

Drug Utilization Pattern and Prescription Auditing of Antiepileptic Drugs and its Adverse Effects in Private Hospital

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ABSTRACT

Background: Epilepsy is a common medical condition characterized by repeated seizures due to a disorder of the brain cells. The data was limited regarding the prescribing pattern and side effects of various antiepileptic drugs in private hospitals. The objective of the present study was to evaluate the prescribing pattern of Antiepileptic drugs in the management of various types of epileptic seizures over a period of twelve months.

Methods: A prospective observational study was conducted among epileptic patients on follow up at neurology department of Life line hospital, Azamgarh. During the twelve months study period, epileptic patients who were prescribed with AED's (antiepileptic drugs) were included in this study. Data were collected through the Patients case files. **Results:** Our study revealed male predominance over female. In 18-30(35.66%) age group, Patients were more prone to epilepsy. Total 145(48.33%) patients were diagnosed with generalized seizure. Headache (27.55%) was most commonly observed ADRs. Total 959 (94.57%) number of drugs were prescribed with brand name. Valproic acid (15.18%) was most commonly

prescribed drugs for treatment of epilepsy for treatment of epilepsy which included 154 encounters. Avg. cost for 6months of epileptic treatment was 64752.02. Average cost per prescription was Rs. 1553.50. **Conclusion:** This study highlights the need of drug utilization evaluation as it will help in analysing on-going health care practices, so that lacunae in the system can be identified and Proper strategies can be planned to rectify them. In recent times, there has been done an immense effort to ensure and implement rational drug use.

Key words: Antiepileptic drugs, Drug utilization study, Epilepsy, Seizure.

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INTRODUCTION

The word epilepsy comes from the Greek which means to be taken, seized or attacked. Epilepsy is a condition characterized by repeated seizures due to a disorder of the brain cells.¹ However, the definition of epilepsy as a tendency to have recurrent seizures excludes seizures that are provoked (i.e. not spontaneous and therefore termed "acute symptomatic") by an obvious and immediate preceding cause e.g. an acute systemic or metabolic imbalance, drugs or toxins etc.^{2,3}

Epilepsy is more common in the developing countries than developed countries. In developing countries, the prevalence has been reported to be more than 40 per 100 populations.⁴ In India 10 million peoples effected with epilepsy (prevalence about 1%).⁵ The incidence is high in rural areas (1.9%) as compared with the urban areas (0.6%).^{6,7}

The etiology of seizure is multifactorial and is mainly due to interaction between various factors like genetically determined seizures thresholds, underlying predisposing pathologies or metabolic derangements and acute precipitating factors.⁸

The general approach to treatment involves the identification of goals, development of a care plan and a follow-up evaluation. The diagnosis of epilepsy is essentially clinical, based on an eyewitness account of the seizure. Neurological examination and investigations may be normal between attacks. Sometimes patients may not be aware of the nature of attacks; seizures occurring at night may go unnoticed and hence may not be reported. It is recommended that the guidelines established by the International league against epilepsy (ILAE) commission of epidemiology and prognosis be followed in epidemiologic studies of epilepsy.⁹

Treatment with anti-epileptic drug (AED) is selected based on the type of seizure and is to be continued till the patient is seizure free often for 1-5 years. However, about 90% of epileptic patients in developing countries are not receiving appropriate treatment due to the cultural attitude, lack of prioritization, poor health care system, economic problems and inadequate supply of AEDs.¹⁰⁻¹³ Treatment outcome depends on several factors such as drug related factors, disease-related factors and patient-related factors. Drug-related factors include pharmacokinetics of the drugs, drug-drug interactions and toxicity among others. Similarly, irrational prescribing will result in poor treatment outcome.

Drug utilization is defined by WHO as the study of marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences.¹⁴ The aim of drug utilization study is to improve rational use of drugs.

The main objectives of the study was to get an insight into the type of epileptic Seizure in the enrolled patients and observe Drug utilization pattern of epilepsy and identify the occurrence of ADRs along with evaluation of cost of treatment in enrolled patients and observe the practice of prescribing the medicine by their generic and brand name.

This study would shed light on prescription pattern of antiepileptic drugs in private hospital. The prescriptions pattern may have changed due to availability of newer anti-epileptic drugs which are less toxic and equally efficacious than older anti-epileptic drugs. Cost of epilepsy had been estimated in several developed countries, but there were few studies which mentioned cost estimation due to epilepsy especially at private set up. Cost estimation is very important in health care planning and

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delivery of services. Keeping all these factors in mind it was decided to conduct current study with objective to study the utilization pattern of anti-epileptic drugs (AEDs) in epileptic patients according to WHO indicators and also to estimate costs of epilepsy treatment, thus emphasizing total financial burden of epilepsy to the patient.

