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Original Research Article

Drug Utilization of Anti-Seizure Drugs in Patients of Seizure Disorder in The Department of Pediatrics at a Tertiary Care Teaching Hospital, Nuh, Haryana

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Abstract

Background: Epilepsy is one of the most common chronic neurological disorders in children, requiring long-term precisional pharmacotherapy. Drug utilization studies (DUS) provide insight into current prescribing trends and rational drug use, which is especially important in resource-limited settings where treatment gaps remain significant.

Aim: To evaluate the utilization pattern of anti-seizure drugs (ASDs) in pediatric patients with seizure disorders and assess prescribing practices using WHO indicators.

Methods: A cross-sectional observational study was conducted in the Department of Pediatrics at a tertiary care teaching hospital in Nuh, Haryana. A total of 105 pediatric patients (1 month–14 years) receiving ASDs were included. Data were collected using a structured proforma from case records and caregiver interviews. WHO prescribing indicators were used for analysis. Descriptive statistics and percentages were calculated, and associations were assessed using appropriate statistical tests ($p < 0.05$ considered significant).

Results: In total 105 patients, most patients were below 5 years (70.5%), with male predominance (62.9%). Infectious etiology was the leading cause (30.5%). Phenytoin (40.1%) was the most prescribed drug. Monotherapy (62.9%) was more common than polytherapy (37.1%). Intravenous route was predominant (87.5%). The average number of drugs per prescription was 6.87. Generic prescribing was low (33.1%), while antibiotic use (78.1%) and injectable use (87.6%) were high. NLEM adherence was excellent (98.7%).

Conclusion: The study demonstrates predominantly rational prescribing with high NLEM adherence and preference for monotherapy. However, polypharmacy, low generic prescribing, and high antibiotic use indicate areas requiring improvement. Regular audits and antimicrobial stewardship programs are recommended.

Keywords: Anti-Seizure Drugs, Seizure Disorder, WHO.

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Introduction

Epilepsy is a chronic neurological disorder characterized by recurrent, unprovoked seizures resulting from abnormal electrical discharges in the brain. It represents a significant global health burden, particularly in pediatric populations where developing neural systems are more vulnerable to injury and long-term sequelae. According to the International League against Epilepsy, epilepsy is diagnosed after two unprovoked seizures occurring more than 24 hours apart or one seizure with a high risk of recurrence [1] Globally, epilepsy affects nearly 50 million individuals, with a higher

incidence in developing countries due to poor healthcare infrastructure and increased prevalence of risk factors such as infections and perinatal complications [2]. In India, epilepsy contributes substantially to neurological morbidity, with approximately 12 million affected individuals, representing nearly one-sixth of the global burden [3]. Pediatric epilepsy is particularly concerning due to its impact on cognitive development, behavior, and quality of life.

The etiology of seizures in children is diverse, including infections, metabolic disturbances, structural abnormalities, and genetic causes. In low-resource settings, infections such as meningitis and encephalitis are major contributors to seizure disorders [4]. These conditions not only increase disease burden but also highlight disparities in immunization coverage and healthcare access.

Pharmacotherapy remains the cornerstone of epilepsy management. The primary goal is to achieve complete seizure control with minimal adverse effects using appropriate anti-seizure drugs (ASDs). Traditionally used drugs such as phenytoin and sodium valproate continue to play a major role, while newer agents like levetiracetam offer improved safety profiles [5]. Treatment usually begins with monotherapy, with polytherapy reserved for refractory cases [6].

Drug utilization studies are essential tools in pharmacoepidemiology, providing insights into prescribing patterns, rationality, and adherence to guidelines. These studies help identify issues such as polypharmacy, irrational prescribing, and inappropriate use of medications [7]. In chronic conditions like epilepsy, where long-term therapy is required, ensuring rational drug use is critical to improving patient outcomes and reducing economic burden.

The World Health Organization (WHO) prescribing indicators are widely used to evaluate rational drug use. These include parameters such as average number of drugs per encounter, percentage of generic prescribing, antibiotic use, injection use, and adherence to essential medicines lists [8]. Application of these indicators in pediatric epilepsy helps in assessing prescribing behavior and identifying areas for improvement.

Despite the importance of DUS, there is a paucity of data from rural, limited health setup and underprivileged regions such as Nuh, Haryana. Variability in prescribing practices, access to healthcare, and socioeconomic factors necessitate region-specific studies to guide policy and improve patient care [9]. Therefore, this study aims to evaluate the utilization pattern of anti-seizure drugs in pediatric patients and assess prescribing practices using WHO indicators, thereby contributing to rational drug use and improved epilepsy management.

