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DRUG UTILIZATION EVALUATION OF ANTI-EPILEPTICS IN A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Neurological diseases are gaining more importance in the developing countries like India in recent times. Epilepsy is one of the most important neurological disorders. It describes a condition in which a person experience recurrent seizures due to a chronic, underlying process. A Prospective Observational study was carried out at Rajiv Gandhi Institute of Medical Sciences, Kadapa. A total of 65 patients were selected in a 6 months period based upon the inclusion and exclusion criteria. In the present study we made an attempt to conduct Drug utilization evaluation (DUE) in epileptic patients to improve treatment rationality in a tertiary care teaching hospital. Demographic and prescription data was collected and assessed based upon the DUE. From that we found that generalized seizures were the most prominent seizure encountered and monotherapy was the most frequently used treatment in all types of epileptic seizures. Our data suggests that unknown cause and stress is main offender of symptomatic epilepsy. Furthermore, we observed that there was some inappropriate usage of Anti-epileptic drugs which comprises drug-drug interaction and incorrect dosage regimen. we found generalized seizures were the most prominent seizure encountered and monotherapy was the most frequently used treatment in all types of epileptic seizures. Most commonly prescribed drug was Phenytoin. We found ADRs, medication errors and drug interactions in

this study and we did interventions too. Through this study we brought awareness about DUE in both health care professionals and in patients.

KEYWORDS: Epilepsy, Anti-epileptic drugs, Drug utilization evaluation, Monotherapy.

INTRODUCTION

Neurological diseases are important causes of long term morbidity. Epilepsy is one of them. It affects about 50 million people worldwide and involving an additional 500 million people as family members and caregivers of patients. Although a number of antiepileptic drugs (AEDs) are available for the treatment of epilepsy. However, the preferred approach for the management of epilepsy is monotherapy with antiepileptic drugs.[1]

Approximately 37 million individuals across the globe suffer from epilepsy and it is estimated that more than80% of them live in developing countries [2]. In developed countries, the prevalence of epilepsy ranges between 5 and 8 / 1000 people whereas in the developing world (e.g. Latin America, Africa) the prevalence has been reported to be more than 40 / 1000. It is the most common neurological condition worldwide with Indian prevalence of 572.8/100,000 population/year. (Banerjee et al., 2010). It has been estimated that India with 6-10 million people with epilepsy accounts for nearly 1/5th of the global burden of the dreaded disease. It is important to recognize that the distribution of epilepsy in the population is not uniform across age groups. Each year, partial epilepsy with partial or secondarily generalized tonic clonic seizures develops in 70,000 to 130,000 adults. If such seizures are not controlled major compromises in the quality of life result.[3,4,5]

In general, a person is not considered to have epilepsy until he or she has had two or more unprovoked seizures separated by at least 24 hours. In contrast, a provoked seizure is one caused by a known precipitating factor such as a high fever, nervous system infections, acute traumatic brain injury, or fluctuations in blood sugar or electrolyte levels. Its prevalence varies in relation to ethnicity, geography, age and sex [6]. Some factors like stroke, head trauma, alcoholism or alcohol withdrawal, Alzheimer's disease, Heart attacks, and other conditions that deprive the brain of oxygen, Abnormal blood vessel formation (arteriovenous malformations) or bleeding in the brain (hemorrhage), Inflammation of the brain, Infections such as meningitis, HIV, and viral encephalitis and unknown causes may leads to seizures which further leads to epilepsy. AED treatment has been demonstrated to control seizure, which decreases morbidity and mortality associated with epilepsy. Nevertheless, the risks of

significant adverse effects and drug interaction increase when more than one drug is used. Hence, drug use evaluation (DUE) programs play a key role in helping managed health care systems understand, interpret, and improve the prescribing, administration, and use of AEDs[7] and up to 70% (7 in 10) people with epilepsy could have their seizures completely controlled with AEDs. There are around 26 AEDs used to treat seizures, and different AEDs work for different seizures.