MATERIALS AND METHODS

Study Site

This was prospective, observational study done at Life Line hospital, Azamgarh, India after taking No Objection Certificate from Hospital Authorities. The duration of the study was 12 months from February 2019-February 2020 where 300 patients were enrolled as per inclusion and exclusion criteria.

Inclusion criteria

All Patients of epilepsy of either gender in the age group of 18 years and above and all those who were willing to give the written informed consent form were included.

Exclusion criteria

Patients who were not willing to sign the informed consent and all Patients of epilepsy of either gender in the age group below 18 years. Pregnant women and Lactating mother were excluded.

Study Procedure

The data was collected during regular visit to Out Patients Department (OPD) and in ward round for collection of data of In Patients Departments (IPD) participation in the Department of Neurology, Life Line hospital, Azamgarh. Standard data entry format was used to enter all the patient details collected during visit to OPD and IPD at the study site. The prescriptions were individually screened to assess the prescribing pattern of antiepileptics. The cost of the antiepileptics was assessed by analysing the prescribed antiepileptics with Generic name and Brand name at Life Line Hospital Azamgarh. Cost of prescribed antiepileptics with Generic name and Brand name at the study places were statistically analysed. All the Patients were followed up for minimum 6 months following their enrolment. Based on the history and Pill count all the Participants were observed for the compliance of the therapy. A specially designed data entry format was used to enter all the information pertaining to the patient and drug therapy given were recorded in a Case Record Form (CRF), the information of which were obtained from Patient case files. During the course of the study the enrolled Patients were followed for occurrence of ADR and the same were reported to ADRs Monitoring centre. The collected data were thoroughly reviewed to maintain the quality of data. Transcribed data were also reviewed against data collection Performa to minimize transcription error's.

After completion of the study, data were collected and analysed using student's *t* test and chi-square test.

RESULTS

A total of 300 Patients undergoing treatment with different kinds of Antiepileptics were enrolled. It was observed that 207(69.08%) were Male whereas 93(30.92%) were female. Out of 300 Patients, it was observed that majority of Patients were in the Age group of 18-30 years (35.66%) followed by Age group of 31-43years (21.33%). While Patients with age group of >69 years was minimum (8.66%) as represented in Table 1 ($\chi^2=3.233$; $d_f=4$).

On analysing types of epileptic Seizures, it was observed that 145(48.33%) patients were diagnosed with generalized seizure followed by 68(22.66%) patients with Partial seizure while 07(2.33%) cases of Unclassified seizure

were diagnosed. Amongst Generalized seizure, 101(33.66%) patients were diagnosed with GTCS which was the most common type of seizure observed while 3(1%) patients were diagnosed with Absence seizure which was the least commonly observed seizure amongst Generalized seizure as depicted in Table 2 ($\chi^2=8.375.233$; $d_f=5$).

The study reports revealed that a total of 98 patients observed side effects and it was more prone among females than male patients. Among the ADRs majority of Patients 27(9%) had headache followed by Nausea and Vomiting in 21(7%) patients while least observed ADRs was Sedation in 3(1%) each patients as represented in Table 3 ($\chi^2=9.057$; $d_f=5$).

In our study done on 300 patients diagnosed with different types of seizures, total drugs prescribed for treating Epileptic seizure were 1014 amongst which 55(5.42%) were prescribed with Generic name and 959(94.57%) were prescribed with Brand name. In our study average no. AEDs used at private Hospital were 3.38 % as represented in Table 4 ($\chi^2=0.000$; $d_f=1$).

On analysing the AEDs used in Patients diagnosed with different types of seizures, the study reports revealed that total utilization of AEDs was 1014 drugs, out of which Valproic acid was prescribed in 154 encounters (15.18%) which was the most commonly prescribed AEDs followed by Phenobarbitone in 149 encounters (14.69%) for the treatment of seizures as shown in Table 5.

The total average cost for 6 months of drug treatment was Rs. 64752.02. Cost of Conventional AEDs for 6 months of drug treatment was Rs. 28427.75 whereas Cost of Newer AEDs for 6 months of drug treatment was Rs. 36324.90. Average cost per prescription was Rs. 1553.50 which includes the cost of consultation as depicted in Table 6 and 7.

DISCUSSION

The overall aim of antiepileptic treatment should be to control seizures with the lowest possible occurrence of adverse effects, allowing the Patients to become an active member of the community and this at the lowest possible overall cost. This comparative, prospective, observational study aims at providing a snapshot of the AEDs usage pattern Government (Tertiary care teaching hospital) and Private Hospital.

