age group 18-30 years. The mean age of onset of disease in the study group is 24.13 ± 13.58 years. In this study group the most commonly age of onset of seizure disorder was 11 to 30 years (54.17%, n=78). The mean duration of illness for the study group was 8.77 ± 6.47 years. In the study generalized seizures observed in 93.75% patients whereas focal seizure was observed only in small group of patients (6.25%). Out of 144 patients most common type of seizure was observed as GTCS (90.97%) followed by focal seizure with impaired awareness (5.55%), absence seizure (2.78%) than focal aware (0.7%) (Table 1).

The overall drug utilization pattern showed that the most commonly prescribed antiepileptic drug (AED) was sodium valproate (VPA) (65.27%), followed by levetiracetam (LEV) (37.50%), clobazam (CLB) (23.61%), carbamazepine (CBZ) (12.50%), phenytoin (PHT) (10.42%), phenobarbitone (PBT) (6.25%), lacosamide (LCM) (6.17%), clonazepam (CLN) (4.86%), lamotrigine (LMT) (3.47%) and oxcarbazepine (OCZ) (1.38%) (Figure 1). Out of 144 patients, almost half of patients, 49.30% (n=71) patients were treated with single AED, 36.11% (n=52) patients treated with 2 AEDs, 11.81% (n=17) patients treated with 03 AEDs combinations, 02 1.39% (n=02) patients treated with 04 AEDs and also only 1.39% (n=2) patients treated with 05 AEDs combinations (Figure 2).

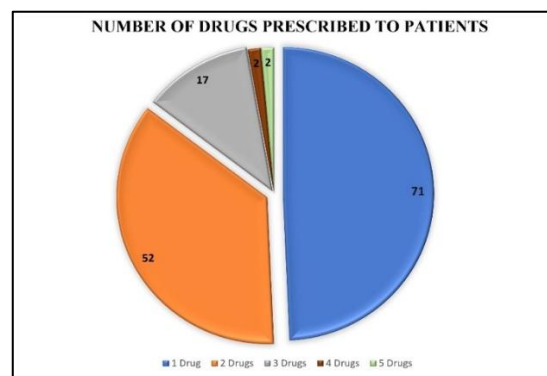


Figure 1: Number of drugs prescribed to patients.

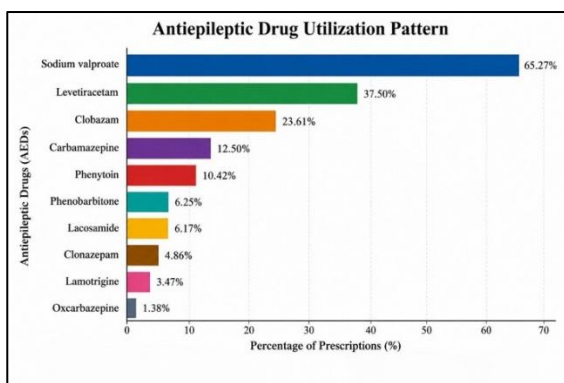


Figure 2: Overall drug utilization patterns of antiepileptic drugs.

As monotherapy most commonly prescribed AED was sodium valproate (27.08%, n=39) followed by levetiracetam (13.89%, n=20), phenytoin (4.86%, n=7), carbamazepine (2.78%, n=4) and phenobarbitone (0.69%, n=1). In patients treated with two AEDs combination, the most commonly, prescribed combination was VPA+CLB (9.03%, n=13) followed by VPA+LEV (6.25%, n=9), LEV+CLB (5.56%, n=8), VPA+PBT (2.08%, n=3), VPA+CBZ (2.08%, n=3), VPA+CBZ (2.08%, n=3). 17 (11.81%) patients were treated with triple drug combination. The most commonly prescribed three AEDs combination was VPA+CBZ+CLN (2.08%, n=3), VPA+LEV+CLB (2.08%, n=3) followed by VPA+LEV+CBZ (1.39%, n=2) and other prescribed 3 drug combination was used along with VPA but least prescribed. Only 1.39% (n=2) patients were treated with four drug combination. VPA+LEV+CBZ+CLB (0.69%, n=1); VPA+LEV+PBT+LCM (0.69%, n=1) these combinations prescribed as four drug combination as well as 1.39% (n=2) patients were treated with five drug

