



A Cross-sectional Observational Study to Find out the Pattern of Drug Utilization and Medication Adherence of Anti-Epileptic Drugs (AEDs) among Epileptic Patients at a Tertiary Care Teaching Hospital

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/JPRI/2021/v33i35B31903

Editor(s):

(1) Dr. Takashi Ikeno, National Center of Neurology and Psychiatry, Japan.

Reviewers:

(1) Chavan Rohankumar Rajaram, Bharati Vidyapeeth College of Pharmacy, India.

(2) M. Niranjan Babu, Seven Hills College of Pharmacy, India.

Complete Peer review History: <http://www.sdiarticle4.com/review-history/70664>

Original Research Article

Received 27 April 2021

Accepted 01 July 2021

Published 07 July 2021

ABSTRACT

Background: Antiepileptic drugs (AEDs) are the mainstay of the therapy for epilepsy, despite the development in recent years of new therapeutic options, such as brain stimulation or Surgery.
Objective: To understand the pattern of drug utilization and medication adherence of anti-epileptic drugs (AEDs) among epileptic patients at a tertiary care teaching hospital.

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Methodology: A cross-sectional observational study of a total of 120 subjects receiving anti-epileptics was done. All the patients with epilepsy were prescribed with anti-epileptic drug who visited, admitted, or referred to the Department of Neurology. All inpatients and outpatients of epilepsy were screened for the study.

Results: A total of 120 patients were included in our study into which (38.33%) were inpatients and (61.67%) were outpatient. The male (56%) patients were more as compared to female (44%) patients. A maximum number of patients were from the age group of 21-40 (41%) year. The majority of the patient were suffered from focal epilepsy (63%), remaining were having a generalized seizure. The highest comorbidities were found to be HTN and diabetes mellitus. Monotherapy was highly prescribed as compare to polytherapy. Among single AED, the maximum prescribed drug was Carbamazepine [30% (N=17)] followed by 25% (N=14) of phenytoin and levetiracetam 21% (N=12). In two AED Combinations, the most prescribed drugs were clobazam + Levetiracetam and Midazolam + phenytoin 12% (N=5) followed by sodium valproate + clobazam 10% (N=4). Highest combination of three AEDs that were prescribed the highest were carbamazepine + Levetiracetam + clobazam and phenytoin + phenobarbitone + sodium Valproate 20% (N=2)

The highest medication adherence was found in patients who were on single AEDs and the lowest adherence was found in the patients who were on more than two AEDs.

Conclusion: Antiepileptic drug monotherapy was highly prescribed as compare to polytherapy. Phenytoin was the most commonly prescribed AEDs followed by carbamazepine and highly prescribed single AEDs were found to be carbamazepine. The patients who were on single epileptic drugs showed the highest adherence as compared to the patients with more than two AEDs.

Keywords: Epilepsy; antiepileptic drugs; drug utilization; medication adherence.

1. INTRODUCTION

The brain disorder is mainly characterized by an enduring predisposition to generate seizures and by its neurobiological, cognitive, psychological, and social consequences is known as Epilepsy [1]. The prevalence rate ranges from 4.15 and 7.03 per 1000 population in a developing country like India, which contributes to nearly one-sixth of the global burden [2]. It is a transient occurrence of signs and symptoms due to abnormal excessive or synchronous neuronal activity in the brain [3]. According to the World Health Organization (WHO), it is the second most common and frequently caused neurological disorder which shows a burden on individuals, the health care system, and family wherein 50 million people with epilepsy on a worldwide basis, 80% reside in developing countries. Antiepileptic drugs (AEDs) are the mainstay of the therapy for epilepsy, despite the development in recent years of new therapeutic options, such as brain stimulation or Surgery. Many have drug-resistant epilepsy due to the underlying presence of abnormalities of the nervous system and atypical responses to antiepileptic drugs (AEDs) that act on the central nervous system. AEDs are also commonly used therapy for conditions like prophylaxis for a manic-depressive disorder, to relieve neuralgic pain, and for many more conditions apart from epilepsy. Data suggest that 45% of AEDs prescriptions were for conditions other than epilepsy. To assess the prescribing

