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## AN EMPIRICAL STUDY ON EVALUATION OF PRESCRIBING PATTERN IN ANTIEPILEPTIC THERAPY IN PEDIATRIC PATIENTS AT A TERTIARY CARE HOSPITAL

### Introduction

Epilepsy is a common pediatric problems and approximately 6-7% of children suffer from at least one or more epileptic seizure. Worldwide prevalence of active epilepsy ranges from 4-5 per 1000 and in India it is 4.15-7.03 per 1000 population<sup>2</sup>. Epilepsy is one of the common and important neurological disorders characterized by seizures and is responsible for substantial morbidity and mortality. Over 10 million children worldwide are believed to have epilepsy<sup>3</sup>. Antiepileptic drug therapy is a mainstay of treatment for most pediatric patient with epilepsy. The present study was undertaken to get an overview of the current trends in prescribing patterns of anti-epileptic drugs (AEDs) in the treatment of epilepsy in pediatrics department<sup>4</sup>.

To take certain medication the term prescription is used. The prescription contain drugs and others instruction given to either pharmacist or chemist to dispense the drugs to

patients for the proper treatment of the diseases<sup>5</sup>. The tool for assessing is the prescription pattern monitoring studies (PPMS), dispensing and distribution of medicine. Quality of life (QOL) is inferior in epileptic patients than in general population. QOL of patient with epilepsy depends upon the effect of antiepileptic therapy. Evaluation on prescribing pattern of antiepileptic drugs in pediatrics with epilepsy is to control seizure, minimize drug side effect and improves the quality life<sup>1</sup>. several of the antiepileptic drugs have narrow therapeutic index like (phenytoin, carbamazepine) and may result in side effects even when prescribed the normal doses. Mono therapy is normally the first line of treatment it has lesser side effect and better tolerability. This study mainly focus on evaluating the prescribing pattern of antiepileptic drugs with therapeutics benefits and minimal side effects<sup>3</sup>. We conducted this studies based on the inspiration from previous studies, as the current trend demonstrates higher prevalence of epilepsy in pediatrics.

### 1.2. Antiepileptic Drugs in children

Phenobarbitone: Phenobarbitone could be used as a first line AED in neonatal seizures febrile seizures established convulsive status epileptics (SE). It is effective in partial, generalized and Myoclonic seizures but have no role in absence seizures. The dosage varies between 3-6mg /kg/day given as a single night- time dose for routine use with low starting dose then gradually building up. In children with status epileptics the dosage is 20mg / kg followed by 3-6 mg/kg maintenance.

Levetiracetam: It is a broad spectrum AEDs effective as an adjunctive treatment in focal seizure in children more than 4years of age, myoclonic seizures in adolescents >12 years of age and primary generalized tonic clonic seizures in children >6 years of age. e. The drug is started at dose of 5-10 mg/kg/day, can be titrated to maintenance dose of 20-40



mg/kg/day given in two divided doses.

**Phenytoin:** Phenytoin is effective in control of tonic clonic seizures and partial seizures and is probable the most widely used AEDs. It is useful in neonatal seizures (refractory to phenobarbitone) and in established status epileptics. It is contraindicated in absences seizure, myoclonic seizures and in epileptic encephalopathy. Maintenance dosages in older children are between 5-6mg/kg given in one or two divided doses

**Carbamazepine:** It is the drug of first choice for focal epilepsies with or without secondary generalization. The dose varies between 10-30mg/kg in the form of twice a day dosing and preferably given as slow release preparations, if syrups are used they should be given three times a day <sup>6</sup>.

## Objective

The aim of this study was to analyze the prescribing pattern of various antiepileptic drugs in pediatric patient with confirmed diagnosis of epilepsy.

## Methods

A prospective observational study was conducted in a 350 bed hospital over a period of 3 months. 40 pediatric patients with confirmed seizure diagnosis and on AED therapy were enrolled from outpatient and

inpatient department. Informed consent was taken from the patient's parents/legal guardian. Data was collected from the patient's case sheets, initial assessment forms, doctor notes, nurse's notes, medication charts, lab reports, EEG etc. The patient information was collected in pre-defined data collection form. In this study all the pediatric patients from age group 1 month to below 13yrs, including both male and female with epilepsy and on antiepileptic therapy were considered. Adults and children above 13 years of age were excluded. IRB approval was taken prior to start of study. All the relevant data was analyzed with the help of hospital protocol, Medscape, Micromedex, Guidelines for Diagnosis and Management of Childhood Epilepsy. Results were expressed as counts and percentages.