Drug use evaluation (DUE) was originally known as drug utilization review (DUR) in the 1970s and early 1980's. The term drug utilization review (DUR) and drug use evaluation (DUE) is interchangeable. It is an ongoing, systematic process designed to maintain the appropriate and effective use of drugs [7]. It is a review and assessment of the appropriateness of prescription drug use and also the prescribing patterns [2]. It involves comprehensive review of patients' prescription and medication data before, during and after dispensing in order to assure appropriate therapeutic discussion making and positive patient outcomes. Pharmacists participating in DUE programs can directly improve the quality of care for patients, individually & as populations, by preventing the use of unnecessary or inappropriate drug therapy & by preventing adverse drug reactions [8]. Thereby improving the rationality of the drugs with the ultimate goal of improving quality of patients' life by seizure free periods, and minimizing side effects[9]. Main aim of this study is to conduct DUE(Drug utilization evaluation) in epileptic patients in a tertiary care teaching hospital and to improve treatment rationality. Medicines may be irrationally used which reduces the quality of life of the patient and causes harm to the patients. So there is a need to do prescription based survey (drug utilization study) to analyze the prescribing patterns and to improve the quality of treatment.

OBJECTIVES

- To assess the prescribing pattern of Anti epileptics
- To promote safety and effective drug therapy.
- To provide awareness in epileptic patients
- To identify and rectify the Drug related problems

MATERIALS AND METHODS

This is a Prospective Observational study conducted in General Medicine and psychiatry wards at Rajiv Gandhi Institute of Medical Sciences (RIMS), Kadapa. This study was approved (Rc No.4226/ Acad. /2015) by Ethical committee of Rajiv Gandhi Institute of Medical Science, Kadapa. A total of 65 patients were selected in a 6 months period and an

informed consent form was collected from each patient prior to the study. Patients were included in this study if they met all of the following criteria:

Inclusion Criteria

- Adult Epileptic patients under the age group of 20 – 60 years with or without psychiatric problems.
- Subjects willing to participate in the study and able to give their consent.
- Subjects who came for regular checkups.

Exclusion Criteria

- Pediatric, Adolescent and Geriatric patients.
- Patients who didn't come to the hospital for regular checkup.
- Pregnancy induced seizures.

The following are the study materials used in this study.

Study Materials

- ✓ Patient Data Collection Form (Annexure I)
- ✓ Medication error form (Annexure II)
- ✓ Adverse drug reactions form (Annexure III)
- ✓ Pharmacist intervention form (Annexure IV)
- ✓ Patient Inform Consent Form (Annexure V)
- ✓ Patient counseling form (Annexure VI)
- ✓ Patient Information Leaflet (Annexure VII)

Method

The patients who visited to the General Medicine (IP and OP) and Psychiatry (IP and OP) departments on daily basis were screened. Demographic data from those subjects and their care takers was collected and assessed by Data collection form (Annexure-I). Subjects who are eligible were included in the study according to inclusion criteria. Patient was interviewed by using self-inform consent form whether he/she is willing to participate in this study or not. It is utmost importance that human volunteer participating in a scientific research project, for instance a clinical study, understands all details of the planned experiment. Patients who are willing to participate in the study their Demographic data, clinical data, and relevant data like past medical history, present illness, drug-food, drug-drug interactions, side effects, dosing information, and allergies were collected and evaluated. Interventions were done for the

identified DRPs (Drug Related Problems), Adverse Drug Reactions, Medication errors and Drug- drug interactions). For the identified and suspected adverse drug reactions, analysis was done by using scales to find out the causality i.e. Naranjo's causality assessment scale, WHO causality assessment scale, Karch and Lasagnans scale. Outcomes was assessed and the patients was counseled regarding medications, disease, adverse drug reaction and lifestyle modification by using patient counseling leaflet.