pattern of AEDs in various diseases (both epilepsy and non-epileptic conditions) is important to know the expanded utilization of these AEDs in various conditions and co-relate with available literature. There are limited studies from India which describe the utilization pattern of AEDs in all conditions. People with epilepsy have a higher risk of mortality in comparison with the general population. This in part reflects intrinsic factors or associated comorbidities, but poor adherence to antiepileptic drugs (AED) has also been shown to contribute to increased risk of death and increased utilization of unscheduled care [4]. We have observed that very few studies have been carried out on this topic in the Gujarat state of India, where the utilization of antiepileptic is very high in a different population of various age groups and also with comorbid conditions. Along with this study, we are also training to find out the adherence of medication in epilepsy patients, as very few such studies have been carried out among epileptics. So, we had done this study at Dhiraj General Hospital, Sumandeep Vidyapeeth, Vadodara, and Gujarat to assess the pattern of drug utilization and medication adherence among epileptics.

2. METHODOLOGY

It was a cross-sectional observational study conducted for 6 months at the Department of Neurology, Dhiraj General Hospital, Vadodara. All the patients with epilepsy and prescribed with

anti-epileptic drug who visited, admitted, or referred to the Department of Neurology were included in a study after explaining to the patients, the details of the study. It was assured that all information and records would be kept confidential. The patient's medical records were checked and the following information was noted in the Patient Medical Record sheet: Patient's demographic details, Patient Medical History, Diagnosis and duration, family history, presence of other co-morbidities, Prescribed drugs including antiepileptic drugs (Generic name, Brand name, Frequency, Dose, Route of administration and Duration) was also collected, Drug interaction, Cost of drugs, Lab investigations reports (which are already mentioned inpatient medical records). All the relevant data was obtained from the patients' medical records and through counseling the patients who visited the Out- Patient Department (OPD) or In-Patient Department (IPD). Morisky's adherence scale [5] was used to assess the adherence of patients to prescribed drugs. All the relevant data collected and recorded electronically. Descriptive statistics used for the analysis of the data. After the data collection, all the data were exported to statistical software (SPSS) for statistical analysis. All the quantitative data were represented in mean \pm standard deviation. Comparative statistical differences were calculated using appropriate parametric tests.

3. RESULT

A total of 120 patients were enrolled in the study. Out of 120 patients, the total number of IPD was 38.33% (N=46) while OPD patients were 61.67% (N=74). Comparing the gender proportionality, male represents 56% (N=67) and female represents 44% (N=53) of the total population. In our study, the age of patients varies from 1 year to 90 years with a mean age of 36.48 ± 17.19 years. The maximum number of patients were from the age group of 21-40 years 41% (N=49) followed by 41-60 years 28% (N=33), then age group 1-20 years 21% (N=25), followed by age group 61-80 years 10% (N=12), and lastly the least number of patients were found in the age group of 81-100 years 1% (N=1) as mentioned in (Table 1).

3.1 The Pattern of Epilepsy among Patients

The majority of our patients suffered from Focal epilepsy (63%) and the remaining patients were having generalized seizures (37%). Patients with

complex seizures, temporal lobe epilepsy, and status epilepticus were considered in the group of focal epilepsy, and patients with generalized tonic-clonic seizures, absence seizures were included in the group of generalized seizures.

3.2 Comorbidity Status among Epileptics

Out of 120 patients, a total of 39% (N=47) of patients had at least one co-morbid condition whereas 61% (N=73) patients had no co-morbid conditions. The most common comorbid conditions found were hypertension, diabetes, cerebrovascular accident, acute kidney disease, hepatitis, and psychiatric disorders. These patients with co-morbidities were further divided into 4 categories. GROUP-A patients 47% (N=22) had at least 1 comorbidity along with epilepsy followed by GROUP-B 32% (N=15) where patients had 2 comorbid conditions with epilepsy. Further. In GROUP-C 15% (N=7) patients had 3 comorbidities with epilepsy and GROUP-D 6% (N=3) patients had 4 comorbidities along with epilepsy. The majority of the patients belonged to GROUP-A while a minimum number of patients were enrolled in GROUP-D. Show pattern of co-morbidities among epileptics. (Fig. 1).

3.3 Overall Prescribing Pattern

A total of 437 medications were prescribed among 120 epilepsy patients with an average of 3.64 ± 2.09 . The majority of the patients were prescribed with the Highest number of drugs that were prescribed was 51% (N=61) in 1-3 groups followed by 4-6 group with 40% (N=48) and least number of populations were found in ≥ 7 with 9% (N=11).