Materials and Methodology

Study Design: The present study was designed as a hospital-based, cross-sectional observational study aimed at evaluating the utilization pattern of anti-seizure drugs (ASDs) in pediatric patients diagnosed with seizure disorders. This design was selected to obtain a real-time snapshot of prescribing practices and drug utilization trends without influencing clinical decision-making.

Study Setting: The study was conducted in the Department of Pediatrics at a tertiary care teaching hospital in Nuh, Haryana, India, which caters predominantly to a rural population. The hospital functions as a referral center for surrounding primary and secondary healthcare facilities, thus providing a representative sample of pediatric seizure cases in a resource-limited setting.

Study Duration: The study was carried out over a period of 12 months, allowing adequate time to capture seasonal variations in disease patterns, particularly infections that may precipitate seizures.

Study Population: The study population consisted of pediatric patients aged between 1 month and 14 years who were diagnosed with seizure disorders and were receiving at least one anti-seizure medication during the study period.

Sample Size Determination: The sample size was calculated using Fisher's formula for cross-sectional studies at a 95% confidence interval and an acceptable margin of error. Based on prevalence estimates from previous studies, the minimum required sample size was calculated, and a total of 105 patients were enrolled to ensure adequate statistical power and reliability of results.

Sampling Technique: A consecutive sampling method was employed, wherein all eligible patients meeting the inclusion criteria during the study period were recruited until the required sample size was achieved.

This approach minimized selection bias and ensured inclusion of a diverse patient population.

Inclusion Criteria

- Pediatric patients aged 1 month to 14 years
- Diagnosed with seizure disorder (any type)
- Prescribed at least one anti-seizure drug
- Informed consent obtained from parents or legal guardians

Exclusion Criteria

- Children with congenital neurological anomalies (e.g., cerebral palsy with seizures)

- Patients who were critically ill or required intensive care support, where drug utilization patterns may differ significantly
- Refusal of consent by parents or guardians.

Data Collection Procedure: Data were collected using a pre-designed, structured data collection proforma, which was developed after reviewing relevant literature and WHO guidelines on drug utilization studies.

A no. of 105 patients prescription /case sheets Containing at least one anti-epileptic drug were taken during the study period from the Department of Paediatrics on a pre designed performa.
-Data was collected by visiting the Hospital / concerned departmental OPD/IPD for 2 hours a day, twice every week. During the study period of 1 year.
-Follow up visit of the patient on anti-seizure drugs were not included again for the study purpose.

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(WHO) indicators were utilized to Measure rationale/appropriate use of drugs with keeping emphasis on the prescribing patterns.

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- All the data was checked and coded for computer entries. After compilation of collected data, it was entered into excel sheets and then appropriate statistical software was used for analysis.
- Percentage was calculated and the results were expressed using descriptive statistics (mean, standard error of mean, standard deviation etc.

Chart 1:

Assessment of Drug Utilization: Drug utilization was evaluated using World Health Organization (WHO) core prescribing indicators, which are widely accepted standards for assessing rational drug use.

The following indicators were calculated:

1. Average number of drugs per prescription
2. Percentage of drugs prescribed by generic name
3. Percentage of prescriptions containing antibiotics
4. Percentage of prescriptions containing injectable drugs
5. Percentage of drugs prescribed from the National List of Essential Medicines (NLEM)

These indicators helped in assessing the rationality, safety, and cost-effectiveness of prescribing practices.

Outcome Measures

The primary outcome measures included:

- Pattern of anti-seizure drug utilization
- Proportion of monotherapy versus polytherapy
- Adherence to WHO prescribing indicators
- Identification of deviations from standard prescribing practices

Secondary outcomes included:

- Association between demographic/clinical variables and drug utilization patterns
- Evaluation of the extent of polypharmacy

Statistical Analysis: All collected data were entered into Microsoft Excel and analyzed using appropriate statistical software.

Descriptive statistics were used to summarize the data:

- Mean and standard deviation for continuous variables
- Frequencies and percentages for categorical variables

Inferential statistics were applied where necessary:

- Chi-square test was used to determine associations between categorical variables
- p-value < 0.05 was considered statistically significant

The results were presented in the form of tables, charts, and graphs for better interpretation.

Ethical Considerations: The study was conducted in accordance with ethical principles for biomedical research involving human subjects.