RESULTS

Patient Distribution Based Upon demographics

1.1.1 BASED ON GENDER

In a total number of 65 patient the gender distribution revealed that number of males and females patients were 52 (80%) and 13 (20%), respectively which were represented in the fig.1.1.

Fig. 1.1.1: Gender Distributions of Patients.

1.1.2. Patient Distribution Based on Age

Total distribution of patients with respect to age group shows that 56.9% were in the age group 20-29 years followed by 16.9% in 50-60 years, 15.3% in 30-39 years then finally 10.7% in 40-49 years were represented in table 1.1.2 and figure 1.2.

Table 1.1.2: Age Distribution of Patients.

Age Group	Number of patients	Percentage (%)
20-29	37	56.9
30-39	10	15.3
40-49	7	10.7
50-60	11	16.9
Total	**65**	**100**

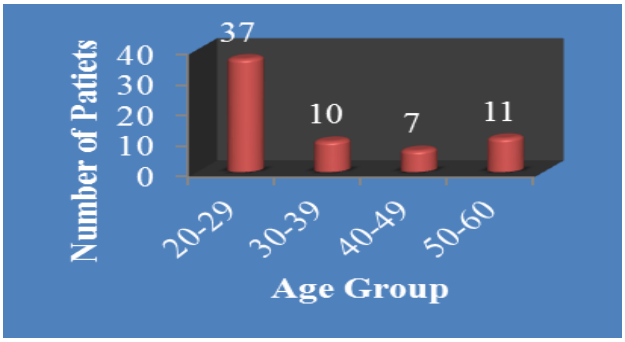


Figure 1.1.2: Age Distribution of Patients.

1.1.3. Patient Distribution Based On Gender

Patients were distributed into age groups based on their gender and which revealed that number of males and females found in between the age group 20-29 years were 51.9% and 76.9% respectively, followed by 17.3% and 7.6% in 30-39 years, 40-49 11.5% and 7.6% in 40-49 years then finally 19.2% and 7.6% in 50-60 years were represented in table 1.1.3.

Table 1.1.3: Age Distribution based on Gender.

Age Group	Males	Percentage (%)	Females	Percentage (%)
20-29	27	51.9	10	76.9
30-39	9	17.3	1	7.6
40-49	6	11.5	1	7.6
50-60	10	19.2	1	7.6
Total	52	100	13	100

1.1.4. Patient Distribution Based On Literacy

Out of 65 patients, 17 (26.1%) were found to be literates in that 15 (28.8%) were male and 2 (71.1%) female patients and remaining 48 (73.8%) were illiterate, of which 37 (15.3%) were males and 11(84.6%) were found to be females, results were represented the figure 1.1.4.

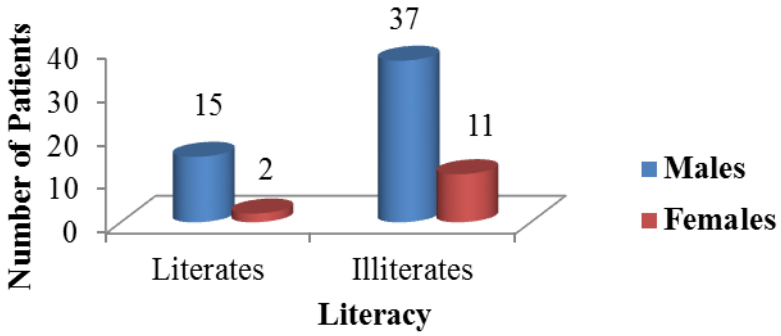


Figure 1.1.4 Literacy Status of the Patients

1.2. Patient Distribution Based On Socio-Economic Status

Based on Occupation

Total distribution of patients with respective to their Occupation were found to be majorly Coolies 22 (33.8%), followed by students, housewives and others.