3.4 AED Utilization Patterns

Out of the total of 437 drugs prescribed; 221 AEDs were prescribed over the study period corresponding to an average of 1.84 ± 1.05 AEDs per patient. Amongst all the patients who received AEDs, 47.50% (N=57) of them prescribed with Single AED followed by Two AEDs prescribed to 34.2% (N=41) of patients, least number of patients 8.3% (N=10) prescribed with three AEDs and 10% (N=12) of patients prescribed with more than three AEDs. (Fig. 2).

Among single AED, the maximum prescribed drug was Carbamazepine 30% (N=17) followed by 25% (N=14) of phenytoin and levetiracetam 21% (N=12). In two AED Combinations, the most prescribed drugs were clobazam + Levetiracetam and Midazolam + phenytoin 12% (N=5) followed

by sodium valproate + clobazam 10% (N=4). Highest combination of three AEDs that were prescribed the highest were carbamazepine + Levetiracetam + clobazam and phenytoin + phenobarbitone + sodium Valproate 20% (N=2) (Table 2).

In this study, Phenytoin was the most common AED prescribed 18.13% (N=39) as monotherapy as well as polytherapy, followed by Levetiracetam 16.74% (N=36), Clobazam 15.81% (N=34), Carbamazepine 15.34% (N=33), Sodium valproate 13.02% (N=28), Midazolam 8.37% (N=18), Topiramate and Phenobarbitone both were prescribed to 1.86% (N=4) patients, and the least prescribed were Diazepam, Zonisamide, and lorazepam prescribed to 0.46% (N=1) of patients. (Fig. 3).

3.5 Other than Antiepileptic Drug Prescribing Pattern

Many other drugs were prescribed with AEDs and they were also further classified into the basic classes that were Anti-hypertensive, Anti-Diabetic, Anti-hyperlipidemia, etc. The highest number of drugs prescribed was from Antihypertensive class 20.2% (N=33) Followed by Antacid 18.4% (N=30), Antipsychotic 14.7% (N=24), and Antibiotic 11% (N=18) class. (Fig. 4).

3.6 Prescribing Indicators Analysis

Assessment was carried out to check prescribing indicators of different parameters, such as an average number of drugs per encounter, percentage of drugs prescribed by generic name, and several antiepileptics prescribed from essential drugs list. The average number of drugs that were prescribed per encounter was found to be 3.64 ± 2.09 . Further, the percentage of the drugs that were prescribed by generic name was found to be 20% (N=88) and the drugs that were prescribed without a generic name was found to be 80% (N=349) which is much higher in comparison to that of prescribed with the generic name. Also, Antiepileptics prescribed from the essential drugs list was found to be 94% (N=203) and about only 6% of the drugs were not prescribed according to the National List of Essential Medicines (NLEM) - 2015, India (Table 3).

3.7 Adherence Analysis

Out of 120 patients, 110 were enrolled for testing medication adherence using Morisky Medication Adherence 8 scale (MMAS). Out of 110 patients with epilepsy, 87.3% (N=96) showed high adherence towards anti-epileptic followed by moderate adherence by 11.8% (N=13). Only 0.9% (N=) patient was seen in the low medication adherence category.

3.8 Association between Patient's Socio-Demographic Characteristics and Adherence Level to AEDs

A total of 120 patients were enrolled in this study. The actual value that was reported, and it was found that in age 1-20 years there was high adherence in 21 patients, moderate adherence in 2 patients, and low adherence in 1 patient. Further in 21-40 years there was high adherence in 39 patients, moderate adherence in 6 patients, and low adherence in 0 patient, followed by age 41-60 years there was high adherence in 27 patients, moderate adherence in 3 patients, and low adherence in 0 patient, consecutively in age 61-80 years there was high adherence in 8 patients, moderate adherence in 2 patients and low adherence in 0 patient, and in age 81-100 years, there was high adherence in 1 patient, moderate adherence in 0 patients and low adherence in 0 patient. Here, the chi-square value was found to be 0.993741. Similarly, it was found that high adherence of single AED in 46 patients, two AEDs in 30 patients, three AEDs in 8 patients, and more than three AEDs in 12 patients, followed by moderate adherence of single AED in 5 patients, two AEDs in 7 patients, three AEDs in 1 patient and more than three AEDs in 0 patients, followed by low adherence of single AED in 0 patients, two AEDs in 1 patient, three AEDs in 0 patients and more than three AEDs in 0 patients. The Chi-square value was found to be 0.94038. Then in gender distribution, it was found that high adherence in 52 male patients and 44 female patients, followed by moderate adherence in 8 males' patients and 5 female patients, followed by low adherence in 1 male patient and 0 female patients. The Chi-square value was found to be 0.587861321. (Table 4).

