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Original Research Article

Antiepileptic Prescribing Patterns and Adherence in North Indian Paediatric Epilepsy: An Observational Study

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Abstract:

Background: Epilepsy is one of the most recognised neurological disorders, particularly in children, which contributes significantly to global morbidity, especially in developing countries like India. Antiepileptic drugs (AEDs) remain the cornerstone of treatment, but the variations in prescribing patterns and poor medication adherence can adversely affect seizure control and quality of life.

Objectives: To evaluate the prescribing patterns of AEDs and assess medication adherence among paediatric patients with epilepsy.

Methods: A hospital-based observational method is utilised for assessing paediatric epilepsy patients on AED therapy. Prescribing patterns, including drug selection, type of therapy and patients' adherence to the treatment regimen are analysed. Medication adherence is assessed along with influencing factors such as adverse drug reactions (ADRs).

Results: In comparison to polytherapy, which is associated with elevated ADR burden and reduced adherence, monotherapy remains the preferred treatment approach, achieving seizure control in most patients. Despite some behavioural adverse effects, newer antiepileptics are increasingly preferred due to better safety and tolerability profiles. Simpler regimens demonstrate better adherence compared to complex multidrug therapies.

Conclusion: Therapeutic success, in paediatric epilepsy, depends on two significant determinants, namely Prescribing patterns and medication adherence. Rational prescribing, preference for monotherapy, and active pharmacovigilance are crucial to improve adherence and clinical outcomes.

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Introduction

Epilepsy is the most common chronic neurological disorder affecting nearly 50 million people worldwide, with a higher burden in low- and middle- income countries. It is characterised by recurrent unprovoked seizures due to abnormal electrical activity in the brain. [1,2]. The impact of pediatric epilepsy is particularly significant as it affects neurodevelopment, behaviour, and overall quality of life [3].

Antipepileptic drugs (AEDs) are the mainstay treatment of epilepsy, helping approximately 70% of patients to achieve seizure control with appropriate treatment [1]. Recent guidelines recommend treatment initiation with monotherapy using a "start low, go slow" approach, followed by rational escalation [4]. Newer agents like levetiracetam and lamotrigine are increasingly preferred due to their better safety and tolerability profiles; however, conventional AEDs such as sodium valproate and carbamazepine continue to be prescribed [5, 6].

Prescribing patterns of AEDs depends on the seizure type, patient characteristics, and drug safety considerations in pediatric epilepsy. However, the risk of

adverse drug reactions (ADRs) may increase with irrational prescribing practices, including unnecessary polytherapy and deviation from evidence- based guidelines [7,8]. The role of pediatric pharmacovigilance is critical as their pharmacokinetic and pharmacodynamics variability is pronounced [9].

Medication adherence determines the therapeutic success in epilepsy. According to World Health Organisation, "Adherence is the extent to which a patient's behaviour corresponds with agreed recommendations from a healthcare provider" [10]. In padiatric populations, adherence depends on caregivers, and is influenced by factors such as regimen complexity, adverse effects, and socioeconomic status [11]. Poor adherence results in increased seizure frequency leading to hospitalizations and reduced overall quality of life [12].

An interconnection exists between prescribing patterns, ADRs, and adherence. Non-adherence is followed by complex regimens and drug-related adverse effects, which in turns, leads to inadequate seizure control and therapy escalation, perpetuating a vicious cycle [13,11]. In Indian settings, integrated studies assessing prescribing patterns along with adherence, particularly in pediatric populations, remain limited [7].

Therefore, the present study aims to assess the prescribing patterns of AEDs along with medication adherence in pediatric epilepsy patients, to promote rational drug utilisation and improve clinical outcomes.

Material and Methods

This hospital-based prospective observational study was conducted in the Department of Pharmacology in collaboration with the Department of Pediatrics at a tertiary care hospital of North India, over a period of 12 months. The ethical clearance was obtained from the institutional ethical committee before the commencement of the study.

A total of 80 paediatric patients were enrolled in the study, after obtaining informed consent, based on inclusion and exclusion criteria specified.

Inclusion Criteria:

- Patients with a clinical diagnosis of epilepsy.
- Age ≤ 18 years for both sexes.
- Parents/ legal guardians giving consent.
- Patients who will be on AEDs for the next 6 months.

Exclusion Criteria:

- Parents/ legal guardians not giving consent.
- Patients with metabolic disorders.
- Patients with status epilepticus.
- Patients leaving the study for any reason.