1.3. Patient Distribution Based Upon Habitual History of Patients

Among 65 patients, Habituated to both Smoking and Alcohol were 39 (59.93%) and non-habituated to Smoking and Alcohol were found to be 26 (40%) as shown in the table 1.3 and figure 1.3.

Table 1.3 Distribution based on Habitual history.

Habitual/ Non - Habitual History	No. of patients	Percentage (%)
Alcoholics & Smokers	39	59.93
Non habituated	26	40
Total	65	100

Figure 1.3: Distribution based on Habitual history.

1.4. Patient Distribution Based Upon Family History

A total of 65 patients, 5 (7.69%) patients showed family history of epilepsy when compared to others.

1.5. Distribution Based On Residence Area

Among 65 patients, rural patients were 41 (63.07%) and urban patients were 8 (36.92%) as represented in the table 1.5 and figure 1.5

Table 1.5: Distribution based on Residence area.

Population	No. of patients	Percentage (%)
Rural	41	63.07%
Urban	24	36.92%
Total	65	100%

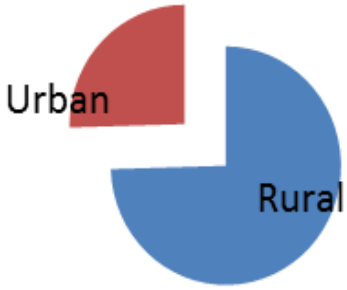


Figure 1.5: Distribution based on Residence area.

1.6. Patients Distribution Based Upon Epilepsy and Psychiatric Co-Morbidities:

Among the observed patients only epileptic patients were 41 (63.07%), followed by Epilepsy with Psychiatric co morbidities 24 (36.92%) as represented in the table 1.6.

Table 1.6: Distribution based on Co morbidities.

Population	No. of patients	Percentage (%)
Only Epileptics	41	63.07
Epilepsy with Mental Retardation	24	36.92
Total	65	100

1.7. Distribution Based Upon Type of Seizure

Out of 65 patients, seizure types of the study population showed that GTCS- 66.1% in 43 patients followed by Drug withdrawal seizures- 10.7% in 7 patients, Alcohol withdrawal seizures- 6.1% in 4 patients, Status epilepticus- 9.2% in 6 patients, Febrile seizures- 6.1% in 4 patients and Tonic seizures- 1.5% in 1 patients, as explained in the figure 1.7.

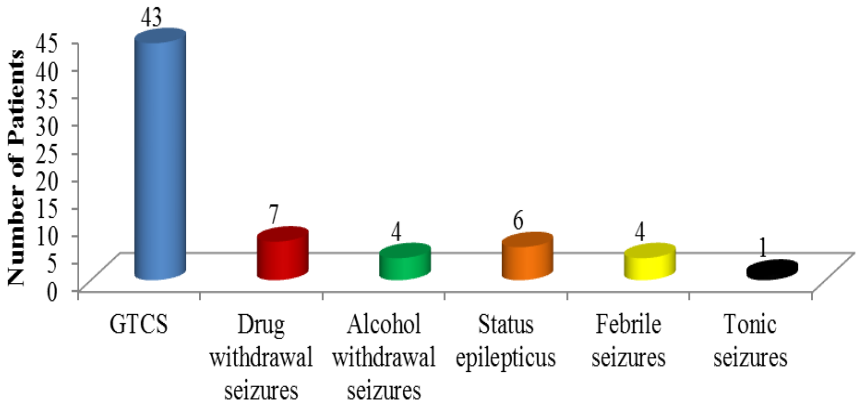


Figure 1.7 Categorization of Seizures

1.8. Prescribing Pattern of Aeds

A total of 105 AEDs were prescribed to 65 patients during the study period,. Table 1.8 summarizes the AED utilization pattern among the study population. In the study population, 33 patients received monotherapy, 24 patients received two drug regimen and 8 patients received three drug regimen for the management of epilepsy.

Table 1.8: Utilization Pattern of AEDs.