Table 1. Distribution of study population according to age

Age-Groups	Total Number of patients	Percentage %
1-20	25	21%
21-40	49	41%
41-60	33	28%
61-80	12	10%
81-100	1	1%
Total	120	100%
Mean	36.48	
SD	17.19	

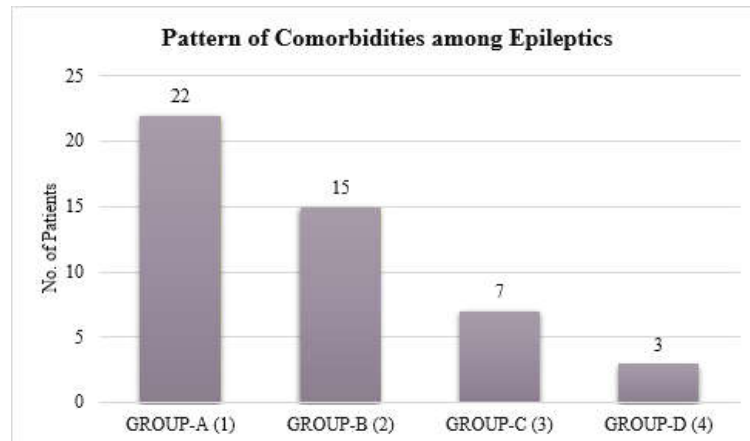


Fig. 1. Pattern of comorbidities among epileptics

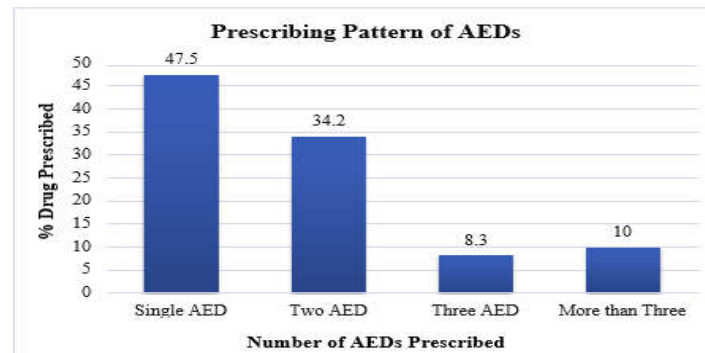


Fig. 2. Prescribing pattern of AEDs

Table 2. Types of combination given to epileptic patients

Therapy type	Number (Percentage)		Number (Percentage)
Single AED	57 (47.5%)	PHENYTOIN	14(25%)
		CARBAMAZEPINE	17(30%)
		OXCARBAZEPINE	2(4%)
		LEVETIRACETAM	12(21%)
		SODIUM VALPROATE	5(9%)
		TOPIRAMATE	1(2%)
		MIDAZOLAM	2(4%)
		CLOBAZAM	3(5%)

