An observational study of pattern of antiepileptic drugs prescribed to patients attending epilepsy outpatient department in tertiary care hospital

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Abstract

Background: Epilepsy is a group of non-communicable neurological disorders characterized by recurrent epileptic seizures. The choice of the most appropriate drug treatment for a patient with seizures depends upon the accurate classification of the seizures and the type of epilepsy or epileptic syndromes. Present study was aimed to analyze the pattern of antiepileptic drugs prescribed to patients attending epilepsy at outpatient department in tertiary care hospital. **Material and Methods:** Present study was single-center, Cross-sectional, Observational, Descriptive study , conducted in patients diagnosed OR having past history with seizure disorder and treated with antiepileptic drugs by neurologist, receiving at least one Antiepileptic medication. **Results:** Out of the total 600 patients enrolled, the majority i.e., 393(65.50%) were males, from the age group of 20 - 40 years (43.66%) followed by age group of 41 to 60 years (34.33%). Majority patients were diagnosed with GTCS (39.5%), followed by 154 with Complex Partial (25.6%), Out of total 786 AEDs, carbamazepine was most commonly prescribed drug (34.2 %), followed by valproate (20.4 %) and levetiracetam (14.2 %). Monotherapy was used in 454(75.66%) number of patients whereas polytherapy was used in 146 (24.34%) number of patients. Out of 146 polytherapy used, dual therapy was used in 108 (73.7%) patients. 721 (91.73%) drugs were prescribed using Generic name and 65 (8.27%) drugs were prescribed using Brand name. The average cost per prescription was 268.25 INR, out of which, the cost borne by the hospital was 40.26 (15%) & the cost borne by the patient was 227.98 INR (85%). **Conclusion:** Monotherapy was given to majority (75.66%) of patients, as recommended by NICE Guidelines to start the treatment of epilepsy with monotherapy and change to polytherapy only in unresponsive & resistant cases.

Keywords: drug utilization pattern,Seizures, carbamazepine, antiepileptic drugs, epilepsy

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Introduction

Epilepsy is a group of non-communicable neurological disorders characterized by recurrent epileptic seizures. [1] Every year, 2.4 million people are diagnosed with epilepsy[2], of which 80% reside in developing countries. [3] Approximately 10 million people with epilepsy live in

India but many patients with active epilepsy do not receive suitable treatment for their condition, leading to a large treatment gap. [4]

The choice of the most appropriate drug treatment for a patient with seizures depends upon the accurate classification of the seizures and the type of epilepsy or epileptic syndromes. The aim of therapy is to minimize the recurrence of the seizures and the adverse drugs. Over 80% of epileptic patients can achieve a significant reduction in seizure frequency with one drug alone. The risks of significant adverse effects and drug interaction increase when more than one drug is used.[5]

According to World Health Organization (WHO), drug utilization can be defined as "the marketing, distribution, prescription and use of drugs in a society emphasizing its medical, social, and economic consequences". [6] Inappropriate usage of drugs may act as barrier in achieving ideal benefit as it may lead to sub-therapeutic effect, antimicrobial resistance, excess medical cost, adverse effects or mortality. Hence, drug utilization studies have become a plausible means in evaluating the health system. [7] Present study was aimed to analyze the pattern of antiepileptic drugs prescribed to patients attending epilepsy at outpatient department in tertiary care hospital.

Material And Methods

Present study was single-center, Cross-sectional, Observational, Descriptive study, conducted in department of pharmacology in association with 'Epilepsy clinic' of Neurology Outpatient Department, at XXX medical college & hospital, XXX, India. Study duration was of one years and 6 months (March 2021 to September 2022). Study approval was obtained from institutional ethical committee.

Inclusion criteria

- ⬚ Patients diagnosed OR having past history with seizure disorder and treated with antiepileptic drugs by neurologist, receiving at least one Antiepileptic medication, willing to participate in present study

Exclusion criteria

- Patient presented with seizures but not otherwise classified as epilepsy as per guidelines (ILAE).
- Patient Noncompliant to the treatment.
- Patient cured.
- Patient with status epilepticus.
- Patient with seizures with acute illness.
- Patients with drug induced epilepsy.
- Patients with progressive CNS infection.
- Patients chronic alcoholism, drug ingestion and psychiatric diseases.
- Pregnant women with epilepsy

Study was explained to patients in local language & written consent was taken for participation & study. Patients were given information about the study and after taking written informed consent form them, the data was collected from patients' prescriptions & was recorded in a structured case record form.