Type of seizures	Mono therapy	Percentage (%)	Two Drug Regimen	Percentage (%)	Three Drug Regimen	Percentage (%)
GTCS	23	69.6	17	70.8	3	37.5
Drug withdrawal seizures	4	12.1	2	8.3	1	12.5
Alcohol withdrawal seizures	3	9	1	4.1	0	0
Status epileptics	0	0	2	8.3	4	50
Febrile seizures	2	6	2	8.3	0	0
Tonic seizures	1	3	0	0	0	0
Total	33	100	24	100	8	100

1.9. Etiological Classification of Seizure

Majorly unknown problems were seen followed by stress, cerebral infection, drug withdrawal seizures, electrolyte disturbance, stress, alcoholic withdrawal and genetic disorders. There were the major reasons in our study population as represented in the figure 1.9.

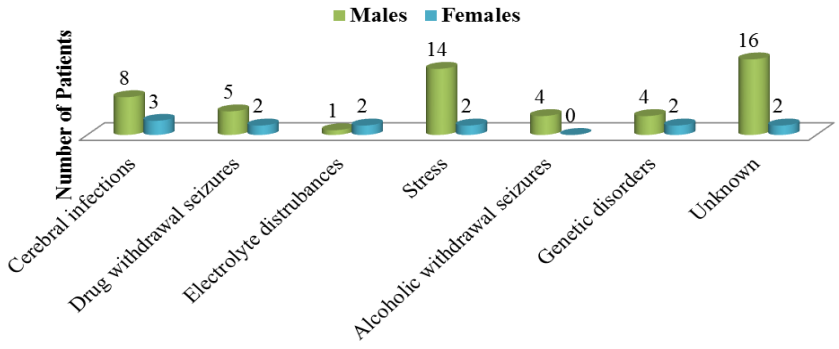


Figure 1.9 Etiological categorization of Seizure

1.10 Utilization of Various Aeds

A total of 6 types anti-epileptic drugs i.e. Phenytoin, Carbamazepine, Midazolam, Levetiracetam, Sodium Valproate and Diazepam were prescribed in 65 patients. Phenytoin had been prescribed to 56 (86 %) patients out of 65 either alone or in a combination, Diazepam 13 (20%), sodium valproate 12 (18 %), Carbamazepine 9 (14 %), Levetiracetam 8 (12%) and Midazolam 7 (11 %). The results were shown in the figure 1.10.

Table 1.10: Utilization of various AEDs.

Name of the drug	Number of patient	Percentage (%)
Phenytoin (P)	24	36.9
Carbamazepine (C)	5	7.6
Levetiracetam (L)	4	6.1
Phenytoin and sodium valproate (PS)	7	10.7
Phenytoin and carbamazepine (PC)	4	6.1
Midazolam and Phenytoin (PM)	3	4.6
Phenytoin and levetiracetam (PL)	3	4.6
Phenytoin and diazepam (PD)	7	10.7
Phenytoin, diazepam and midazolam (PDM)	2	3
Phenytoin, midazolam and sodium valproate (PMS)	1	1.5
Phenytoin, midazolam and levetiracetam (PML)	1	1.5
Phenytoin, diazepam and sodium valproate (PDS)	4	6.1
Total	**65**	**100**

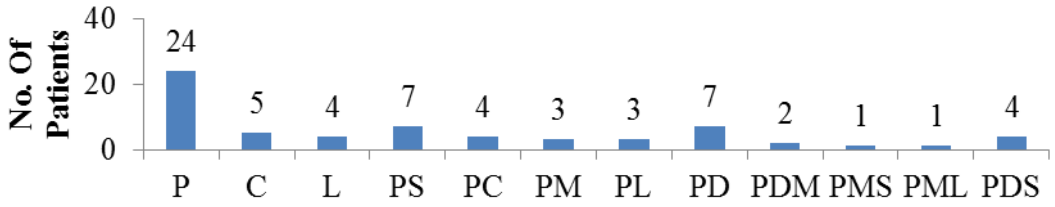


Figure 1.10: Utilization of various AED'S.

