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Original Research Article

Drug Utilization Pattern, Adverse Drug Reactions, and Cost Analysis of Anti-Epileptic Drugs in a Tertiary Care Hospital in Assam: A Prospective Observational Study

Bordoloi P.[1], Devi T.[2], Rajkhowa K.[3]

[1]Associate Professor, Department of Pharmacology, Tinsukia Medical College, Tinsukia, Assam, India
[2]Professor (DACP), Department of Pharmacology, Assam Medical College, Dibrugarh, Assam, India
[3]Assistant Professor, Department of Neurology, Assam Medical College, Dibrugarh, Assam, India

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Corresponding Author: Dr. Pallavi Bordoloi
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Abstract:

Background: Epilepsy is a chronic neurological disorder requiring long-term anti-epileptic drug (AED) therapy. Prolonged AED use is often associated with adverse drug reactions (ADRs), increased treatment cost, and concerns regarding rational prescribing.

Objectives: To evaluate the utilization pattern of AEDs, assess ADRs, and analyse the cost implications of AED therapy in a tertiary care teaching hospital in Assam.

Methods: A prospective observational study was conducted among 328 patients receiving AED therapy over six months. Drug utilization was assessed using World Health Organization (WHO) prescribing indicators and Anatomical Therapeutic Chemical/Defined Daily Dose (ATC/DDD) methodology. ADRs were evaluated using Naranjo's causality assessment scale and Hartwig's severity assessment scale. Statistical analysis was performed using SPSS version 26.0.

Results: Male patients constituted 59.76% of the study population. Generalized tonic–clonic seizures were the most common seizure type (68.29%). Polytherapy was prescribed more frequently (58.54%) than monotherapy (41.46%). Clobazam, levetiracetam, and phenytoin were the most commonly prescribed AEDs. A total of 125 patients experienced ADRs, predominantly central nervous system-related effects. Most ADRs were categorized as probable and mild in severity. Polytherapy was significantly associated with higher ADR incidence and treatment cost compared with monotherapy ($p < 0.001$). Logistic regression analysis showed that polytherapy independently increased the likelihood of ADR occurrence.

Conclusion: Polytherapy and conventional AED use were associated with greater ADR burden and higher treatment cost. Rational prescribing and regular ADR monitoring may improve patient safety and therapeutic outcomes in epilepsy management.

Keywords: Epilepsy; Anti-epileptic drugs; Drug utilization; adverse drug reactions; Pharmacovigilance; Cost-analysis, Polytherapy.

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Introduction

Epilepsy is one of the most common chronic neurological disorders worldwide and is characterized by recurrent, unprovoked seizures resulting from abnormal excessive neuronal activity in the brain. According to the World Health Organization (WHO), more than 50 million people globally are affected by epilepsy, with nearly 80% residing in low- and middle-income countries where healthcare access and affordability remain major challenges. [9]

In India, epilepsy affects approximately 10–12 million individuals and continues to pose a significant public health burden. [5] Pharmacotherapy remains the cornerstone of epilepsy management, with the primary objective of achieving optimal seizure control while minimizing adverse drug reactions (ADRs) and improving quality of life. Anti-epileptic drugs (AEDs) act through multiple mechanisms, including modulation of sodium and calcium channels and enhancement of gamma-aminobutyric acid (GABA)-mediated inhibition. Although monotherapy is generally preferred because of better tolerability and fewer drug interactions, polytherapy is frequently required in refractory epilepsy.

Conventional AEDs such as phenytoin, carbamazepine, and sodium valproate continue to

be widely prescribed because of their effectiveness and affordability. However, these drugs are commonly associated with dose-related toxicities, hypersensitivity reactions, and significant drug interactions. Newer AEDs such as levetiracetam offer improved safety profiles and fewer interactions but are often associated with higher treatment costs. [7]

Drug utilization studies are important for evaluating prescribing trends, rational drug use, and safety profiles of medications in clinical practice. [1,3] The World Health Organization recommends the Anatomical Therapeutic Chemical/Defined Daily Dose (ATC/DDD) methodology for standardized assessment of drug utilization patterns. [10] Comparison of Prescribed Daily Dose (PDD) with WHO-defined DDD helps identify variations in prescribing practices and provides insight into rationality of therapy.

