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Research Article

PRESCRIPTION PATTERN OF ANTIEPILEPTIC DRUGS IN CHILDREN WITH EPILEPSY: A CROSS-SECTIONAL STUDY

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ABSTRACT

Objective: To evaluate the pattern of prescription of antiepileptic drugs (AED) in children with epilepsy attending a tertiary care hospital in North India.

Methods: An observational cross-sectional study was conducted for a duration of 1 year. Data on demographic variables including age, gender, type of epilepsy, and prescription of all AEDs and their different combinations were collected from the patients of epilepsy coming to the Department of Pediatrics, Rajindra Hospital attached to Government Medical College, Patiala, Punjab, India and analyzed using WHO core prescription indicators.

Results: Out of 100 prescriptions analyzed, 55% of patients were males and 45% were females. The mean age of patients was 8.65 years (±3.80). Generalized epilepsy (78%) was the most commonly diagnosed epilepsy. 92% of patients were prescribed monotherapy, while polytherapy was used in 8% of patients. Valproate was the most common drug used in monotherapy (44.56%), followed by phenytoin (21.74%) and phenobarbitone (15.22%). In polytherapy, the most common combination used was valproate with clobazam (62.5%). 96.6% of prescriptions were based on the National List of Essential Medicines (NLEM), 2022.

Conclusion: Monotherapy was the preferred modality of treatment in our hospital. Conventional drugs were favored in monotherapy, while benzodiazepines and newer drugs were more commonly used as an add-on drugs in polytherapy. Valproate was the most commonly used AED in monotherapy as well as polytherapy.

Keywords: Epilepsy, Antiepileptic drugs, Prescription pattern.

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INTRODUCTION

Epilepsy is one of the most common serious neurological disorders prevalent in childhood and more than 50% of seizures have their onset in childhood [1]. As per the International League Against Epilepsy (ILAE), epilepsy is a disease of the brain defined by any of the following conditions:

1. At least two unprovoked (or reflex) seizures happening >24 h apart,
2. One unprovoked (or reflex) seizure and a probability of further seizures similar to the general recurrence risk (at least 60%) after two unprovoked seizures, occurring over the next 10 years,
3. Diagnosis of an epilepsy syndrome [2].

As per a community-based study published in 2013, the prevalence rate for childhood epilepsy was found to be 6.24/1000 population [1]. The various causes of epilepsy are categorized into: structural, genetic, infectious, metabolic, immune, and unknown. For example, it can occur due to brain damage from prenatal or perinatal causes (loss of oxygen or trauma during birth, low birth weight); congenital abnormalities or genetic conditions with concomitant brain malformations; a severe head injury; a stroke; an infection of the brain like meningitis, encephalitis or neurocysticercosis, certain genetic syndromes; or a brain tumor [3].

Early diagnosis and treatment of seizure disorders with a single appropriate antiepileptic drug offer the best prospect of achieving prolonged seizure-free periods with the lowest risk of toxicity. Antiepileptic drugs are divided into older/conventional drugs and newer drugs based on their introduction into the market before and after 1991, respectively. Older/conventional drugs include phenytoin, carbamazepine, valproic acid, and ethosuximide, which are commonly used as first-line drugs. These are relatively cheaper than the newer antiepileptic drugs such as gabapentin, lamotrigine, vigabatrin, topiramate, tiagabine, and zonisamide [4].

Prescription is a written medicolegal document by an authorized person for the treatment of the patient and is a reflection of the quality of health-care service being delivered to the patient. Prescribing errors embolden the irrational use of drugs and decrease patient compliance. Irrational prescriptions also result in increased cost and duration of the treatment, emergence of drug interactions, drug resistance, and adverse drug reactions, which ultimately increases the mortality, morbidity, and financial burden on the patient [5]. Thus, in order to promote the rational use of drugs in children, this study was conducted to evaluate the prescription pattern of antiepileptic drugs (AED) in 100 eligible pediatric patients coming to our hospital.