1.11. Formulation of Aeds

A total of 105 drugs were prescribed to 65 patients, in which 76 (72.3%) drugs were orals and 29 (27.6%) drugs were injectables, they were represented in table 6.16 and figure 6.16. It is further elaborated in table 1.11

Table 1.11: Types of Formulation.

Formulation	Drugs	Percentage
Oral	76	72.3
Injectables	29	27.6
Total	105	100

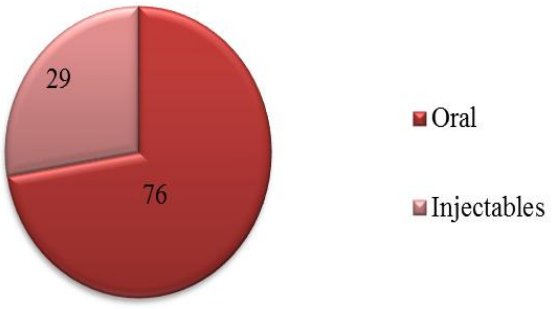


Figure 1.11 Types of Formulation.

1.12. Drug Related Problems

A total of 18 DRPs were found out of 65 patients, in which 8 (44.4%) were medication errors, followed by 7 (38.8%) ADRs and 3 (16.6%) drug interactions and 18 interventions were done, which are represented in table 1.12 and figure 1.12.

***Table 1.12 Drug Related Problems (DRP's).**

DRPs	Number of patients	Percentage (%)
Medication error	8	44.4
ADR's	7	38.8
Drug interactions	3	16.6
Interventions done	18	100

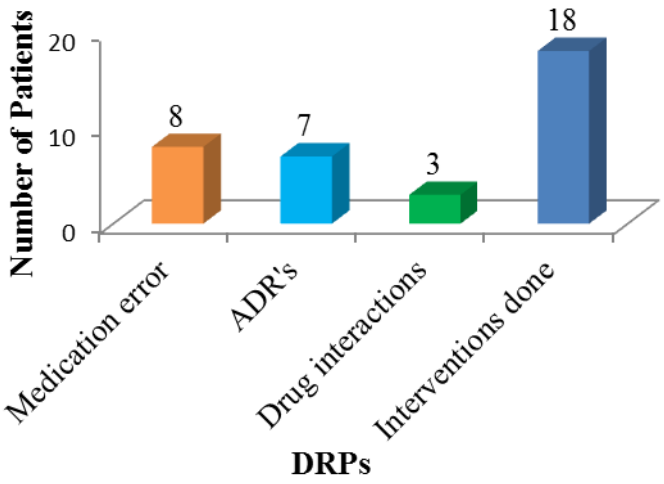
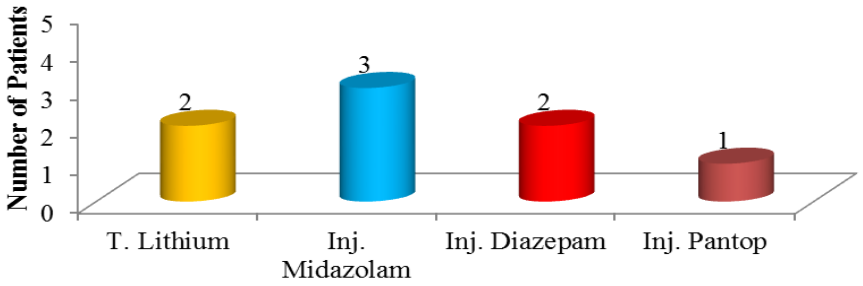


Figure 1.12 Drug Related Problems and…

1.13 Medication Errors: A total of 8 MEs were observed and all the errors were related to the "dose". Inj. Midazolam dose was omitted 3 (37.5 %) errors, inj. Diazepam dose was omitted in 2 (25 %), inj. Pantop dose was omitted in 1 (12.5 %) and Tab. Lithium dose was prescribed wrong in 2 (25 %) errors, as represented in table 1.13and figure 1.13.