Long-term AED therapy increases the risk of ADRs, which may adversely affect treatment adherence and therapeutic outcomes. [2] Several studies evaluating AED utilization and ADR profiles have been conducted in different parts of India; however, data from Northeast India remain limited. [1,3] Regional differences in prescribing practices, healthcare access, and socioeconomic factors may influence AED utilization patterns and treatment outcomes.

Therefore, the present study was undertaken to evaluate the utilization pattern of AEDs, assess ADRs, and analyse the cost implications of AED therapy in a tertiary care teaching hospital in Assam. The findings may help promote rational prescribing practices and strengthen pharmacovigilance in epilepsy management.

Materials and Methods

Study Design and Setting: This was a single-centre prospective observational study conducted over a period of six months (May to October 2017) in the Department of Pharmacology in collaboration with the Department of Neurology at a tertiary care teaching hospital in Assam, India. All the participants included in the study were well explained about the purpose of the study in the language they understood and were included in the study only after obtaining a written Informed Consent (ICF) and consent to publish has been received from all participants.

The study aimed to evaluate the utilization pattern of anti-epileptic drugs (AEDs), assess adverse drug reactions (ADRs), and analyse the cost implications associated with AED therapy in patients with epilepsy.

Ethical Considerations: The study protocol was reviewed and approved by the Institutional Ethics Committee (IEC) of Assam Medical College & Hospital, Dibrugarh under approval No. AMC/EC/1305 dated 17/05/2017.

Study Population: Patients diagnosed with epilepsy and receiving anti-epileptic drug therapy in the outpatient and inpatient departments of Neurology and General Medicine during the study period were included in the study.

Inclusion Criteria

- Patients of either sex diagnosed with epilepsy.
- Patients of all age groups diagnosed with epilepsy
- Patients receiving one or more anti-epileptic drugs.
- Patients willing to provide written informed consent.

Exclusion Criteria

- Patients unwilling or unable to provide consent.
- Patients with incomplete medical records.
- Pregnant and lactating women.
- Patients with severe psychiatric illness or serious comorbid conditions interfering with assessment.

Sample Size and Sampling Technique: A total of 328 patients fulfilling the inclusion criteria were enrolled consecutively during the 6 months study period using a convenience sampling technique.

Data Collection: Data were collected using a predesigned and pre-validated case record form. Information obtained included:

- Demographic details,
- Clinical diagnosis,
- Seizure type,
- Duration of illness,
- Prescribed anti-epileptic drugs,
- Dosage regimen,
- Duration of therapy,
- Concomitant medications,
- Adverse drug reactions,
- Treatment cost.

Relevant laboratory investigations and clinical findings were recorded wherever applicable.

Assessment of Drug Utilization Pattern: Drug utilization analysis was performed using the WHO prescribing indicators and the Anatomical Therapeutic Chemical/Defined Daily Dose (ATC/DDD) methodology recommended by WHO Collaborating Centre for Drug Statistics Methodology. [10]

The following prescribing indicators were assessed:

- Average number of AEDs per prescription,
- Percentage of monotherapy and polytherapy prescriptions,
- Frequency of individual AED use,

- Utilization of conventional and newer AEDs.

Prescribed Daily Dose (PDD)

The Prescribed Daily Dose (PDD) was calculated using the following formula:

Total Quantity of Drug Administered

PDD = ----------

Total Number of Treatment Days: The PDD values were compared with WHO-defined daily dose (DDD) values to determine prescribing trends and rationality of drug use.

Assessment of Adverse Drug Reactions: Patients were monitored prospectively during outpatient follow-up visits and hospital stay for the occurrence of suspected ADRs related to anti-epileptic drugs.

All suspected ADRs were documented and evaluated for:

Causality using Naranjo's causality assessment scale. [17]

Severity using Hartwig's severity assessment scale. [18]

The incidence and pattern of ADRs associated with individual AEDs were analysed.