The following data was collected as patient demographic details like patient's initial, age, gender, address, etc., Prescription details like date, number of drugs, names of individual drugs, and any Fixed Drug Combination prescribed, dosing schedule and the duration for which it is prescribed, Type of Seizure, Number of drugs per prescription, Different classes of drugs used, Number of drugs used in each class of drugs, Cost of various agents as per the Hospital Drug Store and/or various drug indices.

The data was compiled into Microsoft Office Excel worksheet 2021 version and a descriptive statistical analysis was carried out. The results on continuous measurement scale were presented as Mean ± SD and results on categorical measurement type were presented as simple percentage (%).

RESULTS

Out of the total 600 patients enrolled, the majority i.e., 393(65.50%) were males and the rest 207 (34.50%) were females. The approximate ratio of Male: Female was 1.92:1. Majority of the patients were from the age group of 20 - 40 years (43.66%) followed by age group of 41 to 60 years (34.33%). Mean age was 40.33 ± 15.86 years.

Table 1: General characteristics

Age groups (in years)	MALES (%)	FEMALES (%)	TOTAL (%)
<20	25 (44.6 %)	31 (55.3 %)	56 (9.33 %)
20 - 40	171 (65.2 %)	91 (34.8 %)	262 (43.66 %)
41 - 60	137 (66.5 %)	69 (33.5 %)	206 (34.33 %)
>60	60 (78.9 %)	16 (21 %)	76 (12.66 %)
Total	395 (65.83 %)	205 (34.16 %)	600

Patients were diagnosed by the consulting Neurologist according to ILAE Guidelines. Majority patients were diagnosed with GTCS (39.5%), followed by 154 with Complex Partial with or without secondary generalization (CP/CPSG) (25.6%), Simple Partial with or without secondary generalization (SP/SPSG) (21.3%), Myoclonic Epilepsy (12.3%) and Absence and Atonic Seizures (1.16%).

Table 2 Pattern of Epileptic disorders

Types of epilepsy	No. of Patients	Percentage (%)
Generalised tonic clonic seizures (GTCS)	237	39.5
Complex partial seizures	154	25.6
Simple partial seizures	128	21.3
Myoclonic seizures	74	12.3
Absence/atonic seizures	7	1.16

It was observed that out of 237 patients diagnosed with GTCS, Phenytoin was drug of choice prescribed to 74 patients as a monotherapy followed by Valproate which was prescribed to 6 patients. Among 154 cases of complex partial seizures with or without secondary generalization, carbamazepine was dug of choice in 103 patients followed by Levetiracetam in 12 patients followed by valproate in 4 patients.

Among simple partial seizures with or without secondary generalization patients, Carbamazepine was dug of choice in 91 patients followed by valproate in 3 patients followed by levetiracetam in 2 patients. Among patients with myoclonic seizures, Levetiracetam was dug of choice in 25 patients followed by valproate in 22 patients. Among patients diagnosed with Absence and atonic seizures, Valproate was given to 3 patients whereas levetiracetam was given to only 2 patients as a monotherapy.

Table 3: Antiepileptic drugs prescription in epilepsy

Monotherapy	GTCS.		Simple partial seizures	Myoclonic	Absence and Atonic Seizures
Phenytoin	74				

Valproate	66	4	3	22	3
Levetiracetam	40	12	2	25	2
Phenobarbitone	7				
Carbamazepine		103	91		
Dual Therapy					
Phenytoin + Phenobarbitone	13				
Phenytoin + Valproate	10				
Phenobarbitone + Clobazam	6				
Phenytoin + Levetiracetam	4				
Valproate+ Phenobarbitone	4				
Valproate + Levetiracetam	3				
Carbamazepine + Phenobarbitone		13	13		
Carbamazepine + Levetiracetam		4	7		
Carbamazepine + Clonazepam		3	6		
Valproate + Clonazepam				13	2
Valproate + Lamotrigine				7	
Triple Therapy					
Phenytoin + Valproate + Phenobarbitone	5				
Phenytoin + Clonazepam + Lamotrigine	3				
Phenytoin + Clobazam + Phenobarbitone	2				
Carbamazepine + Valproate + Phenobarbitone		6			
Carbamazepine + Valproate + Levetiracetam		5	6		
Carbamazepine + Lacosamide + Clobazam		3			
Carbamazepine + Clonazepam + Lamotrigine				5	
Levetiracetam + Clonazepam + Lamotrigine				2	
Quadruple Therapy					
Carbamazepine + Clobazam + Lacosamide + Brivaracetam		1			
Total	237				

In this study, 600 patients were prescribed 10 different types of drugs either as monotherapy or as part of polytherapy. Out of total 786 AEDs, carbamazepine was most commonly prescribed drug (34.2 %), followed by valproate (20.4 %) and levetiracetam (14.2 %).