Table 1.13 Drugs involved in MEs (Medication Errors).

No. of patients	Drug involved	Error	Intended
2	T. Lithium	400mg	Available dose of lithium is 300mg and 450mg
3	Inj. Midazolam	Dose was not mentioned	2.5mg
2	Inj. Diazepam	Dose was not mentioned	5mg
1	Inj. Pantop	Dose was not mentioned	40mg



Drug Name

Figure 1.13 Drugs involved in MEs

1.14. ADRs

Out of 7 ADRs, 4 (%) were carbamazepine induced ADRs followed by 3 (%) phenytoin induced ADRs. All the 7 ADRs were found to be possible ADRs according to the Narinjo's Scale. In 1 patient the suspected drug was withdrawn and treatment was provided for the ADR and in remaining 6 patients dose of the suspected drug was reduced, which are represented in table 1.14 and figure 1.14.

Table 1.14 Drugs involved in ADRs.

No. of patients	ADR reported	Suspected drug	Causality relationship	Whether treatment with AED continued / stopped	Antidote given/Action Taken
2	Gingivitis	Phenytoin	Possible	Continued	Dose reduced
1	Aplastic anemia	Phenytoin	Possible	Stopped	Blood Transfusion done
3	Sedation	Carbamazepine	Possible	Continued	Dose reduced
1	Constipation	Carbamazepine	Possible	Continued	Laxative (Bisacodyl)

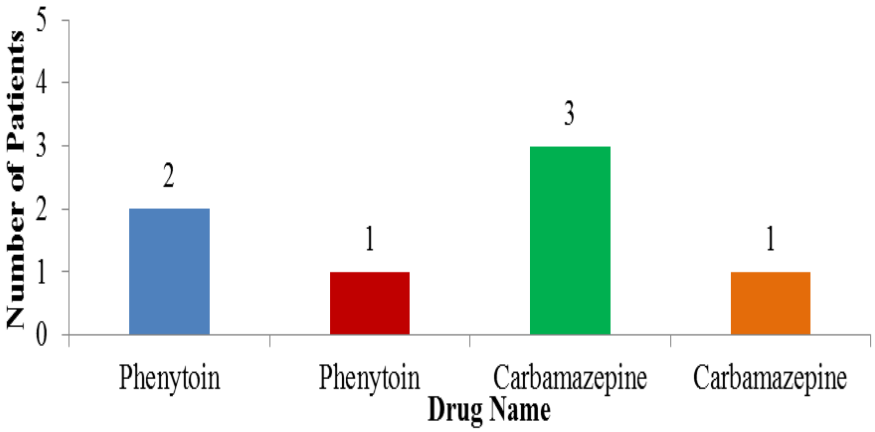


Figure 1.14 Drugs involved in ADRs

1.15 Observed Drug-Drug Interactions

A total of 3 drug-drug interactions were observed and the interactions were occurred by using Phenytoin drug i.e., 1 (33.3%) Phenytoin + Diazepam, 1 (33.3%) Phenytoin + Sodium valproate, 1 (33.3%) Phenytoin + Pantop as represented in table 6.21 and figure 6.21.

Table 1.15 Drug involved in interactions.