ADR Incidence: ADR incidence was calculated using the formula:

Number of patients with an ADR

ADR Incidence (%) = ---------- × 100

Total number of patients at risk

Pharmacoeconomic Analysis: The monthly treatment cost of AED therapy was calculated based on the prescribed dosage regimen and prevailing hospital/pharmacy drug prices. Cost comparison was performed between monotherapy and polytherapy groups.

Statistical Analysis: Data were entered into Microsoft Excel and analysed using Statistical Package for Social Sciences (SPSS) software version 26.0. Categorical variables were expressed as frequency and percentage, whereas continuous variables were expressed as mean ± standard deviation (SD). Statistical analysis included chi-square test, independent t-test, odds ratio estimation, and subgroup analysis. A p-value of less than 0.05 was considered statistically significant.

The study was conducted and reported in accordance with strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines. [21]

Results

Demographic and Clinical Characteristics: A total of 328 patients receiving anti-epileptic drug (AED) therapy were included in the study. Among them, 196 (59.76%) were males and 132 (40.24%) were females, indicating a male predominance. Most patients were known cases of epilepsy (72.56%), while 27.44% were newly diagnosed cases (Table 1).

Table 1: Demographic and Clinical Characteristics of Study Population (n = 328)

Variable	Number of Patients (n)	Percentage (%)
Sex		
Male	196	59.76
Female	132	40.24
Case status		
Known epilepsy	238	72.56
Newly diagnosed	90	27.44
Total	328	100

Data are presented as frequency and percentage.

Generalized tonic–clonic seizures (GTCS) were the most common seizure type, accounting for 224 (68.29%) cases. Other seizure types included focal seizures, absence seizures, and myoclonic seizures (Table 2).

Table 2: Distribution of Seizure Types among Study Participants (328)

Seizure Type	Number of Patients (n)	Percentage (%)
Generalized tonic–clonic seizures (GTCS)	224	68.3
Focal seizures	94	28.7
Absence seizures	6	1.8
Myoclonic seizures	4	1.2
Total	328	100

Utilization Pattern of Anti-Epileptic Drugs: Polytherapy was prescribed more frequently than monotherapy. Out of 328 patients, 192 (58.54%) received polytherapy, whereas 136 (41.46%) received monotherapy (Table 3A). The average number of AEDs prescribed per patient was 1.65.

Table 3. Pattern of Anti-Epileptic Drug Utilization

Table 3A: Therapy Pattern (n = 328)

Therapy Type	Number of Patients (n)	Percentage (%)
Monotherapy	136	41.46
Polytherapy	192	58.54
Total	328	100

Average number of AEDs per prescription = 1.65: Among individual AEDs, Clobazam was the most commonly prescribed drug (46.34%), followed by Levetiracetam (35.37%) and Phenytoin (34.76%) (Table 3B). Conventional AEDs such as Phenytoin continued to be widely used despite increasing utilization of newer agents.

Table 3B: Frequency of Individual AED Use

Anti-epileptic Drug	Number of Prescriptions (n)	Percentage (%)
Clobazam	152	46.34
Levetiracetam	116	35.37
Phenytoin	114	34.76
Carbamazepine	46	14.02
Sodium valproate	79	24.08

Drug utilization analysis using the WHO ATC/DDD methodology showed that the prescribed daily dose (PDD) of phenytoin (0.29 g) was closely comparable to its WHO-defined daily dose (DDD) of 0.30 g, with a PDD/DDD ratio of 0.97. Sodium valproate demonstrated a lower PDD/DDD ratio, suggesting relatively conservative dosing practices (Table 4).

Table 4: Comparison of Prescribed Daily Dose (PDD) and WHO Defined Daily Dose (DDD)

Drug	Prescribed Daily Dose (PDD)	WHO Defined Daily Dose (DDD)	PDD/DDD Ratio
Phenytoin	0.29 g	0.30 g	0.97
Carbamazepine	0.80 g	1.0 g	0.80
Levetiracetam	1.2 g	1.5 g	0.80
Sodium valproate	1.0 g	1.5 g	0.67

Adverse Drug Reactions: A total of 125 patients experienced at least one ADR during the study period. Central nervous system-related adverse effects such as drowsiness, dizziness, sedation, ataxia, and diplopia constituted the majority of ADRs. Gingival hypertrophy, dermatological reactions, hair fall, and facial coarsening were among the commonly observed non-central nervous system adverse effects. Phenytoin contributed substantially to the ADR burden, particularly gingival hypertrophy, facial coarsening, and dermatological reactions. Sedation and drowsiness were frequently associated with clobazam therapy.