Among 300 patients studied Males (N=207, 69.08%) predominance was seen over females (N=93, 30.98%) which also complemented with a study done at Private hospital by Ashli *et al.* who also reported predominance of males overfemales.¹⁵ Similar findings were reported by Bhojan *et al.* in a study done at corporate hospital.¹⁶ While the reasons behind gender differences are not clear, it has been generally observed that men have a higher incidence of focal epilepsy while women are influenced by genetic factors or hormones where it supposed that estrogen has a seizure

Table 1: Gender wise Age group distribution of Epileptic Patients at the time of Diagnosis (n=300).

Age group(years)	Patients		Total (%)
	Male (%) (n=207)	Female (%) (n=93)	
18-30	79 (38.16)	28 (30.10)	107 (35.66)
31-43	41 (19.80)	23 (24.73)	64 (21.33)
44-56	37 (17.87)	22 (23.65)	59 (19.66)
57-69	31 (14.97)	13 (13.97)	44 (14.66)
>69	19 (9.17)	07 (7.52)	26 (8.66)
Total (%)	207 (100)	93 (100)	300 (100)
Grand Total (%)	69	31	100

$\chi^2=3.233$ $d_f=4$ $p=0.5195$

Table 2: Distribution of types of Epileptic Seizures Gender wise (n=300).

S.No	Type of Seizure	Patients		Total (%) (n=300)
		Male (%) (n=207)	Female (%) (n=93)	
1.	Generalized Seizure			
	GTCS(Grand mal)	79 (38.16)	22 (23.65)	101 (33.66)
	GTS	13 (6.28)	05 (5.37)	18 (6.00)
	GCS	03 (1.44)	04 (4.30)	07 (2.33)
	AS(Absence)	03 (1.44)	00 (0.00)	03 (1.00)
	As	06 (2.89)	04 (4.30)	10 (3.33)
	MS	03 (1.44)	03 (3.22)	06 (2.00)
	2.	Partial Seizure		
SPS		19 (9.17)	14 (15.05)	33 (11.00)
CPS		15 (7.24)	10 (10.75)	25 (8.33)
	Partial seizure with secondary generalization	07 (3.38)	03 (3.22)	10 (3.33)
3.	Status Epilepticus	55 (26.57)	25 (26.88)	80 (26.66)
4.	Unclassified Seizure	04 (1.93)	03 (3.22)	07 (2.33)
	Total (%)	207 (100)	93 (100)	300 (100)
	Grand Total (%)	69	31	100

$\chi^2_5 = 8.375.233$ $d_f = 5$ $p = 0.1201$

Table 3: ADRs observed in Epileptic Patients (n=300).

ADRs observed	Patients		Total (%) (n=98)
	Male (%) (n=39)	Female (%) (n=59)	
Hematological reactions	04 (10.25)	02 (3.38)	06 (6.12)
Hyperglycemia	03 (7.69)	01 (1.69)	04 (4.08)
Rash, Urticaria	02 (5.12)	07 (11.86)	09 (9.18)
Gum Hyperplasia	01 (2.56)	02 (3.38)	03 (3.06)
Sedation	02 (5.12)	01 (1.69)	03 (3.06)
Headache	13 (33.33)	14 (23.72)	27 (27.55)
Nausea and Vomiting	04 (10.25)	17 (28.81)	21 (21.42)
GIT disturbances	06 (15.38)	07 (11.86)	13 (13.26)
Others	04 (10.25)	08 (13.55)	12 (12.24)
Total (%)	39 (100)	59 (100)	98 (100)
Grand Total (%)	39.79	60.20	100

$\chi^2_5 = 9.057$ $d_f = 5$ $p = 0.1068$

Table 4: Drugs Prescribed by Generic Name/Brand Name (n=1014).

Types of Name	ANTIEPILEPTICS DRUGS (AEDs)		No. of AEDs (%)
	Patients		
	Male (%)	Female (%)	
GENERIC NAME	38 (5.42)	17 (5.41)	55 (5.42)
BRAND NAME	662 (94.57)	297 (94.58)	959 (94.57)
Total (%)	700 (100)	314 (100)	1014 (100)

$\chi^2_1 = 0.000$ $d_f = 1$ $p = 1.575$

Table 5: AEDs use profile as a function of the type of epileptic seizure (n=1014).