Results

Table 1: Sociodemographic Profile of Study Population (n = 105)

Variable	Category	Frequency (n)	Percentage (%)	Short Interpretation
Age Distribution	Infant (<1 year)	34	32.38%	High proportion of infants indicating early-life vulnerability to seizures
	Preschool (1–5 years)	40	38.10%	Majority belonged to preschool age, suggesting peak incidence in early childhood
	School Age (6–10 years)	22	20.95%	Moderate representation in school-aged children
	Adolescent (>10 years)	9	8.57%	Lowest occurrence seen in adolescents
	Total	105	100%	Early childhood predominance observed
Gender Distribution	Male	66	62.86%	Male predominance suggests possible biological or healthcare-seeking bias
	Female	39	37.14%	Lower proportion of females in comparison
	Total	105	100%	Overall male preponderance
Geographical Distribution	Rural	100	95.24%	Majority from rural areas indicating higher burden or referral bias
	Urban	5	4.76%	Very few urban participants
	Total	105	100%	Rural dominance in study population

Table 2: Etiological Distribution

Etiology of Seizures	Idiopathic / Primary	5	4.8%	Low proportion of primary epilepsy cases
	Infectious Causes	32	30.5%	Most common cause, highlighting infection burden
	Post-Hypoxic / Ischemic	5	4.8%	Reflects perinatal complications
	Structural Abnormalities	4	3.8%	Less common but clinically significant
	Metabolic Causes	3	2.8%	Least common etiology
	Febrile Seizures	8	7.6%	Common in younger age groups
	LONS	9	8.6%	Notable contributor among neonatal causes
	Neurodevelopmental Disorders	5	4.8%	Associated with chronic neurological deficits
	Post-Infectious Sequelae	1	0.9%	Rare occurrence
	Acute Systemic Illness	4	3.8%	Associated with acute conditions
	Undifferentiated	29	27.6%	High proportion indicates diagnostic challenges
	Total	105	100%	Infectious and undifferentiated causes predominate

The study population demonstrated a clear predominance of early childhood seizures, particularly in the preschool age group (38.10%), followed by infants (32.38%). A male predominance (62.86%) was observed, which may reflect biological susceptibility or sociocultural healthcare-seeking patterns. The overwhelming majority of patients were from rural areas (95.24%), indicating a higher disease burden or referral trends in rural populations. From an etiological perspective, infectious causes (30.5%) emerged as the leading contributor, emphasizing the role of preventable conditions such as meningitis and encephalitis. A significant proportion of cases (27.6%) remained undifferentiated, highlighting diagnostic limitations and the need for improved investigative facilities. Other causes such as febrile seizures, neonatal sepsis, and neurodevelopmental disorders contributed modestly.

Table 2: Pattern of Anti-Seizure Drug Utilization and Therapy Regimen (n = 105; Total Drugs = 152)

Variable	Category	Frequency (n)	Percentage (%)	Short Interpretation
Overall Drug Utilization	Phenytoin	61	40.13%	Most commonly prescribed ASD indicating first-line preference
	Valproate	27	17.76%	Second most common drug, widely used for generalized seizures
	Levetiracetam	24	15.79%	Increasing use due to better safety profile
	Midazolam	21	13.82%	Commonly used in acute seizure control
	Diazepam	12	7.89%	Used for emergency seizure management
	Phenobarbitone	5	3.29%	Limited use, mainly in neonates
	Clobazam	2	1.32%	Least commonly used adjunct drug
	Total	152	100%	Reflects overall prescribing pattern
Monotherapy (n = 66)	Phenytoin	33	50.00%	Most preferred single-drug therapy
	Valproate	21	31.80%	Common alternative monotherapy
	Levetiracetam	7	10.60%	Moderate use as monotherapy
	Phenobarbitone	5	7.60%	Used mainly in specific indications
	Total	66	100%	Majority managed with monotherapy
Combination Therapy (n = 39)	Dual Therapy	—	—	Most common form of polytherapy
	Midazolam + Phenytoin	13	33.33%*	Most frequent combination for acute control
	Levetiracetam + Phenytoin	8	20.51%*	Common combination for refractory seizures
	Other dual combinations	10	25.64%*	Less frequent combinations used
	Triple Therapy	4	10.26%*	Used in resistant cases
	Quadruple Therapy	1	2.56%*	Rare, severe refractory cases
	Total	39	100%	Polytherapy used in minority

***Percentages calculated within combination therapy group (n=39)**

The study demonstrates that phenytoin (40.13%) was the most frequently prescribed anti-seizure drug, highlighting its continued role as a first-line agent, particularly in acute and generalized seizure management. Valproate (17.76%) and levetiracetam (15.79%) were also commonly used, indicating a balance between conventional and newer antiepileptic drugs. The notable use of benzodiazepines such as midazolam (13.82%) and diazepam (7.89%) reflects their importance in emergency seizure control. With respect to ATC classification, the majority of drugs belonged to the antiepileptic category, while benzodiazepines were primarily used for short-term seizure termination. This suggests rational pharmacological selection based on clinical indications. Monotherapy (62.9%) was more commonly employed than polytherapy, aligning with standard epilepsy treatment guidelines that recommend single-drug therapy whenever possible. Among monotherapy regimens, phenytoin (50%) was the most preferred agent, followed by valproate (31.8%).