METHODS

This observational, cross-sectional study was conducted in Paediatric Outpatient Department (OPD) in Rajindra Hospital, Patiala, for the duration of 1 year, i.e., from June 2021 to May 2022. A total of 100 children with epilepsy were enrolled after having fulfilled the inclusion and exclusion criteria.

Inclusion criteria

Children of either sex aged <18 years and diagnosed with epilepsy (idiopathic or symptomatic) were included in this study.

Exclusion criteria

Children suffering from known intellectual disability, global developmental delay, autism, attention deficit hyperactivity disorder, cerebral palsy, or any other pre-existing chronic illness, for example, renal or liver diseases, were excluded from our study.

Study procedure

This cross-sectional study was conducted after obtaining approval from

the Institutional Ethics Committee, Government Medical College, Patiala (Approval no. BFUHS/2K21p-TH/14873). All the patients coming to the Pediatric OPD were screened according to inclusion/exclusion criteria, and eligible patients were enrolled after explaining the aim of the study. Written informed consent was taken from the parents, and assent was taken from children older than 7 years of age. All the demographic data and complete prescriptions of eligible participants were collected on a pre-designed prescription proforma, which were then analyzed using WHO core prescribing indicators:

1. Average number of drugs per encounter.
2. Percentage of drugs prescribed by generic name.
3. Percentage of encounters with an antibiotic prescribed.
4. Percentage of encounters with an injection prescribed.
5. Percentage of drugs prescribed from the essential drugs list.

Statistical analysis

The data were entered into an Excel sheet and statistical analysis was done using the statistical program IBM SPSS (Statistical Product and Service Solutions) version 22.0. The Chi-square test was used to test the statistically significant difference in categorical data, and $p<0.05$ was considered statistically significant.

RESULTS

In our study, there was a higher proportion of males (55%) than females (45%) (Fig. 1).

The age of the study population ranged from 1 year 6 months to 17 years, and the mean age was 8.65 years (±3.80). The maximum number of patients (55%) were in the age group of 6–11 years, followed by 23% in the age group of 0–5 years. The minimum number of patients (22%) belonged to the age group of 12–17 years (Table 1).

Generalized epilepsy was seen in the maximum number of patients (78%), followed by focal epilepsy (18%) and unknown epilepsy (4%) (Fig. 2).

Family history of epilepsy was present in only 11% of the study population, while majority (89%) of patients had no family history. Immunization was complete in 74% and partially complete in 19% of the study population, while 7% of patients were non-immunized (Table 2).

Monotherapy was seen in 92% of patients, followed by polytherapy in 8% of patients (Fig. 3).

Out of the total of 100 patients, in patients on monotherapy (n=92), valproate (41) was the most common prescribed AED, followed by phenytoin (20), phenobarbitone (14), levetiracetam (8), oxcarbazepine (7) and carbamazepine (2). In patients on polytherapy (n=8), the most common combination of AED used was valproate+Clobazam (5), followed by Valproate+Levetiracetam, Valproate+Topiramate and Levetiracetam+Clobazam in 1 patient each (Fig. 4).