## Results

### Demographic data

This study enrolled total 40 pediatrics patients. All 40 cases with epilepsy were reviewed and patient details collected using Data Entry Form as per inclusion and exclusion criteria. Out of 40 patients, females 24 (60%) are predominant over the male patients 16 (40%). Age distribution indicated there were more patients from (5-9 years) age group and less in the (1-2months) age. The age and gender distribution of the study population is shown in table 1.

**Table 1: Age and gender distribution among study population**

Age	Male	Female	Total no.
1-4 years	5	6	11
5-9 years	6	8	14
10-12 years	3	6	9
1-2 months	2	4	6



### Frequency of routes of administration

According to the prescription analysis on the route of administration - Oral route was used 15 (37%) and IV 25 (62%), indicating greater prevalence of antiepileptic drugs intravenous drug administration over oral route

### Distribution of comorbidities in the sample population.

The lower respiratory tract infection was predominantly seen as comorbid condition. The detailed comorbidities have been shown in table 2.

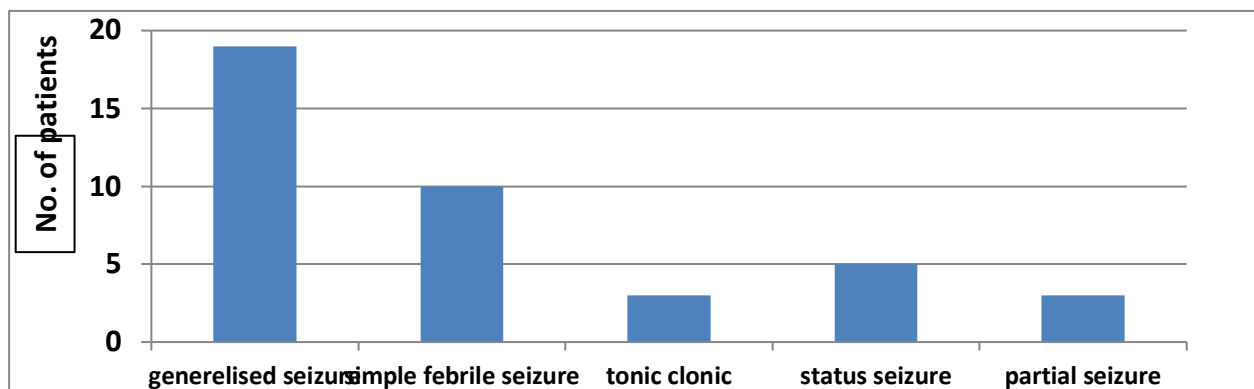
**Table 2 shows distribution of comorbidities in the pediatric patients**

Comorbidities	No. of patient
viral fever	7
lower respiratory infection	10
Dengue	6
Pneumonia	1
Bronchiolitis	4
Cough	6

### Types of seizure observed in the sample Population

The generalized seizure was frequently observed and the details are shown in figure 1.

**Fig:1 Distribution of different seizure types in the study population**





## AED prescription pattern

The AED prescription behavior is represented in table 3.

**Table 3: Pattern of AED therapy based on the type of seizure**

Type of Therapy	Type of seizures	Drugs	Number of patients
<b>Monotherapy</b>	GTCS (N=19)	Leviteracetam	9
		Phenobarbitone	2
		Phenytoin	4
		Valproate	2
		Lorazepam	1
	Simple febrile seizure(N=10)	Lorazepam	1
		Phenobarbitone	2
		Phenytoin	4
		Carbamazepine	2
		lamotrigine	1
	Tonic clonic seizure (N=3)	Leviteracetam	2
		Phenytoin	1
	Status seizure (N=5)	Leviteracetam	1
		Lorazepam	1
		clobazam	2
		lamotrigine	1
	Partial Seizures (N=3)	Carbamazepine	2
		Oxcarbazepine	1
<b>Dual Therapy</b>	GTCS	clonazepam-lamotrigine	1



## Prescribed antiepileptic drugs in pediatrics according to the hospital protocol in a tertiary care hospital.

On observation, levetiracetam was found to be highly prescribed. The details are represented table 4.