Table 4: Utilization pattern of Antiepileptic drugs

Types of Antiepileptic Drugs	Number of cases
Carbamazepine	269(34.2%)
Valproate	161(20.4%)
Levetiracetam	112(14.2%)

Phenytoin	111(14%)
Phenobarbitone	68(8.6%)
Clonazepam	26(3.3%)
Lamotrigine	19(2.4%)
Clobazam	15(1.9%)
Lacosamide	4(0.5%)
Brivaracetam	1(0.1%)
Total	786

All the AEDs were prescribed either as primary therapy or as an add-on therapy. Carbamazepine was used most commonly as a primary therapy in 195 cases & in 17 cases it was used as an add-on therapy. Phenobarbitone was used most commonly as an add-on therapy in 40 patients.

Table 5: Selection Pattern of AEDs prescribed as Primary or Add-on therapy

Type of AED	Primary AED	Add-on Therapy
Carbamazepine	195	17
Valproate	97	32
Levetiracetam	81	21
Phenytoin	74	14
Phenobarbitone	7	40
Clonazepam	0	23
Lamotrigine	0	19
Clobazam	0	15
Lacosamide	0	4
Brivaracetam	0	1
Total	453	186

Monotherapy was used in 454(75.66%) number of patients whereas polytherapy was used in 146 (24.34%) number of patients. Out of 146 polytherapy used, dual therapy was used in 108 (73.7%) patients. Triple therapy was used in 37 (25.34%) patients followed by quadruple therapy, used only in 1 patient.

Table 6: - Pattern of Prescription of Monotherapy and Polytherapy

Type of Therapy	Number of cases	Percentage (%)
Monotherapy	454	75.66
Polytherapy	146	24.34
● Dual Therapy	108	73.7%
● Triple Therapy	37	25.34%
● Quadruple Therapy	1	0.68%
Total	600	100

Overall, 9 different class of drugs excluding the miscellaneous were prescribed in the 600 prescriptions. The total number of drugs accounting to 1215. Analgesics and Antipyretics class of drugs accounted for the most (18.43%) followed by antacids (17.44%), antihypertensives (15.47%) & antimicrobials (10.61%).

Table 7: Prescription Pattern of Concomitant Drugs

Class of Drugs	No. of cases (%)
Antipyretics	224 (18.43%)
Antacids	212 (17.44%)

Antihypertensives	188 (15.47%)
Antimicrobials	129 (10.61%)
Multivitamins	126 (10.37%)
Antidiabetics	122 (10.04%)
Calcium	85 (6.99%)
NSAIDS	71 (5.84%)
Antihistaminics	58 (4.77%)
Total	1215

It was observed that out of 786 AEDs prescribed to 600 patients ,721 (91.73%) drugs were prescribed using Generic name and 65 (8.27%) drugs were prescribed using Brand name.

Out of the total 786 drugs and drug combinations prescribed exclusively for the treatment of epilepsy, 721 (91.73%) of the drugs were available and dispensed from the Hospital pharmacy and the rest of the 65(8.27%) drugs were purchased from the outside medical store.

Table 8: Prescription Pattern of AEDs using Generic and Brand names.

Drug Nomenclature	No. of Drugs
Generic Name	721 (91.73%)
Brand Name	65 (8.27%)
Pattern of drug dispensing	
Hospital Pharmacy	721 (91.73%)
Outside medical store	65 (8.27%)

The different drugs of various classes prescribed among the study population were classified according to the Anatomical Therapeutic Chemical (ATC) – Daily Defined Dose (DDD) classification. The Prescribed Daily Dose (PDD)/ Daily defined Dose (DDD) ratio of the prescribed drugs was calculated. Out of 10 different ratios observed, 2 (20%) had ratio equal to 1, 7(70%) had ratio <1 and 1(10%) had ratio >1.