Combination therapy (37.1%) was used in patients with refractory or severe seizures. Dual therapy was the most common form, with midazolam + phenytoin being the predominant combination, reflecting its effectiveness in acute seizure episodes.

Triple and quadruple therapies were rarely used, indicating cautious escalation of treatment.

Table 3: Route of Administration and WHO Prescribing Indicators (n = 152 drugs; n = 105 prescriptions)

Variable	Category	Frequency (n) / Observed Value	Percentage (%)	WHO Ideal Value	Short Interpretation
Route of Administration	Intravenous (I.V.)	133	87.50%	—	Predominant use indicates acute/emergency management setting
	Oral	18	11.84%	—	Limited use, likely due to hospital-based treatment
	Nasal	1	0.66%	—	Rare use, reserved for specific indications
	Total	152	100%	—	Injectable route overwhelmingly preferred
WHO Prescribing Indicators	Avg. drugs per encounter	6.87	—	1.6–1.8	Significantly higher, indicating polypharmacy
	Avg. ASDs per prescription	1.44	—	NA	Acceptable, suggesting controlled ASD use
	Generic prescribing	—	33.1%	100%	Suboptimal, indicating need for cost-effective prescribing
	Antibiotic encounters	—	78.1%	20–26.8%	Excessively high, may increase resistance risk
	Injection encounters	—	87.6%	13.4–24.1%	Very high, reflects inpatient/emergency care bias
	NLEM adherence	—	98.7%	100%	Excellent adherence to essential medicines

The findings reveal that the intravenous route (87.50%) was overwhelmingly preferred, indicating that most patients were managed in acute or emergency settings where rapid drug action is required. Oral administration was relatively low (11.84%), suggesting limited use of maintenance therapy during hospitalization, while nasal administration was negligible.

Analysis of WHO prescribing indicators highlights several important trends. The average number of drugs per encounter (6.87) was markedly higher than the WHO recommended range, reflecting polypharmacy, possibly due to the use of supportive medications and management of comorbid conditions. However, the average number of anti-seizure drugs per prescription (1.44) remained within acceptable limits, indicating rational use of ASDs with preference for monotherapy or minimal combination therapy. The percentage of drugs prescribed by generic name (33.1%) was considerably lower than the WHO ideal, suggesting a need for promoting generic prescribing to reduce treatment costs. The high percentage of antibiotic use (78.1%) may be attributed to the significant proportion of infectious etiologies but still exceeds recommended limits, raising concerns about antimicrobial stewardship.

Similarly, the high use of injections (87.6%) reflects the inpatient and emergency nature of care but deviates significantly from WHO standards, indicating potential overuse. In contrast, the near-complete adherence to the National List of Essential Medicines (98.7%) demonstrates a strong alignment with national prescribing guidelines and rational drug selection.

Discussion

The present study provides a comprehensive evaluation of anti-seizure drug (ASD) utilization patterns in pediatric patients in a rural tertiary care setting. The findings reflect both adherence to standard treatment principles and context-driven variations influenced by demographic, clinical, and healthcare system factors.

The age distribution in this study showed a clear predominance of seizures in early childhood, particularly in the preschool (38.10%) and infant groups (32.38%). This observation is consistent with previous studies, which report a higher incidence of seizures in younger age groups due to immature neuronal networks, increased susceptibility to infections, and perinatal complications [2]. Early childhood is a critical period for brain development, and any neurological insult during this stage may predispose children to seizure disorders.

A male predominance (62.86%) was observed, which aligns with earlier reports indicating a higher incidence of seizures in males. This trend may be attributed to biological differences, genetic susceptibility, or sociocultural factors influencing healthcare-seeking behavior, particularly in rural settings where male children may receive more medical attention [4].

The overwhelming majority of patients belonged to rural areas (95.24%), reflecting either a higher burden of disease or referral patterns from peripheral healthcare centers. Rural populations are often associated with limited access to healthcare, poor sanitation, and inadequate immunization coverage, all of which contribute to increased risk of seizure disorders [10].