Therapy type	Number (Percentage)		Number (Percentage)
Two AED	41 (34.2%)	CLONAZEPAM	1(2%)
		PHENYTOIN+LEVETIRACETAM	6(15%)
		SODIUM VALPROATE+CARBAMAZEPINE	2(5%)
		CARBAMAZEPINE+CLOBAZAM	3(7%)
		MIDAZOLAM+LEVETIRACETAM	1(2%)
		MIDAZOLAM+PHENYTOIN	5(12%)
		SODIUM VALPROATE+CLOBAZAM	4(10%)
		SODIUM VALPROATE+CLONAZEPAM	3(7%)
		CLOBAZAM+LEVETIRACETAM	5(12%)
		CLOBAZAM+OXCARBAZEPINE	2(5%)
		CARBAMAZEPINE+PHENYTOIN	2(5%)
		SODIUM VALPROATE+MIDAZOLAM	3(7%)
		SODIUM VALPROATE+LEVETIRACETAM	1(2%)
		CLOBAZAM+PHENYTOIN	2(5%)
		MIDAZOLAM+CLONAZEPAM	1(2%)
Three AED	10 (8.3%)	SODIUM VALPROATE+PHENYTOIN	1(2%)
		LEVETIRACETAM+CLOBAZAM+CARBAMAZEPINE	2(20%)
		PHENYTOIN+PHENOBARBITONE+SODIUM VALPROATE	2(20%)
		CARBAMAZEPINE+CLOBAZAM+PHENYTOIN	1(10%)
		CARBAMAZEPINE+ZONISAMIDE+CLONAZEPAM	1(10%)
		PHENYTOIN+CLOBAZAM+PHENOBARBITONE	1(10%)
		CARBAMAZEPINE+CLOBAZAM+LEVETIRACETAM	1(10%)
		CARBAMAZEPINE+SODIUM VALPROATE+LEVETIRACETAM	1(10%)
		SODIUM VALPROATE+LEVETIRACETAM	1(10%)
		SODIUM VALPROATE+PHENYTOIN+MIDAZOLAM	1(10%)
More than Three	12 (10%)		

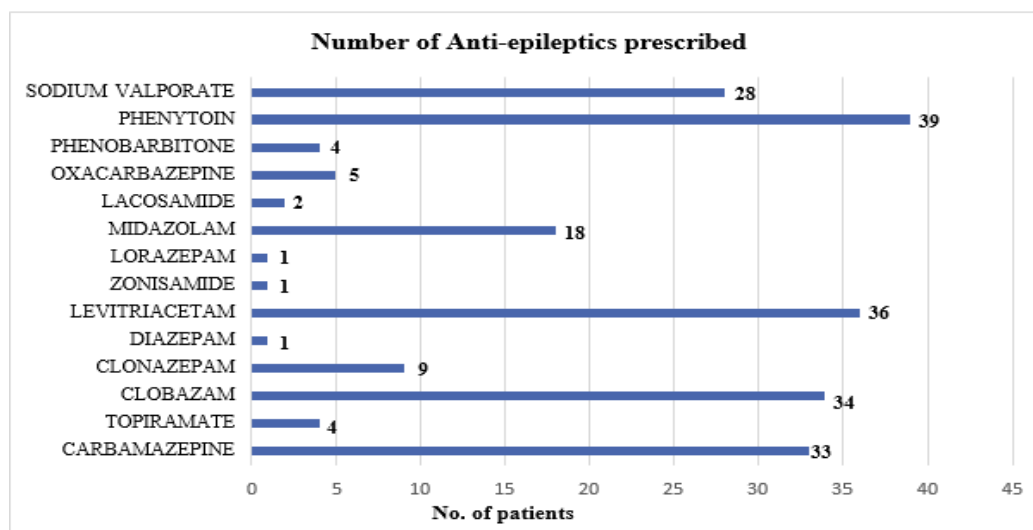


Fig. 3. Number of anti-epileptics prescribed

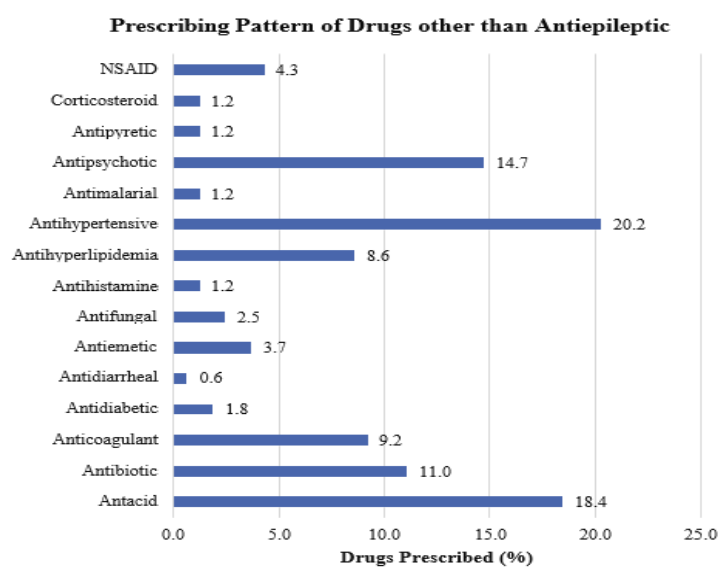


Fig. 4. Prescribing pattern of drugs other than anriepleptic

Table 3. Prescribing Indicators of various Parameters Average number of drugs per encounter