Table 9: ATC/DDD classification of AEDs prescribed in the study population.

Drug	ATC Code	DDD*(grams)	PDD*(gram)	PDD/DDD
Carbamazepine	N03AF01	1	1	1
Valproate	N03AG01	1.5	1.2	0.8
Phenytoin	N03AB02	0.3	0.2	0.6
Phenobarbitone	N03AA02	0.1	0.12	1.2
Clobazam	N05BA09	0.02	0.01	0.5
Levetiracetam	N03AX14	1.5	1	0.6
Clonazepam	N03AE01	0.08	0.01	0.12
Lamotrigine	N03AX09	0.3	0.2	0.6
Lacosamide	N03AX18	0.3	0.1	0.33
Brivaracetam	N03AX23	0.1	0.1	1

The average cost per prescription was 268.25 INR, out of which, the cost borne by the hospital was 40.26 (15%) & the cost borne by the patient was 227.98 INR (85%).

Table 10: - Cost analysis of the prescription

Parameters	Amount (INR)
Total cost for all 600 prescriptions	160950.59
Average cost per prescription	268.25
Total cost borne by the hospital	24,157.29
Average cost per prescription borne by the hospital	40.26

Total cost borne by the patient	136793.3
Average cost per prescription borne by the patient	227.98

Various WHO drug use indicators were calculated. Average number of drugs prescribed per prescription were 3.35. 91.73% of drugs were prescribed by generic name. 93.63% of drugs were prescribed from the National List of Essential Medicines (NLEM), 2022. 79.89% of drugs were prescribed from WHO list of Essential Medicines, 2021. 96.75% of drugs were prescribed from Hospital Pharmacy. Average cost per prescription was 268.25 rupees.

Table 11: WHO drug use indicators

Average number of drugs prescribed per prescription	3.35
Percentage of drugs prescribed by generic name	91.73%
Percentage of drugs prescribed from the National List of Essential Medicines (NLEM), 2022	93.63%
Percentage of drugs prescribed from WHO list of Essential Medicines, 2021	79.89%
Percentage of drugs prescribed from Hospital Pharmacy	96.75%
Average cost per prescription	268.25 INR

Discussion

Drug utilization studies are primarily conducted to encourage rational usage of drugs. Drug utilization study in chronic diseases like epilepsy is essential because in such diseases patients are exposed to drugs for a long time and sometimes lifelong.[8] The main target of the treatment is make patient completely free from the seizures, without any unwanted side effects of the medications given with an optimal quality of life. The standard treatment of epilepsy is optimal use of AEDs; wherein monotherapy is the usual dictum.

Drug utilization studies play a crucial role in the health sector and ultimately provide insight into the efficiency of drug use and results of such research can be used to help set priorities for the rational use of medicines and allocation of health care budgets. These are practically appreciated in different clinical settings, health care management programs, hospitals, and communities by considering therapeutic drug class and disease conditions to assess the fundamental part of the patient care system. [8] These studies or audits thus ensure correct and rational use of drugs and are useful to identify the problems and provide feedback to prescribers so as to create awareness about the rational use of drugs.[9]

A total of 600 patients were enrolled in this study who were prescribed AEDs, out of which majority of the patients were between the age of 20-40 years (s43.66 %) of age followed by 41-60 years (43.33%). This was similar from the findings of other such study done by Murthy V *et al.*,[10] which reported 60%of study population was of age group of 30-60 years.

It was found that in our study higher prevalence of epilepsy was found more in males compared to females. Male: Female ratio being 1.89 (65.5% male patients and 34.5% female patients. The same results are echoed in other studies as well which were conducted by Chanrarathna *et al.*,[11] Mandal S *et al.*,[12] and Patel *et al.*,[13] where males were affected more frequently than females.

All the AEDs were prescribed as per recommendations of NICE Guidelines 2022 and more so because these drugs were available in hospital pharmacy. Carbamazepine was most frequently prescribed drug (35.2%) followed by valproate (20.4 %), levetiracetam (14.2 %), phenytoin (14 %) & phenobarbitone (8.6 %). A higher percentage of carbamazepine use was attributed to the 54% of patients diagnosed with different kinds of partial seizures.