Overall ADR incidence = 38.11% (125/328 patients) (Table 5).

Table 5: Incidence and Pattern of Adverse Drug Reactions (ADRs)

Type of ADR	Number of Cases (n)	Percentage of Total ADRs (%)
CNS effects (Drowsiness, Dizziness, Ataxia, Diplopia)	49	39.2
Gingival Hypertrophy	18	14.4
Dermatological Reactions	12	9.6
Hair Fall	15	12.0
Facial Coarsening	31	24.8
Total ADR cases	125	100

Causality assessment using Naranjo's scale revealed that most ADRs were categorized as "probable," while severity assessment using Hartwig's scale showed that the majority of reactions were mild to moderate in severity. No severe or life-threatening ADRs were reported.

Comparative Analysis between Monotherapy and Polytherapy: Patients receiving polytherapy experienced a significantly higher incidence of ADRs compared with those receiving monotherapy. ADRs were observed in 98 (51.04%) patients in the polytherapy group, whereas only 27 (19.85%) patients receiving monotherapy developed ADRs. This difference was statistically highly significant ($\chi^2 = 31.52$, $p < 0.001$). The mean monthly treatment cost was significantly higher among patients receiving polytherapy (₹1450 ± 620) compared to monotherapy (₹472 ± 210).

Independent t-test analysis demonstrated a statistically highly significant difference between the two groups ($t = 20.28$, $p < 0.001$) (Table 6).

Table 6: Comparative Analysis between Monotherapy and Polytherapy Groups

Parameter	Monotherapy (n = 136)	Polytherapy (n = 192)	Statistical Test	p-value
Patients with ADRs [n (%)]	27 (19.85%)	98 (51.04%)	X^2 =31.52	<0.001
Average monthly treatment cost (INR), mean±SD	Rs 472±210	**₹1450 ± 620**	Independent t test t= 20.28	<0.001

Subgroup analysis demonstrated a significantly higher incidence of adverse drug reactions (ADRs) among patients receiving polytherapy compared with those receiving monotherapy.

ADRs were observed in 98 of 192 patients (51.04%) receiving polytherapy, whereas only 27 of 136 patients (19.85%) receiving monotherapy developed ADRs. Patients receiving polytherapy had approximately 4.21 times higher odds of developing ADRs compared with patients receiving monotherapy (Odds Ratio [OR] = 4.21; 95% Confidence Interval [CI]: 2.52–7.03).

The association was statistically highly significant ($\chi^2 = 31.52$, $p < 0.001$). (Table 7)

Table 7: Subgroup Analysis of ADR Incidence According to Therapy Pattern

Therapy Type	Patients with ADRs	Patients without ADRs	ADR Incidence (%)	Odds Ratio (95% CI)	p-value
Monotherapy (n = 136)	27	109	19.85	Reference	—
Polytherapy (n = 192)	98	94	51.04	4.21 (2.52-7.03)	<0.001

Chi-square test applied; statistically significant at $p < 0.05$.

Binary logistic regression analysis was performed to identify predictors associated with occurrence of adverse drug reactions among patients receiving anti-epileptic drugs.

Polytherapy was independently associated with significantly increased odds of ADR occurrence (AOR = 4.18; 95% CI: 2.48–7.01; $p < 0.001$). Use of conventional AEDs was also significantly associated with ADR development (AOR = 2.06; 95% CI: 1.21–3.52; $p = 0.008$).