From an etiological standpoint, infectious causes (30.5%) emerged as the leading contributor, followed closely by undifferentiated cases (27.6%). These findings are consistent with studies conducted in developing countries, where central nervous system infections such as meningitis and encephalitis remain major causes of seizures [11]. The high proportion of undiagnosed cases highlights the limitations in diagnostic infrastructure and the need for improved neuroimaging and laboratory facilities. Preventive strategies such as vaccination, early diagnosis, and prompt management of infections could significantly reduce the burden of seizure disorders [7].

In terms of pharmacotherapy, phenytoin (40.13%) was the most commonly prescribed ASD, followed by valproate (17.76%) and levetiracetam (15.79%). The continued dominance of phenytoin reflects its affordability, availability, and familiarity among clinicians, especially in resource-constrained settings. However, the increasing use of levetiracetam indicates a gradual shift toward newer ASDs with better safety profiles, minimal drug interactions, and ease of use [9]. Valproate remains a widely used broad-spectrum agent, particularly for generalized seizures. The study demonstrated a preference for monotherapy (62.9%), which is in accordance with standard epilepsy management guidelines recommending single-drug therapy as the initial approach [12]. Monotherapy minimizes adverse effects, reduces drug interactions, and improves patient compliance. Among monotherapy regimens, phenytoin was the most commonly used agent (50%), followed by valproate (31.8%), indicating rational drug selection based on seizure type and clinical presentation.

Polytherapy (37.1%) was reserved for patients with refractory or severe seizures. Dual therapy was the most commonly used combination, with midazolam + phenytoin being the predominant regimen. This combination is particularly effective in acute seizure management due to the rapid onset of action of benzodiazepines [11]. The limited use of triple and quadruple therapy suggests cautious escalation of treatment, which is desirable to avoid unnecessary drug burden.

The route of administration analysis revealed a strong preference for the intravenous route (87.50%), reflecting the acute and emergency nature of seizure management in hospitalized patients. Benzodiazepines such as midazolam and diazepam were frequently used via parenteral routes for rapid seizure control, consistent with established clinical protocols [12]. Oral therapy was comparatively limited, as most patients required immediate intervention.

Evaluation of WHO prescribing indicators revealed important insights into prescribing practices. The average number of drugs per encounter (6.87) was significantly higher than the WHO recommended range, indicating polypharmacy. This may be attributed to the use of supportive medications such as antibiotics, antipyretics, and adjunct therapies, particularly in patients with infectious etiologies [13]. While polypharmacy is sometimes unavoidable in complex cases, it increases the risk of adverse drug reactions and drug interactions.

The average number of ASDs per prescription (1.44), however, was within acceptable limits, suggesting rational use of anti-seizure medications. This indicates that while overall drug use was high, the use of ASDs specifically was controlled and appropriate.

The percentage of drugs prescribed by generic name (33.1%) was considerably lower than the WHO ideal of 100%. This finding is consistent with other studies from India, where brand-name prescribing remains common due to physician preference, pharmaceutical marketing, and perceptions of quality [14]. Promoting generic prescribing is essential to reduce treatment costs and improve accessibility, particularly in low-income populations.

The high percentage of antibiotic use (78.1%) reflects the significant contribution of infectious etiologies in this study population. While justified in many cases, such high usage exceeds WHO recommendations and raises concerns about antimicrobial resistance [15]. Implementation of antimicrobial stewardship programs is necessary to ensure rational antibiotic use.

Similarly, the high use of injections (87.6%) far exceeds WHO standards, although it can be partly justified by the inpatient and emergency nature of care. Nonetheless, unnecessary use of injectable formulations should be minimized to reduce costs, complications, and patient discomfort. A notable

positive finding was the high adherence to the National List of Essential Medicines (98.7%), indicating rational drug selection and compliance with national guidelines. This reflects good prescribing practices and ensures availability of cost-effective and evidence-based medications.

Overall, the study demonstrates a balanced approach to seizure management, with appropriate use of monotherapy, rational selection of ASDs, and high adherence to essential medicine guidelines. However, areas such as polypharmacy, excessive antibiotic use, high injection rates, and low generic prescribing require targeted interventions.

Conclusion

The study concludes that anti-seizure drug utilization in pediatric patients is largely rational, with a preference for monotherapy and adherence to essential medicine guidelines. However, significant concerns related to polypharmacy, excessive use of antibiotics and injections, and low generic prescribing highlight the need for regular prescription audits, clinician education, and implementation of stewardship programs to optimize therapeutic outcomes.

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