Total no drugs	437	
Mean	3.64	
SD	2.09	
Percentage of drugs prescribed by generic name		
No	349	79.86
Yes	88	20.14
Total	437	100
Percentage of drugs prescribed from essential drugs list or formulary		
Yes	203	94.42
No	12	5.58
	215	100

Table 4. Association between patient's socio-demographic characteristics and adherence level to AEDs

Clinical Parameters	High	(%)	Moderate	(%)	Low	(%)	Total
Actual age(YRS)							
1-20	21	87.5	2	8.3	1	4.16	24
21-40	39	86.6	6	13.3	0	0	45
41-60	27	90	3	10	0	0	30
61-80	8	80	2	20	0	0	10
81-100	1	100	0	0	0	0	1
Actual AEDs prescribed							
Single AED	46	90.1	5	9.8	0	0	51
Two AED	30	78.9	7	18.42	1	2.6	38
Three AED	8	88.8	1	11.1	0	0	9
More than Three AED	12	100	0	0	0	0	12
Actual gender distribution							
Male	52	85.2	8	13.1	1	1.6	61
Female	44	89.7	5	10.2	0	0	49

4. DISCUSSION

Epilepsy is a neurological disorder characterized by the onset of seizures and performing repetitive movements, change in sense of smell/ taste/ hearing/ touch, tingling and twitching of limbs, sudden blackout, fainting, twitching, or trembling as well as stiffness of muscle. The present study was carried out to evaluate the prescribing pattern of AEDs and to check the medication adherence among epileptic patients [6].

A total of 120 patients were enrolled in the study according to the inclusion and exclusion criteria. The study included all the patients with 1-90 years with a mean age of 36.48 ± 17.19 years. It has been reported that the highest number of patients were in the range of 21-40 (41%) years and the least number of patients were from 81-100 years (1%) which was found similar in the study conducted in JSS college Tamil Nadu, which reported, highest number patients in the age group of 21-50 (40%) years [7].

In our study, 38.33% of inpatients and 61.67% of outpatients were reported respectively. Among those 120 AEDs patients, the proportion of epilepsy was more prevalent in male (56%) patients than in female (44%) patients which are supported by the study conducted in the neuroscience center of a national hospital of India where the male (67.9%) patients were highest [8].

According to our study, a higher percentage of patients were diagnosed with focal epilepsy (63%), in contrast to the study conducted in the neurology department, New Delhi which reported generalized seizure (33%) and focal epilepsy (27.5%) respectively. It is further classified as complex seizure, temporal lobe epilepsy, and status epilepticus followed by generalized seizure (37%) then it is further classified as generalized tonic-clonic and absence seizures [3].

In our study, it is reported that the number of patients having co-morbidities was considerably lower (39%) as compared to the patients without co-morbidities (61%). The most prevalent comorbid conditions with epilepsy were hypertension, diabetes. These results were supported by the study conducted in a Brazilian tertiary care hospital [9] and a study conducted in the child neurology division, New Delhi [10] which reported patients without comorbidities

(69%) were found to be higher as compare to comorbid patients (39%) where there was the highest occurrence of hypertension and followed by a cerebrovascular accident, acute kidney disease, hepatitis, psychiatric disorder. Out of 120, co-morbidities were found in 47 patients. It was further divided into four groups, patients with one comorbidity were classified in group A (47%) whereas with two comorbidities were group B (32%) followed by group C (15%) in which patient had 3 comorbid conditions and in last patients with 4 comorbid conditions were classified in group D. In our study, total medication prescribed was 437, with an average mean of 3.64 ± 2.09 . The highest number of drugs prescribed was 1-3 (33.3%), followed by 5-6 (24.2%). The least number of patients have been prescribed 7-8 (9.2%) drugs; therefore, we conclude that majority of patients were prescribed 1-3 epileptic drugs.