Male sex and seizure type were not found to be significant predictors of ADR occurrence. (Table 8)

Table 8: Binary Logistic Regression Analysis for Predictors of ADRs in Patients Receiving AED Therapy

Variable	Adjusted Odds Ratio (AOR)	95% CI	p-value
Polytherapy vs Monotherapy	4.18	2.48–7.01	<0.001
Male sex	1.12	0.68–1.84	0.64
GTCS vs other seizure types	1.39	0.81–2.38	0.22
Conventional AED use*	2.06	1.21–3.52	0.008
Use of Clobazam	1.74	1.02–2.96	0.041

***Conventional AEDs included phenytoin, carbamazepine, and sodium valproate.**

Causality assessment of adverse drug reactions was performed using Naranjo's causality assessment scale. Among the 125 reported ADRs, the majority were categorized as "Probable" (65.60%), while 34.40% were classified as "Possible." No reactions were categorized as "Definite" or "Doubtful" (Table 9).

Table 9: Causality Assessment of ADRs Using Naranjo's Scale

Causality Category	Number of ADRs (n)	Percentage (%)
Definite	0	0
Probable	82	65.60
Possible	43	34.40
Doubtful	0	0
Total	125	100

Severity assessment of adverse drug reactions was performed using Hartwig's severity assessment scale. Most ADRs were mild in severity, accounting for 81 (64.80%) reactions, while 44 (35.20%) ADRs were categorized as moderate. No severe ADRs were reported during the study period (Table 10).

Table 10: Severity Assessment of ADRs Using Hartwig's Scale

Severity Category	Number of ADRs (n)	Percentage (%)
Mild	81	64.80
Moderate	44	35.20
Severe	0	0
Total	125	100

Discussion

The present prospective observational study was conducted to evaluate the utilization pattern of anti-epileptic drugs (AEDs), assess adverse drug reactions (ADRs), and analyse the cost implications of AED therapy in patients attending a tertiary care teaching hospital in Assam.

Demographic and Clinical Profile: In our study, males constituted the majority of the study population. A comparable male predominance has also been observed in earlier Indian studies, possibly reflecting differences in healthcare-seeking behaviour and access to tertiary care services. [1,3] Generalized tonic–clonic seizures (GTCS) were the most common seizure type observed in the study population. Comparable findings regarding predominance of generalized tonic–clonic seizures have also been reported in previous Indian studies, [3,15] The higher prevalence of GTCS may be due to its clinically recognizable presentation and greater likelihood of referral for specialized care.

Utilization Pattern of AEDs: Polytherapy predominated over monotherapy in the present study. Although monotherapy is generally recommended as the initial therapeutic strategy because of better compliance, reduced toxicity, and fewer drug interactions, tertiary-care hospitals often manage refractory and difficult-to-control epilepsy cases requiring combination therapy.

The average number of AEDs prescribed per patient was 1.65, which is comparable with previous Indian drug utilization studies. [1,3] Increasing utilization of levetiracetam reflects a gradual shift towards newer AEDs because of their favourable safety profile, fewer pharmacokinetic interactions, and better tolerability.

Clobazam was the most commonly prescribed AED in the present study, followed by levetiracetam and phenytoin. The frequent use of clobazam may be attributed to its role as adjunctive therapy in uncontrolled seizures and seizure clusters. The frequent use of levetiracetam in our study may indicate a gradual transition toward newer AEDs with improved tolerability and lower interaction potential. [12]. Despite the availability of newer AEDs, conventional agents such as phenytoin continued to be widely prescribed. Despite its well-known adverse effect profile, phenytoin continues to be widely prescribed, likely because of its lower cost and long-standing clinical familiarity.[7]

PDD–DDD Analysis: Evaluation of prescribed daily dose (PDD) in relation to WHO-defined daily dose (DDD) is an established approach for assessing rational drug utilization. [10,16] In our study, phenytoin showed close concordance between PDD and DDD, suggesting relatively standardized prescribing practices.

Lower PDD/DDD ratios observed with sodium valproate may indicate cautious dose titration, individualized therapy, or use in combination regimens. Variations between prescribed doses and WHO-defined doses may also reflect differences in patient characteristics, seizure severity, and clinician preference. However, persistent under-dosing may potentially compromise seizure control and requires further evaluation.