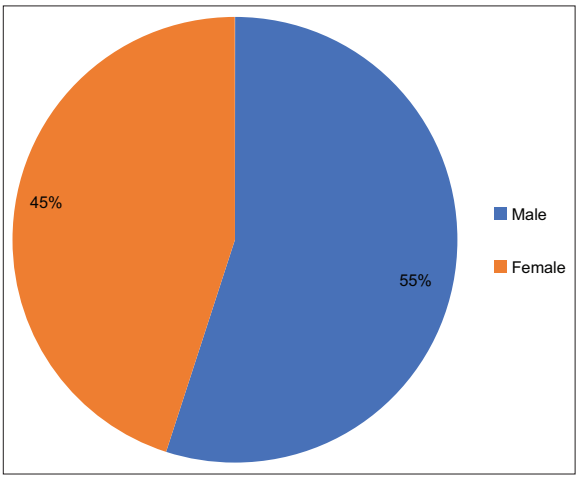

Fig. 1: Gender distribution of study population

In patients on monotherapy, 77 out of 92 drugs prescribed were conventional drugs and 15 were newer drugs. In polytherapy, a combination of conventional and benzodiazepines was prescribed in 5 patients and a combination of conventional and newer drugs was given in 2 patients, while the combination of newer drugs and benzodiazepines was given in 1 patient. Thus, in polytherapy, benzodiazepines were the most commonly prescribed add-on drugs (Table 3).

In our study, total number of drugs prescribed were 235, of which 108 were AED and 127 were co-prescribed drugs. Out of 127 co-prescribed drugs, the most common drug prescribed was calcium (49.6%), followed by Vitamin D3 (23.6%), folic acid (10.2%), multivitamin (8.7%), Vitamin B complex (5.5%), and dicyclomine (2.4%) (Table 4).

In the present study, majority of drugs (96.6%) were prescribed from the National Essential List of Essential Medicines (NLEM), 2022. Calcium (27.75%) was the most common essential drug prescribed, followed by valproate (21.14%), Vitamin D3 (13.22%), phenytoin (8.81%), phenobarbitone (6.17%), folic acid (5.73%), multivitamin (4.85%), levetiracetam (4.41%), Vitamin B complex (3.08%), clobazam (2.20%), dicyclomine (1.32%), and carbamazepine (0.88%).

Table 1: Age distribution of the study population

Age group (Years)	Number of patients	Percentage
0–5 years	23	23
6–11 years	55	55
12–17 years	22	22
Total	100	100
Mean±SD	8.65±3.80	
Median	9	
Range	1Y6M-17Y	

Table 2: Immunization status of the study population

Immunization status	Number of patients	Percentage
Complete	74	74
Partial	19	19
Non-immunized	7	7
Total	100	100

Table 3: Distribution of AED based on conventional or newer drugs

Therapy	Type of AED	Patients	Percentage
Monotherapy (n=92)	Conventional drugs	77	77
	Newer drugs	15	15
Polytherapy (n=8)	Conventional+Benzodiazepines	5	5
	Conventional+Newer drugs	2	2
	Newer drugs+Benzodiazepines	1	1
Total		100	100

Table 4: Distribution of co-prescribed drugs in study population

Co-prescribed drugs	Frequency	Percentage
Calcium	63	49.6
Vitamin D3	30	23.6
Folic Acid	13	10.2
Multivitamin	11	8.7
Vitamin B-complex	7	5.5
Dicyclomine	3	2.4
Total	127	100