Baseline data (demographic details, clinical history, and drug therapy) were recorded using a structured case recording form. Patients were followed up at 0, 6, 12, and 24 weeks. The analysis of prescribing patterns was based on the number of drugs per prescription, drug utilization, and monotherapy versus polytherapy. Medication adherence was assessed during follow-up visits using a seizure diary method, based on caregivers' reports and clinical evaluation. A predefined checklist was utilised for monitoring ADRs at every follow-up visit. The chi-square test was applied to analyse the association between type of therapy and ADR occurrence.

Statistical Analysis: Data were analyzed using SPSS version 29.0. Descriptive statistics were used for categorical variables, and results were expressed as percentages. A p-value < 0.05 was considered statistically significant.

Results

Table 1: Demographic details of the patients who completed the study (N = 80)

Sr. No.	Characteristic	Category	Number of Patients (%)
1	Gender	Male	49 (61.25%) *
		Female	31 (38.75%) *
2	Age group (years)	<= 2	13 (16.25%) *
		3 – 5	19 (23.75%) *
		6 – 11	29 (36.25%) *
		12 – 18	19 (23.75 %) *
3	Demography	Rural	46 (57.5%) *
		Urban	31 (38.75%) *
4	Type of epilepsy	Generalized epilepsy	46 (57.5%) *
		Focal epilepsy	12 (15%) *
		Dravet Syndrome	6 (7.5%) *
		Lennox Gestaut Syndrome	6 (7.5%) *
		Unclassified Epilepsy	9 (11.25%) *
5	Number of Drugs Prescribed per Patient	Mean ± SD	1.125 ± 0.332
6	Total number of patients who completed the study	80	

*Percentage in parentheses.

Demographic Characteristics (Table 1): A total of 91 paediatric patients were enrolled in the study, out of which 11 patients were lost to follow-up. Analysis included only patients who completed the study, i.e., 80 patients.

Table 2: ADR incidence associated with monotherapy and polytherapy of Antiepileptic Drugs

Type of Therapy	Total number of patients (%)	Number of patients who reported ADR (%)
Monotherapy	70 (87.5%)	26 (37.14%)
Polytherapy	10 (12.5%)	10 (100%)
p-value	0.00068 *	

* Chi – square test is applied for analysis. A p-value <0.05 shows statistical significance.

ADRs and Type of Therapy (Table 2): A total of 36 patients reported ADRs, where 26 patients on monotherapy and the remaining patients on polytherapy experienced ADRs. The association between ADR occurrence and type of therapy was found to be statistically significant, highlighting the increased risk of ADRs with polytherapy.

Table 3: Prescribing Pattern of Antiepileptic Drugs

Antiepileptic drug prescribed	Number of patients (n)	Percentage (%)
Sodium Valproate	23	28.75
Levetiracetam	18	22.5%
Carbamazepine	16	21.25%
Valproate + Clobazam	7	8.75%
Phenytoin	6	7.5%
Phenobarbitone	6	7.5%
Valproate + Phenytoin	2	2.5%
Valproate + Levetiracetam	1	1.25%

- N = 80 (Total number of patients).
- Results are expressed as frequencies and percentages (%).

Prescribing Pattern of AEDs (Table 3): The study demonstrated predominance of monotherapy with sodium valproate being prescribed most. Whereas polytherapy accounted for 12.5% of prescriptions.

Table 4: Medication Adherence exhibited by patients

Follow-up period	Number of patients on AEDs (N)	Adherent patients, (%)	Non-adherent patients, (%)	Breakthrough seizures observed
0 weeks (baseline)	80	33 (41.25%)	47 (58.75%)	3
6 weeks	80	37 (46.25%)	43 (53.75%)	3
12 weeks	80	41 (51.25%)	39 (48.75%)	2
24 weeks	80	49 (61.25%)	38.75%)	2

- N = 80 (Total number of patients).
- Results are expressed as a percentage (%).

Medication Adherence (Table 4): Breakthrough seizures occurred more frequently during early follow-up (0-12 weeks), but their frequency decreased over time, indicating improved adherence.

Discussion

The study enrolled a total of 80 pediatric patients with epilepsy, demonstrating male predominance compared to females, with the largest age group being 6-11 years, followed by 3-5 years and 12-18 years, and the smallest age group ≤ 2 years. These findings were comparable with other Indian studies, Kaur et al., documenting male predominance with a similar male-to-female ratio and a higher incidence of ADR in the 6 -11-year age group constituted a total of 46 (68.65%) children [14]. Additionally, our study found the most common type of epilepsy was Generalised tonic-clonic seizures, followed by Focal epilepsy, Dravet syndrome and Lennox-Gastaut syndrome, and unclassified epilepsy. The mean number of drugs prescribed per patient was 1.125 ± 0.332 (Table 1), reflecting a predominance of monotherapy. The rural patient representation and predominance of Generalised tonic-clonic seizures correspond to national epidemiological trends, highlighting disparities in healthcare access and awareness of rural settings.