combination. VPA+LEV+LMT+CLB+PHT (0.69%); VPA+LEV+CBZ+CLN+LCM (0.69%) these combinations prescribed as five drug combination. Drug utilization pattern according to the different type of seizure disorder was as followings. In GTCS, the most commonly prescribed AED was sodium valproate (64.1%) followed by levetiracetam (47%). In Absence seizure, the most commonly prescribed AED was sodium valproate (100%) followed by lamotrigine (75%). In focal aware, the most commonly prescribed AED was levetiracetam (100%). In focal seizure with impaired awareness the most commonly prescribed AED was sodium valproate (75%) followed by levetiracetam (62.5%) (Table 2).

As per WHO drug utilization study prescribing indicators was calculated. Average number of anti-epileptic drugs (AEDs) prescribed per encounter was 1.69. All the drugs were prescribed by generic names only. FDC and injectable drugs were not used as well as no antibiotic was prescribed. 82.78% of drugs were prescribed from WHO essential drugs list and 94.67% of drugs were prescribed from National List of Essential Medicines (NLEM 2022) of India. PDD was found less than DDD in all prescribed AEDs except oxcarbazepine. PDD/DDD ratio ranged between 0.06-1.05 with oxcarbazepine having maximum ratio 1.05 than other AEDs phenytoin (0.82), phenobarbitone (0.73), lamotrigine (0.67), levetiracetam (0.65), sodium valproate (0.60), carbamazepine (0.57), lacosamide (0.50), clobazam (0.50), clonazepam (0.06) was found PDD less than DDD (Table 3). In the study, large proportion was adherent to AEDs treatment. 71.53% (n=103) patients were adherent to treatment while 28.47% (n=41) were non-adherent to treatment. The most common reason behind non-adherence to treatment was lack of education, lack of awareness about the disease and misconceptions spread in the society.

Table 1: Distribution of patients according to different type of seizure disorder.

Type of seizure disorder	Number (%)
Generalized (n=134)-93.75%	GTCS
	131 (90.97)
Focal (n=09)-6.25%	Absence seizure
	4 (2.78)
	Focal aware
	1 (0.70)
	Focal seizure with impaired awareness
	8 (5.55)
Grand total	144 (100)

Table 2: Drug utilization pattern of different AEDs in different type of seizure disorders.

Type of seizure disorder	Most commonly used AED (%)	2 nd Most commonly used AED (%)	Other used AEDs (%)
GTCS	Sodium valproate (64.1)	Levetiracetam (47)	Clobazam (24.4)
			Carbamazepine (10.7)
			Phenytoin (10.7)
			Phenobarbitone (6.1)
			Clonazepam (4.6)
			Lacosamide (2.3)
			Lamotrigine (1.5)
			Oxcarbazepine (1.5)

Continued.

Type of seizure disorder	Most commonly used AED (%)	2 nd Most commonly used AED (%)	Other used AEDs (%)
Absence seizure	Sodium valproate (100)	Lamotrigine (75)	Levetiracetam (25)
			Clobazam (25)
			Phenytoin (25)
Focal aware	Levetiracetam (100)		
Focal seizure with impaired awareness	Sodium valproate (75)	Levetiracetam (62.5)	Carbamazepine (50)
			Lacosamide (37.5)
			Clobazam (12.5)
			Clonazepam (12.5)
			Phenobarbitone (12.5)

Table 3: ATC classification of AEDs and PDD/DDD ratio.