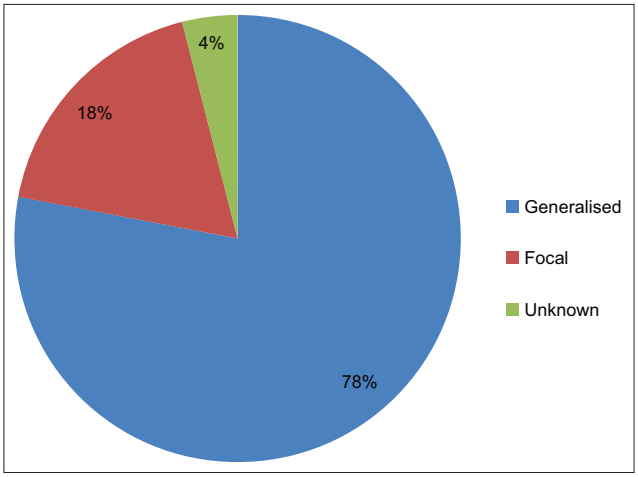

Fig. 2: Type of epilepsy in study population

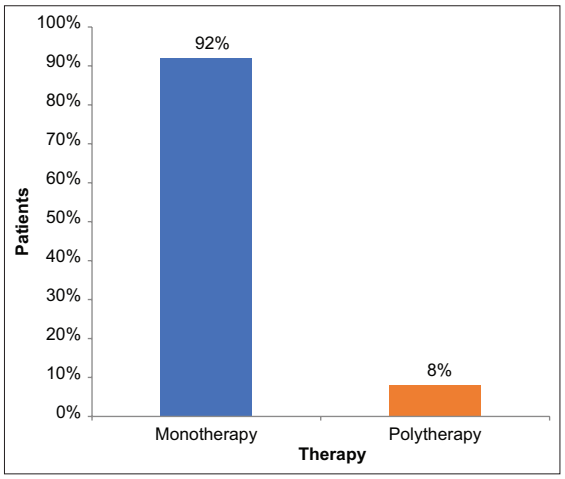

Fig. 3: Type of AED therapy in study population

Oxcarbazepine, which was prescribed in 8 patients, is not included in NLEM, 2022 (Fig. 5).

As described in Table 5, average number of drugs per prescription were 2.35. Percentage of drugs prescribed by generic name were 100%. The percentage of drugs prescribed from the essential drug list were 96.6%. No antibiotics or injections were prescribed in our study.

DISCUSSION

In our study, the preponderance of male patients over female patients was comparable to the study done by Albsoul-Younes *et al*., Khosdel *et al*., and Maity *et al*. [6-8]. However, this finding was different from a study done by Halwai *et al*. in which it was found that a higher percentage of patients were female (59.3%) than male patients (40.7%), attributing seizure activating effect to estrogen [9]. The mean age of the study population in our study (8.65±3.80 years) was in consonance with study done by Albsoul-Younes *et al*., where the mean age of patients at enrolment was 7.2±4.7 years [6]. The maximum number of patients (55%) were in the age group of 6-11 years, which was comparable to the study done by Pandey *et al*. and Bansal *et al*., who observed that the highest percentage of their study population was in 5- to 10-year age group [1,10]. However, this observation was different from the study done by Khosdel *et al*. and Halwai *et al*., in which the majority of patients were in the age group of 2–6 years (42%) and 11–15 years (43.8%), respectively [7,9].

In our study, majority of the patients were diagnosed with generalized epilepsy (78%), which was comparable to studies done