As the findings demonstrated in our study, monotherapy (87.5%) remains the dominant therapeutic approach whereas, the remaining were prescribed polytherapy (Table 2). These findings were comparable with the results by the study by Begum et al., where 90% of the patients were prescribed mono-

therapy and Kaushal et al., where 75% of 180 children were prescribed monotherapy [15] [12]. The limited use of polytherapy suggests its preservation for refractory cases. Additionally, our study also demonstrated 100% ADR incidence associated with polytherapy (Table 2). These findings are consistent with a study by Anderson et al., which reported that 60% of the children on polytherapy displayed a higher incidence of ADR compared to those on monotherapy [16]. These findings point towards the vulnerability of paediatric groups to drug toxicity, which may occur due to polypharmacy and drug interactions.

The gold-standard treatment modality in epilepsy is monotherapy, probably due to its cost-effectiveness and lower incidences of ADRs associated, which, in turn, results in better adherence to the regimen. In our study, sodium valproate emerged as the most commonly prescribed AED (28.75%) (Table 3). Some studies have revealed similar findings, Kaushal et al., reporting valproate as the first-line treatment in 77.36% of pediatric patients with epilepsy [12]. These observations precisely highlight the broad-spectrum efficacy of valproate across multiple seizure types, including generalised tonic-clonic, atonic, myoclonic, absence and focal seizures. Moreover, its cost-effectiveness and multiple preparations available for paediatric groups add to its being prescribed as the first-line treatment. Furthermore, conventional AEDs such as phenytoin and phenobarbitone were prescribed relatively less (Table 3), highlighting their continued use, as demonstrated by Indian studies by Dwajani et al., which showed 8 out of 100 (8%) patients received phenytoin, and Khosdel et al., which demonstrated that 9 out of 117 patients (7.7%) received phenobarbitone, respectively [17,18]. This, probably, may have been due to their well-known ADR profiles and cost-effectiveness.

Sodium valproate was followed closely by levetiracetam and carbamazepine (Table 3). These findings depicted the gradual shift towards newer AEDs for the management of epilepsy. Recent hospital-based Indian studies, Gowda et al., documented comparable findings where levetiracetam was prescribed to patients with focal epilepsy (42%), generalised tonic-clonic seizures (42.4%), and myoclonic seizures (46.5%) [19]. This may be attributed to its known minimal hepatic metabolism and better safety profile in children.

Polytherapy was prescribed to 12.5% of patients, in which valproate with clobazam was the most prescribed combination (Table 3). This, primarily, may be attributed to inadequate control of seizures on monotherapy.

The present study also demonstrated a gradually improving medication adherence among patients from 41.25% at 0-weeks (baseline) to 61.25% at 24-weeks (end of follow-up) (Table 4), which may be attributed to improved familiarity with the regimen, reinforcement of uninterrupted therapy on regular follow-up visits, and early recognition of ADRs and their timely management. As recommended by the WHO, continuous monitoring and patient-centric interventions form an integral part of epilepsy care (20).

The improved adherence was accompanied by a reduction in breakthrough seizures over the follow-up period. Early phases of the AED therapy witnessed breakthrough seizures predominantly, which, likely, may have been due to lower adherence to the regimen. Such observations are supported by findings of the studies, such as Modi et al. and Anderson et al, respectively [21] [22]. These studies demonstrated that poor adherence is a significant predictor of recurrent episodes of seizure, more hospitalisations and in children with epilepsy. By utilising electronic adherence monitoring, they derived that children showing high adherence experienced lower seizure recurrence compared to those showing lower adherence. These findings point towards the importance of adherence in therapeutic success in the management of epilepsy. While showing improvement, the study's results also indicate that nearly 40% of patients remained non-adherent at 24 weeks (Table 4). This may be attributed to factors such as medication side effects, socioeconomic constraints, and barriers to healthcare access.

The major limitations of our study were a shorter follow-up period and a small sample size. For better research in understanding of relationship between prescribing patterns of AEDs and medication adherence, larger cohorts with longer follow-up periods might help in future.

Conclusion

This study acknowledges the growing role of newer AEDs like levetiracetam while reinforcing the preference of monotherapy, particularly with sodium valproate, in the management of paediatric epilepsy in North India. Medication adherence demands continued efforts with follow-up and education to show visible improvement and cease being suboptimal. The findings precisely align with regional and international literature, with some contrasting observations reflecting local prescribing habits, resource availability and patient demographics. Larger cohorts with longer follow-up periods may help future researchers to explain the complex relationships between prescribing patterns, adherence, ADRs, and clinical outcomes in the paediatric population.

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