Adverse Drug Reactions: A total of 125 ADRs were reported during the study period. Central nervous system-related adverse effects such as drowsiness, dizziness, sedation, ataxia, and diplopia constituted the majority of ADRs. A similar trend was reported in previous pharmacovigilance studies involving anti-epileptic drugs. [2]

Phenytoin contributed substantially to ADR burden, particularly gingival hypertrophy and dermatological reactions. The observed pattern of gingival hypertrophy and dermatological reactions aligns with the established long-term adverse effect profile of phenytoin.

Causality assessment using Naranjo's scale revealed that most ADRs were categorized as "Probable," indicating a reasonable temporal relationship between drug administration and occurrence of adverse effects. Severity assessment using Hartwig's severity scale demonstrated that the majority of ADRs were mild to moderate in severity.

Most ADRs observed in the study were mild to moderate in severity and were effectively managed with dose adjustment, symptomatic treatment, or close monitoring. The absence of severe ADRs may reflect careful clinical supervision and prompt recognition of adverse effects in the study population.

Comparative Analysis of Monotherapy and Polytherapy: Patients receiving polytherapy experienced a significantly higher incidence of ADRs compared with those receiving monotherapy. More than half of the patients receiving multiple AEDs developed ADRs, whereas the incidence was considerably lower in the monotherapy group. The increased ADR burden associated with polytherapy may be attributed to cumulative drug toxicity, additive central nervous system depressant effects, and increased potential for pharmacokinetic interactions. Earlier Indian studies have also reported higher ADR frequency among patients receiving multiple AEDs. [2]

Subgroup analysis further demonstrated that patients receiving polytherapy had more than four-

fold higher odds of developing ADRs compared with those receiving monotherapy. This finding emphasizes the importance of rational AED selection and cautious use of combination therapy, particularly in resource-limited settings where ADR-related morbidity and treatment cost may negatively influence long-term treatment adherence.

Binary logistic regression analysis further demonstrated that polytherapy independently increased the likelihood of adverse drug reactions among patients receiving AED therapy. Patients receiving multiple AEDs showed significantly higher odds of developing ADRs compared with those receiving monotherapy. In addition, use of conventional AEDs such as phenytoin and carbamazepine was associated with increased ADR occurrence. These findings suggest that cumulative drug exposure and pharmacokinetic interactions may contribute substantially to treatment-related adverse effects in epilepsy management. Similar observations regarding increased ADR burden with polytherapy and conventional AED use have been reported in previous pharmacovigilance studies. [2,8]

Our study also demonstrated significantly higher treatment cost among patients receiving polytherapy. Increased use of multiple AEDs, particularly newer agents such as levetiracetam, substantially contributed to the economic burden of therapy. Similar concerns regarding affordability and cost burden of anti-epileptic drugs in resource-limited settings have been reported previously. [7] Higher treatment cost and ADR burden associated with polytherapy may negatively affect long-term treatment adherence, particularly in chronic disorders such as epilepsy. Recent evidence suggests that medication nonadherence remains a major challenge among patients receiving long-term AED therapy. [13]

These observations reinforce the importance of rational monotherapy whenever seizure control can be achieved with a single agent.

Clinical Implications: Our study highlights the continuing reliance on conventional AEDs in tertiary-care practice despite increasing utilization of newer agents. Regular monitoring for ADRs, individualized dose optimization, and rational selection of AED combinations are essential to improve therapeutic outcomes and minimize drug-related morbidity.

The absence of severe ADRs in our study suggests that most AED-related adverse effects can be effectively managed through appropriate monitoring and individualized therapy.

Regular ADR monitoring and evidence-based prescribing may help improve long-term safety and adherence among patients receiving chronic AED therapy.

Limitations of the Study: Our study was conducted at a single tertiary care centre, which may limit generalizability of the findings to the broader population. The relatively short duration of follow-up may have resulted in underreporting of delayed or rare ADRs. In addition, pharmacoeconomic analysis was based primarily on direct drug cost and did not include indirect costs related to loss of productivity or hospitalization. The relatively short duration of the study and single-centre design may limit the generalizability of the findings.

Despite these limitations, our study provides valuable region-specific data regarding AED utilization patterns, ADR profile, and cost implications in patients with epilepsy from Northeast India.

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