Antiepileptic drug	Nomenclature	DDD (mg)	PDD (mg)	PDD/DDD (Ratio)
Sodium valproate	N03AG01	1500	906.38	0.6
Levetiracetam	N03AX14	1500	973.15	0.65
Clobazam	N05BA09	20	10	0.5
Clonazepam	N03AE01	8	0.5	0.06
Carbamazepine	N03AF01	1000	566.67	0.57
Phenytoin	N03AB02	300	246.67	0.82
Lacosamide	N03AX18	300	150	0.5
Lamotrigine	N03AX09	300	200	0.67
Phenobarbitone	N03AA02	100	73.33	0.73
Oxcarbazepine	N03AF02	1000	1050	1.05

DISCUSSION

This study was conducted to evaluate drug utilization pattern of antiepileptic drugs and adherence to treatment in outdoor patients of neurology department at a tertiary care teaching hospital.

In the study male population (59%) was comparatively higher than female. Almost similar finding was observed in study of Joshi et al, Mathur et al, Shilpa et al.¹⁰⁻¹² Many reasons can be possible that males have more chances of occupational hazards, road accidents, head trauma, substance abuse etc. which linked to higher risk of occurrence of seizure disorders, more social stigma in females, misconception or myths about seizure disorders in females leads to avoid seeking medical care, missed or under-diagnosed due to complicating diagnosis during pregnancy and menstrual cycle (catamenial epilepsy).

In the study mean age of onset of epilepsy was 24.13±13.58 years and maximum patients (50.70%) were of age group 18-30 years. Higher prevalence in this adolescents and younger population may be justified by multiple possible factors like life style factors such as substance abuse, sleep deprivation and high risk of trauma, head injury, CNS infections, occupational hazards as well as some late-onset genetic disorders such as (JME). Generalized seizure was observed in 93.75% whereas focal seizure was observed in only 6.25%. The most common type of seizure disorder was GTCS in 90.97% patient. Sodium valproate was the most commonly used (65.27%) as both monotherapy or in

combination with other AEDs followed by levetiracetam was used in 37.50% patients. In absence seizure sodium valproate was used in all patients followed by lamotrigine is used in 75% patients. In the study, 49.30% patients were treated with monotherapy. In other our similar studies Mathur et al, Magar et al, Gurumurthy et al, monotherapy was used 53.95%, 53%, 53.4% respectively.^{11,13,14} As comparison to these studies our finding is almost similar. Sodium valproate followed by levetiracetam was most commonly used as monotherapy.

Average number of anti-epileptic drugs (AEDs) prescribed per encounter was 1.69. All the drugs were prescribed by using generic name only. Total 94.67% and 82.78% drugs prescribed from essential drug list of NLEM and WHO essential drug list respectively. No fixed dose combination was used. PDD was less than DDD (as per Anatomical therapeutic chemical classification) of all prescribed drugs except oxcarbazepine.

In the study, 71.53% patients were adherent to AEDs treatment. For successful treatment of epilepsy, adherence to treatment is very important. There were many wrong and superstitious concepts related to epilepsy found during interaction of patients which influences adherence. Due to lack of education and awareness about the disease various misconceptions are spread in society which lead to poor compliance. Sometimes, due to myths about seizure disorder, the patient does not get treatment on early stage and proper time.

CONCLUSION

From this research, an important conclusion was obtained that while giving treatment, it is very important for the doctor to educate the patient and his family about epilepsy and the importance of adherence to the treatment. If any treatment is not effective for the patient, then first of all it is necessary to check the compliance or adherence to the ongoing treatment and only after that the treatment should be changed or modified.

Funding: No funding sources

Conflict of interest: None declared

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

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Cite this article as: Chaudhary MM, Singh H, Suthar AM, Menon AS, Bhut YS. Evaluation of drug utilization pattern of antiepileptic drugs and adherence to treatment in outdoor patients of neurology department at a tertiary care teaching hospital. *Int J Basic Clin Pharmacol* 2026;15:858-62.