S.No	ANTIEPILEPTIC DRUGS	SEIZURE TYPE				Total (%)
		Generalized seizures (%)	Partial seizures (%)	Status epilepticus (%)	Unclassified Seizure (%)	
1.	Phenytoin	54 (10.22)	24 (7.12)	10 (10.20)	01 (1.96)	89 (8.77)
2.	Carbamazepine	47 (8.90)	20 (5.93)	07 (7.14)	03 (5.88)	77 (7.59)
3.	Phenobarbitone	96 (18.18)	36 (10.68)	13 (13.26)	04 (7.84)	149 (14.69)
4.	Valproic acid	91 (17.23)	51 (15.13)	09 (9.18)	04 (7.84)	154 (15.18)
5.	Levetiracetam	36 (6.81)	43 (12.75)	00 (0.00)	02 (3.92)	81 (7.98)
6.	Lamotrigine	25 (4.73)	25 (7.41)	03 (3.06)	02 (3.92)	56 (5.52)
7.	Topiramate	12 (2.27)	21 (6.23)	04 (4.08)	02 (3.92)	39 (3.84)
8.	Zosinamide	00 (0.00)	02 (0.59)	00 (0.00)	00 (0.00)	02 (0.19)
9.	Clonazepam	47 (8.90)	32 (9.49)	11 (11.22)	03 (5.88)	93 (9.17)
10.	Fosphenytoin	12 (2.27)	00 (0.00)	30 (30.61)	00 (0.00)	42 (4.14)
11.	Zolpidem	36 (6.81)	20 (5.93)	09 (9.18)	03 (5.88)	68 (6.70)
12.	Gabapentin + Pregablin	17 (3.21)	34 (10.08)	00 (0.00)	00 (0.00)	51 (5.02)
13.	Oxcarbamazepine	54 (10.22)	28 (8.30)	00 (0.00)	03 (5.88)	85 (8.38)
14.	Ethosuximide	00 (0.00)	00 (0.00)	00 (0.00)	19 (37.25)	19 (1.87)
15.	Midazolam	01 (0.18)	00 (0.00)	02 (2.04)	06 (11.76)	09 (0.88)
	Total	528 (100)	337 (100)	98 (100)	51 (100)	1014 (100)
	Grand total (%)	52.07	33.23	9.66	5.02	100

Table 6: Cost Estimation of AEDs for 6 months (n=1014).

S. No	Type of antiepileptic drugs	Prescribed by Generic name	Prescribed by Brand name	No. of Encounters	Average Cost estimation for 6 months of drug treatment
1.	Conventional AEDs (%)	37 (5.58)	625 (94.41)	662 (100)	28427.75
2.	Newer AEDs (%)	20 (5.68)	332 (94.31)	352 (100)	36324.90
Total (%)		57(5.62)	957(94.37)	1014(100)	Avg. cost/6months = 64752.02

Table 7: Estimation of direct Cost of Epilepsy treatment in a 6 months follow-up.

Parameters					
		Dose (mg)	Cost/strip(10 tab) (INR)	No. of Encounters	Total (Rs.)
Drugs (Oral)	Phenytoin	50	22.50	8	180
		100	38.00	47	1786
		300	56.66	34	1926.44
	Carbamazepine	100	70.00	5	350
		200	110.00	17	1870
		300	35.00	39	1365
	Phenobarbitone	400	45.75	16	732
		30	24.54	109	2674.86
		60	35.00	40	1400
	Valproic acid	200	46.00	34	1564
		300	56.00	69	3864
		500	134.00	51	6834
	Levetiracetam	250	99.00	18	1782
		500	186.00	47	8742
		750	280.90	16	4494.40
	Lamotrigine	25	50.00	14	700
		50	90.50	23	2081.50
		100	158.00	19	3002
	Topiramate	25	38.00	11	418
		50	85.00	23	1955
100		158.00	5	790	
Zosinamide	50	59.40	1	59.40	
	100	160.00	1	160	
Clonazepam	0.25	20.35	67	1363.45	
	0.5	45.00	26	1170	
Gabapentin	100	65.00	6	390	
	300	124.00	13	1612	
Zolpidem	10	30.00	68	2040	
	150	50.00	16	800	
Oxcarbamazepine	300	85.00	55	4675	
	600	134.00	14	1876	
	20	42.00	8	336	
Ethosuximide	40	74.00	11	814	

		Cost/Ampoule			
Parenteral	Midazolam	5mg	22.00	9	198
	Fosphenytoin	15 mg	17.80	42	747.60
		Cost/ Test			
Diagnostic test	EEG		900	53	47700
	CT Scan		1250	112	140000
	X-ray		500	171	85500
Consultation fees			Rs. 350	366	128100
	Total				466052.65

Average cost/Prescription= Total cost (in Rs) /No. of patients
 = 466052.65/300
 = Rs. 1553.50

activating the effect, whereas progesterone exerts a seizure protective effect leading to a higher incidence of generalized epilepsy.