**Table 4: Commonly prescribed AEDS in the study population**

Therapy	AEDS prescribed	no of patients	Percentages
Monotherapy	Levetiracetam	12	30
	Phenytoin	9	22.5
	sodium valproate	2	5
	Lorazepam	3	7.5
	Clobazam	2	5
	Lamotrigine	2	5
	Phenobarbitone	4	10
	Carbamazepine	4	10
	Oxcarbamazepine	1	2.5
	combination therapy	clonazepam-lamotrigine	1

**AEDs = (antiepileptic drugs)**

### Discussion

This study enrolled only pediatrics patients with confirmed epilepsy and on antiepileptic therapy. The epidemiological studies indicate the incidence of epilepsy is more common in pediatrics' (younger than 13 years) than adults. The analysis of the results revealed that there were 16 (40%) male patients and 24 (60%) female patients. The most prescribed drug was levetiracetam 12 (30%). In this study, the majority of the populations prescribed are treated by using the single drug therapy (97.5%) as compared to that of multiple drug therapy (2.5%). In our study on AED's prescribed, majority of patients received mono-therapy rather than dual therapy. Monotherapy results in less interaction and minimal adverse effect when compared to polytherapy. Poly-therapy exposes the patients to unnecessary hazards like drug allergy, drug interactions, noncompliance, and economic burden.

Parenteral route was more preferred in patients than oral route. In this study generalized seizures (19) was more common in pediatric population, followed by simple febrile seizure (10) tonic clonic (3), status seizure (5), partial seizure (3) respectively. During drug therapy, seizure episodes were controlled in patients with lesser likelihood of recurrence A higher percentage of patient were found to have Generalized seizures (42.5%), as in other study done by Ajay Kumar Halwai et. al same result was observed<sup>2</sup>. The incidence of ADRs in the study population was not observed during the study period.

According to the hospital protocol for the neonates, injection phenobarbital 200mg/ml; 1ml ampoules, loading doses 20mg/kg iv or IM is 1<sup>st</sup> line therapy, followed by 2<sup>nd</sup> line lorazepam injection 2mg/ml, loading dose 0.05 mg/kg iv and 3<sup>rd</sup> line phenytoin injection 100mg/2ml, loading dose 15-20mg/kg iv this was found to be consistent with my study results. With respect to long term



therapy as well, monotherapy was the preferred choice of treatment and in this, phenobarbitone was the preferred drug of choice followed by phenytoin.

According to a study conducted by Lekshmi et al it was found that 52.4% of the patients received drugs orally and 26.7% received drugs both by oral and IV routes and only 21% by IV route. In contrast in this study it was observed that majority of the patient received drugs through IV route 25 (62%). For the purpose of analyzing the data of AEDs prescribed for the treatment of seizure disorder, the pharmacotherapy was classified as according to the types of seizures. Therapy was further classified as monotherapy or dual therapy, based on the number of AED prescribed. According to the study conducted by Shaik et al.,<sup>4</sup> it was found that phenobarbitone was prescribed for maximum number of patients 19(50%), followed by phenytoin 15(39.5%) and valproate in 2(5.3%) patients. Interestingly, this study observed that Levetiracetam was prescribed for maximum number of patients 12(30%) , followed by phenytoin 9(22.5%) and phenobarbitone in 4(10%). Also Shaik et al., documented for the long term management of seizures, monotherapy was seen in majority of the patients 38(70.3%) followed by dual 12(22.3%) and triple therapy 4(7.4%), surprisingly this study did not show any triple therapy.

## Conclusion

For the acute management of seizures, monotherapy was found to be the most preferred choice of treatment and in this, levetiracetam was the preferred drug of physicians choice because it has a higher safety profile compared to other drugs who have a narrow therapeutic index, less adverse drug reactions, can be used in different classes

of epilepsy and is well tolerated in pediatric population.

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