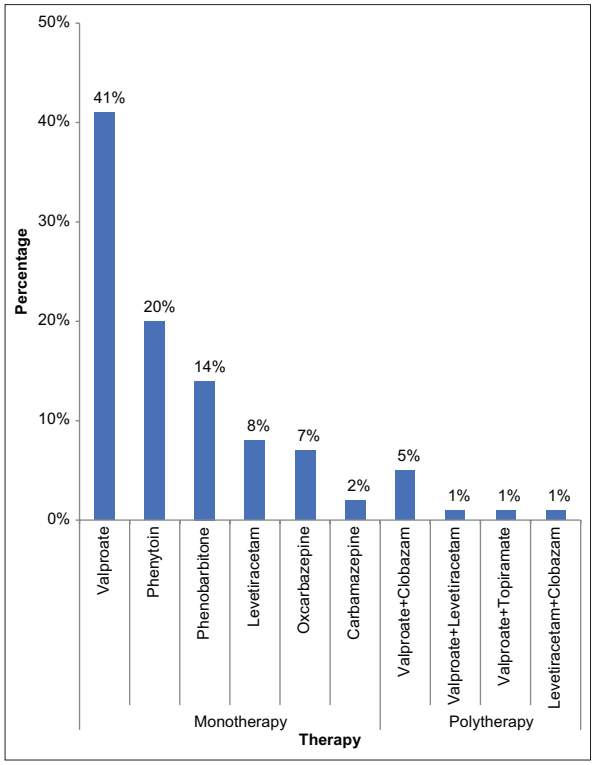

Fig. 4: Distribution of antiepileptic drugs in monotherapy and polytherapy

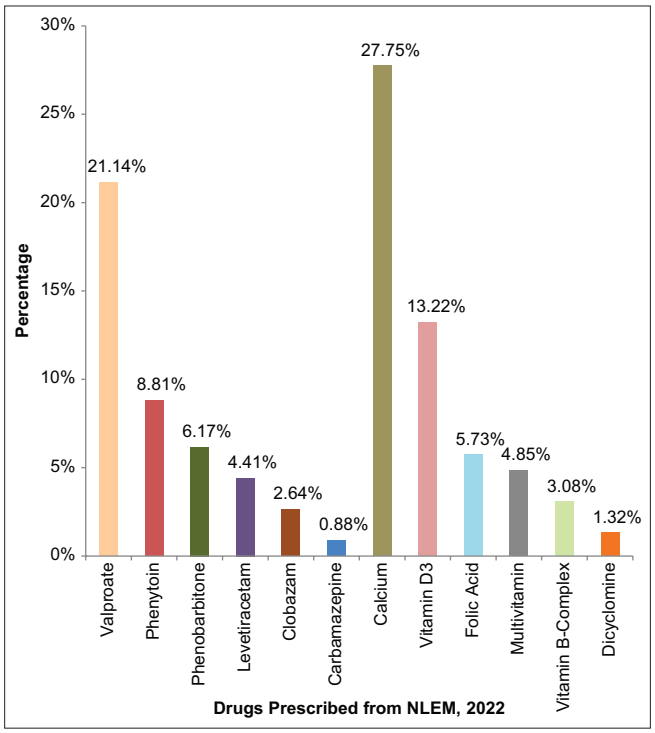

Fig. 5: Distribution of drugs prescribed from NLEM (National List of Essential Medicines), 2022

by Sil *et al*., Shah *et al*. and Dent *et al*. (81%, 71.43%, and 73.5%, respectively) [11-13]. However, a study done by Egunsola *et al*. observed structural focal epilepsies in the majority of patients (36%) [14]. Immunization was complete in 74% and partially complete in 19% of the study population, while 7% of patients were non-immunized. These

Table 5: WHO prescribing indicators

S. No.	WHO Prescribing Indicators	Observations
1	Average number of drugs per prescription	2.35
2	Percentage of prescriptions with an antibiotic prescribed	0
3	Percentage of prescriptions with an injection prescribed	0
4	Percentage of drugs prescribed by generic name	100
5	Percentage of drugs prescribed from an Essential Medicine List	96.6

findings were in consonance with other studies done by Dave *et al*., which observed that 86% of patients were immunized [15]. Certain diseases such as measles, diphtheria, pertussis, tetanus, etc., cause brain damage as well as febrile episodes, which may lead to febrile convulsions. Hence, immunization plays a pivotal role in the prevention of epilepsy.

Monotherapy was seen in 92% of the study population, followed by polytherapy in 8% population, which is in accordance with the study done Halwai *et al*., Sil *et al*., and Thampi *et al*. as they all observed predominance of monotherapy in their study population [9,11,16]. However, a study done by Joshi *et al*. found polytherapy in 63.4% of cases [17]. This showed that in majority of patients, monotherapy is helpful in achieving good seizure control, but for patients with poor seizure control, polytherapy was preferred. In patients on monotherapy, valproate was the most common AED prescribed, followed by phenytoin. This observation was supported by Kwong *et al*. and Tan *et al*., who also found valproate as the most common prescribed AED respectively [20,21]. Furthermore, majority of drugs (83.70%)prescribed in monotherapy were conventional drugs and others (16.30%) were newer drugs. This finding was supported by Bhatt *et al*. and Mistry *et al*., who also observed that the majority of AEDs prescribed were conventional (84.25%) and newer drugs were prescribed as an add-on drugs in patients on polytherapy [22,23]. In patients on polytherapy, the most common combination of AED used was Valproate+Clobazam. Thus, clobazam was the most common add-on drug used in polytherapy. This finding was in consonance with a study done by Kaushik *et al*., which also observed clobazam (42.3%) as the most common add-on drug in polytherapy, followed by levetiracetam (22%), valproate (15.4%), carbamazepine (11.5%), phenytoin (3.8%), and topiramate (3.8%) [24]. However, studies conducted by Halwai *et al*. and Thampi *et al*. observed valproate with phenytoin (48.7%) and Phenytoin with clobazam (44.4%) as the most commonly used two-drug combination, respectively [9,16]. Valproate was the most commonly used AED in our study. Due to its broad spectrum of activity, valproate was preferred to control most of the seizures. Newer AED were less commonly prescribed as monotherapy and were mostly used as an add-on drugs. The reason ascribed for preference of conventional drugs as first-line AED is that these are effective and quite cheaper than newer AED, which are costly and are not available in government supply. Thus, conventional drugs are convenient for patients coming to our government hospital, who are mainly from lower socioeconomic class.