In our study it was observed that majority of Patients were from age group of 18-30 (35.66%) followed by age group between 31-43 (21.33%) which almost complemented to a study done by Pal *et al.*¹⁷ who reported around 40% of patients aged between 15-40 and to a study done by Ashli *et al.*¹⁵ who reported 45% belonged to age group below 40. It is suggestive of slightly higher incidence rate of epilepsy among age group of people less than 40 years in India.

In our study at Private hospital, total 145(48.33%) patients were diagnosed with Generalized Tonic-Clonic Seizure followed by 68(22.66%) patients with Partial seizure, Status epileptics (26.66%) and Unclassified seizure (2.33%) which was contradictory from study done by Bhojan *et al.* at corporate hospital who reported Generalized Tonic-Clonic Seizure to be 8.2%.¹⁶ There is wide range of variety in occurring of various types of seizures in various geographical areas of world. In our study, the lack of a peak in the elderly was probably because of the relative young and middle age of our study population.

ADRs studies revealed a predominance of the female over male. These observations were similar to the study done by Pal *et al.* who reported predominance of the female over male.¹⁷ Our study revealed a total number of 98(32.66%) ADRs of which Headache was the most common adverse effect faced by 27 (9%) patients, which was followed by Nausea and vomiting 21 (7%). These findings were different to the other studies.¹⁷ In our study, Phenobarbitone and Phenytoin were most common drugs causing ADRs.

During the study period on analysing the no. of drugs prescribed by Generic and Brand name, it was observed that out of 1014 AEDs prescribed at Private hospital, 5.42% of AEDs were prescribed by Generic name and 94.57% of AEDs were prescribed by Brand name. Our study revealed that average no. AEDs used were 3.38% per prescription. Our study results were slightly lower than the findings of Mane *et al.* in context of drugs prescribed with generic name which was 8.72% while it was contradictory in context of findings of average no. AEDs used which was 1.99%.¹⁸ Higher numbers of drugs prescribed with brand name, in our study, is not suggestive of rational prescribing practice. Such irrational prescribing practice should be discouraged. Higher number of drugs per prescription, e.g. 3.38%, is suggestive of polypharmacy and will have impact on economic aspects of healthcare due to increase in cost of therapy. We observed that 34.71% of newer AEDs were prescribed.

On analysing out of 1014 AEDs it was observed that valproic acid was the most commonly prescribed AEDs drug (15.18%) followed by phenobarbitone (14.69%). These findings were similar to study done by Pal *et al.* at tertiary teaching hospital while contradictory

to the findings of Shaheed *et al.* who stated levetiracetam as the most commonly prescribed AEDs in their study done at private hospital.^{17,19} In our study, among Newer Antiepileptic drugs, oxcarbamazepine was the most commonly prescribed drug (8.38%) followed by levetiracetam (7.98%). In most of the studies, we can see that conventional AEDs are still preferable due to better proven efficacy and available safety profile of drugs over newer AEDs.

Average costs of drugs borne by epileptic patient were Rs. 64752.02 for a period of 6 months for treating Epilepsy. We found that average cost per prescription was Rs. 1553.50 which includes the cost of consultation. It is on higher side for patients in developing country like India. Increased cost may be due to increase in the percentage of drugs prescribed with brand name. Our results were different from the findings of an Indian study done by Thomas *et al.*²⁰ Prescribing AEDs by generic names can solve this issue to the some level.

CONCLUSION

Through our study it was concluded that prescribing patterns were according to the indicators mentioned by WHO/INRUD except that very less drugs were prescribed by generic name. Older antiepileptic drugs were still commonly prescribed drugs as compared to newer drugs. Although newer drugs were prescribed less, but due to increased consultation fee, prescribing brand name and increased diagnostic test at private set up economic burden has increased in epilepsy management which needs to be minimized. This study highlights the need of drug utilization evaluation as it helps to analyse on going health care practices, so that lacunae in the system can be identified and Proper strategies can be planned to rectify them.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

ILAE : International league against Epilepsy, **AEDs**: Antiepileptic drugs; **WHO**: World Health Organization; **ADRs**: Adverse Drug Reactions; **CRF**: Case record form; **OPD**: Outpatient departments; **IPD**: In patient department; **GTCS**: Generalized Tonic clonic Seizure.

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