These results were similar to other studies done by K Radhakrishnan *et al.*,[14] a Sri

Lankan study by S.H. Kariyawasam *et al.*,[15] and a Taiwan study by Liang-Po Hsieh *et al.*,[16] where carbamazepine was the most commonly prescribed drug followed by valproate. Drug utilization pattern of AEDs in present study differ from other studies done by Chandrarathna *et al.*,[11] and Shobhana Mathur *et al.*,[17] in which phenytoin was most commonly used drug and study done by Abhishek Pal *et al.*,[18] Arulkumaran *et al.*,[19] and Mandal S *et al.*,[12] which reported valproate as most commonly used drug.

The present treatment of epilepsy is primarily centered on the administration of appropriate AEDs after the proper identification of type of seizure and an accurate categorization of the epilepsy syndrome.[14] Its well known fact that lesser the number of prescribing drugs minimal are the chances of adverse drug reactions, drug-drug interactions and economic burden on patients are also reduced to greater extent. In the present study, the various drug usage and type of treatment given (mono or polytherapy) to patients were analysed.

Polytherapy offers no advantage over monotherapy,[19] moreover it increases the risk of chronic toxicity including neurocognitive problems, may affect compliance and is associated with the increase necessity for TDM. If the dose of AED is titrated for every single patient carefully and by gradually increasing the dose to maximum tolerated dose, seizures episodes can be well controlled in many patients by monotherapy alone. In the present study, polypharmacy data revealed similar findings.

Out of total 600 prescriptions, 454 (75.66%) prescriptions were having single type of AEDs and rest i.e.,146 (24.34%) prescriptions with more than one AEDs. There were 108(18%) prescriptions with two AEDs,37(6.16%) prescriptions with three AEDs and only one (0.16%) prescription with four AEDs. These findings suggest limited usage of polypharmacy and thus rationality in therapeutic practices. These findings are in accordance with similar such studies carried out in India where monotherapy was used more frequently than polytherapy.[13,19] However, our finding contrasts the study conducted by Chandrarathna *et al.*,[11] and Mandal S *et al.*,[12] in which patients were prescribed polytherapy more frequently than monotherapy. These difference may be due to less sample size used in the study as compared to our study.

In present study average number of AEDs per prescription is 1.3 which is in consonance with study done by Patel *et al.*,[13] which reported 1.33 AEDs per prescription and 1.3 by Arul Kumaran *et al.*,[19] These figures attributed to maximum number of monotherapy and dual therapy prescribed in this study. Average number of total drugs per prescription is 3.35.

Considering Cost analysis of the present study , average cost per prescription was 268.25 INR, out of which, the cost borne by the hospital was only 40.26 INR & the cost borne by the patient was 227.98 INR. This huge difference between cost born by the patients and cost born by the hospital is because of higher costs of AEDs prescribed using brand name, unavailability of some of the drugs in the hospital pharmacy or absence of some of the drugs in the rate contract (RC) list of the state government.

There exist some limitations of this present study such as cross-sectional study design (no follow up of the patients involved), limited size and site of the study population, study conducted in an urban tertiary care hospital (community level study is recommended) & we didn't analyse other factors that influence the cost of treatment like the travel expenditure, the money spent on consulting the physician which should also be taken into account while doing the cost analysis. Therefore, future studies should be planned which will focus on this parameter as well.

The present study observed polypharmacy and prescription of more drugs with branded names so doctors should be encouraged to prescribe more drugs with the generic

name. Rational prescription is the need of the hour. This will also reduce the cost burden on the patients, particularly for the treatment of a disease that requires long-term therapy. This study recommends that principles of rational prescribing should be followed as per standard guidelines i.e. ILAE guidelines (2017) & drug utilization should be done in order to ensure the adherence, to increase patient's compliance, to minimize the errors and encourage rational prescribing pattern.

Conclusion

The present study provides valuable insights into the overall pattern of drugs prescribed in patients diagnosed with epilepsy. The drug utilization pattern among patients attending Neurology outpatient department (OPD) at our tertiary care hospital is as per the guidelines and recommendations laid down by WHO. Overall, carbamazepine was the most commonly prescribed AED.

Monotherapy was given to majority (75.66%) of patients, as recommended by NICE Guidelines to start the treatment of epilepsy with monotherapy and change to polytherapy only in unresponsive & resistant cases. Maximum number of drugs were prescribed by using their generic name and were mentioned or present in the essential list of medicines, which is an encouraging sign.

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