Out of all 437 drugs, the total number of AEDs prescribed was found to be 221 with an average mean of 1.84 ± 1.05 per patient. Monotherapy of AEDs accounted for more than 47.5% of prescriptions. These study results were supported by the study conducted in Columbia [4] and the study conducted in the department of medicine, Oman [11] where the monotherapy was highly prescribed as compare to polytherapy. Polytherapy with two or three AEDs combination was accounted for 34.2% and 10% respectively, least number of patients (8.3%) received polytherapy of AEDs, which in contrast to our study highest number of polytherapy with two-three drugs prescribed in (37.9%) patients [10].

The highest number of monotherapies prescribed were phenytoin (30%) followed by levetiracetam (16.74%), clobazam (15.34%), sodium valproate (13.02%), midazolam (8.37%), topiramate, and phenobarbitone (1.84%). These results were similar to a study conducted in J.K.K Nataraja College of Pharmacy Tamil Nadu [12] where phenytoin (92.10%) was highly prescribed, another study conducted in KMCH college, Coimbatore [13] reported that valproic acid (33.2%) and carbamazepine (53.1%) were highly prescribed which was a contrast to our study. A similarity was found between studies conducted at New Delhi college that the most common drug that was prescribed at tertiary care hospitals was phenytoin in both monotherapies as well as polytherapy [10]. The highest single AEDs prescribed were found to be 57% in comparison to the study carried out at Tamil Nadu Hospital was found to be 41% whereas in the same study

we found the contrast in our findings 41% whereas in the reference study it was found to be 8% and in three AEDs prescribed our study showed 10% whereas in the reference study it was found to be 1%.

Other than antiepileptic drugs, the most often drugs prescribed along with AEDs were found to be antihypertensive, antidiabetic, antihyperlipidemic and the least number occupied by antibiotic medication. Prescribing indicators are the assessment tool for calculating the average number of drug encounters per prescription & how many numbers of drugs were prescribed by generic name from the essential drug list. by this study, we conclude that an average 3.64 ± 2.09 number of drugs encounter by prescription.

Our study reported that the highest number of drugs were prescribed without a generic name (80%) and the least number of drugs (20%) are reported to be prescribed by generic name which was in contrast to the study reported that generic drug prescribing is more as compare to nongeneric drug prescribing [12] Our study reported the proportion of nongeneric drugs were exceed to the generic drugs. Furthermore, antiepileptic prescribed from the essential drug list was found to be (94%) & the remaining (6%) of the drugs were not prescribed according to the national list of essential medicine.

4.1 Medication Adherence

Our study reported, among 120 patients 110 were tested for medication adherence using medication adherence Morisky's 8 scales (MMAS). In our study, we found that only 1% were nonadherent whereas in the reference study we found a contrast to the study by 57% low adherent to AEDs. In our study, most of the patients with epilepsy were compliance with their AEDs.

5. CONCLUSION

Epilepsy is a neurological disorder characterized by sudden recurrent episodes of sensory disturbances, loss of consciousness, or convulsion, associated with abnormal electrical activity in the brain. Antiepileptic drugs are the treatment of choice for epilepsy. Total 221 antiepileptic drugs were prescribed among 120 patients. The highest number of patients were prescribed single epileptic drugs followed by two & three respectively. The highest single AEDs prescribed were found to be carbamazepine followed by phenytoin. Medication adherence

was assessed and it was checked in 110 patients. The highest adherence was found among patients who were on one antiepileptic drug, below that the lowest antiepileptic drug adherence was found in the patient who was on more than one AEDs. The utilization of antiepileptic drugs is very necessary because some of the epileptic drugs belong to a narrow therapeutic index. Which can lead to adverse drug reactions. Further, AEDs are a bit costlier compare to other groups of therapy, utilization analysis can reduce the unnecessary administration of drugs and reduced the cost of therapy. Also, medication adherence for epileptic patients is very essential because if the patient skips taking the AEDs, then the patient might have the chance of reoccurrence. It may further increase the chances of mortality or chances of complications development. The routine analysis of the prescriptions of AEDs by the clinical pharmacist may improve the prescribing pattern of AEDs which can further increase the patient's awareness about their medications and hence improves adherence. A clinical pharmacist can also help to assess the prescription for the presence of any drug interactions and adverse drug reactions of AEDs.

ETHICAL APPROVAL AND CONSENT

The study obtained ethical approval from the Sumandeep Vidyapeeth Institutional Ethics Committee (Ref no: SVIEC/ON/Phar/BNPG18/D19003). Informed consent was taken from patients.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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