In present study, the most common drug co-prescribed was Calcium (49.6%), followed by Vitamin D3 (23.6%). The studies conducted by Deopa *et al*. and Kothare *et al*. observed that deficiency of vitamin D and folate was common in children with epilepsy on long-term AED therapy [25,26]. Thus, it signifies the need for pharmacological vitamin D, calcium, folate and multivitamin supplementation in children with epilepsy. The process of drug utilization in the outpatient setting is considered a multidimensional approach of the prescriber, the patient, and the pharmacist. The WHO has designed prescription indicators to evaluate the prescription pattern/drug utilization so as to promote the rational use of drugs. The average number of drugs prescribed per prescription in our study was 2.35, which was in consonance with a study done by Mistry *et al*., i.e., 2.26 [23]. Prescription of co-prescribed drugs such as calcium and vitamin D, vitamin B complex, folic acid, etc., to manage the side effects of AED therapy contributed to higher "drugs prescribed per prescription rate" than the WHO recommended range of 1.6–1.8. The average number of AED prescribed per patient was 1.08, which was somewhat comparable to Kousalya *et al*., who found it to be 1.42 [27]. Injection form was not prescribed as the study was done in pediatric outpatient department only. 100% of drugs were prescribed by generic name, which was in accordance with a study conducted by Mistry *et al*. who observed prescription by generic name in 88.7% of patients [23]. However, as per a study done by Bhatt *et al*., the percentage of drugs prescribed by generic name observed was 8.2% [22]. Percentage of drugs prescribed from the National List of Essential List of medicines (NLEM), 2022 was 96.6%, which was supported by Magar *et al*. (100%) [28]. This confirms that trend of prescribing drugs by generic name is high in our government hospital, which follows the National List of Essential Medicines so that financially weak patients can obtain the drug from government pharmacy. The strength of our study was that a detailed assessment of prescription pattern in children was done based on the latest National List of Essential medicines, 2022. The main limitations to our study were small sample size due to which generalization of the findings are limited, and it was a cross-sectional study, thus follow-up was not done, which can explore further findings evaluating any switching pattern of AED.

CONCLUSION

Our study on prescription pattern of epilepsy in children in a tertiary care hospital showed male preponderance with majority of the patients in the age group 6–11 years. Generalized epilepsy was the most common type of epilepsy, and monotherapy was the favored treatment due to better compliance and safety profile. Conventional drugs were preferred in monotherapy, while benzodiazepines and newer drugs were more commonly used as add-on drugs in polytherapy. Valproate was the most commonly used AED in monotherapy as well as polytherapy. Clobazam was preferred as the most common add-on drug in polytherapy. Our study concluded that prescription pattern of AED in our study is relevant with the current trend. However, further studies on utilization of newer drugs should be explored so as to increase the spectrum of treatment of epilepsy in children.

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CONFLICT OF INTEREST

None.

AUTHORS FUNDING

Nil.

ETHICAL APPROVAL

Approved.

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