No. of patients	Drug interactions	Consequences
1	Phenytoin + Diazepam	Slurred speech
1	Phenytoin + Sodium valproate	Vomtings
1	Phenytoin + Pantop	Constipation

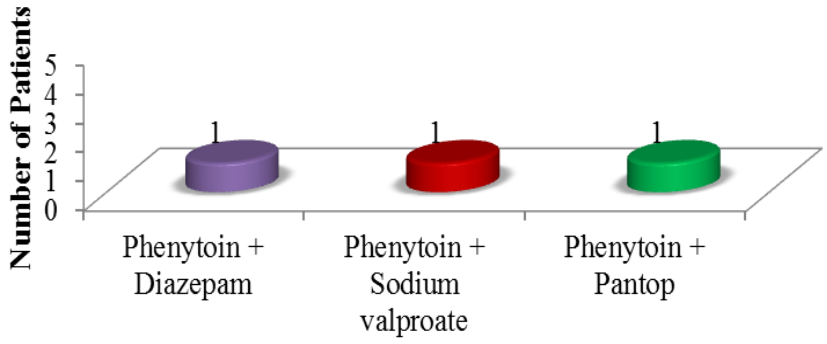


Figure 1.15 Drug involved in interactions

1.16. Pharmacist Interventions

A total of 18 (27%) Pharmacist interventions were done for all adverse drug reactions, drug-drug interactions and medication errors found.

DISCUSSION

Prescription based survey is considered to be one of the most effective methods to access and evaluate the prescribing attitude of physicians and dispensing practice of pharmacists. It is also important to consider the recommendations of international bodies on epilepsy that help to improve prescribing practice of the physician and ultimately, the clinical standards, to promote the rational use of drugs.

In our study we have recruited 65 subjects of which males constitute 52 (80%) and females constitute 13 (20%). According to the age group categorization, the patients in the age group of 20-29 were found to be maximum (56.9%) following 50-60 age group (16.9%). Our study had been supported by "y. Hanssens et al.[10] Drug utilization pattern of anti-epileptic drugs: a pharmacoepidemiologic study in oman" where they have reported that 35.7% of the patients

were in the age group of 21-30 years and it is similar to our study that majority of patients were recruited in the age group of 20-29 (56.9%).

We categorized study subjects based on literacy status and found majority of them were illiterates (73.8 %), similar to our study Abhik sinha et al[1] reported that very few of the study subjects were illiterates. Our study had been contrast by **"**Neuroepidemiology Of Epileptic Seizures: A Study From A Tertiary Care Setting Of Eastern India (2015)" where they have reported that 14.3% of the patients were illiterates and it is not similar to our study.

We categorized patients based upon the occupation in which we found majorly Coolies i.e. 33.8%, as the study site is a govt. hospital and majority of the patients consulting to this hospital were from this group only.

We categorized patients based on their habitual history in which 59.93 % were alcoholics and smokers. Our study had been contrast by "Neuroepidemiology of Epileptic Seizures: A Study From A Tertiary Care Setting Of Eastern India (2015)**"** where they have reported that 43.8% of the patients were Alcoholic and smokers and it is not similar to our study that indicates 59.93% patients.

As study disease is genetically transferable, we made an attempt to find family histories of the study population to confirm the etiology, and found 7.69% patients were having family history of epilepsy. Our study had been contrast by "Neuroepidemiology of Epileptic Seizures: A Study from a Tertiary Care Setting of Eastern India (2015)" where they have reported that in 315 patients.14.3 per cent cases of the patients were having family history of epilepsy.

Many studies revealed that the area of residence is having the influence on the occurrence of epilepsy so we distinguished patients based on their residence and found that 41 (63.07%) were from rural area when compared to urban population i.e. 8 (36.92%). Our study had been contrast by "Neuroepidemiology of Epileptic Seizures: A Study from a Tertiary Care Setting of Eastern India (2015)" here they have reported that 78(24.8%) cases of the patients were from rural area

In this study we tried to assess the psychiatric complications of the study subjects, as these are the major complications of epilepsy, and found around 35 % of the study patients were developed psychiatric complications.

We categorized patients based on seizure types, in that we found patients was majorly affected by GTCS i.e. 43 (66.1%) followed by 7 (10.7%) drug withdrawl seizures. Our study had been supported by "badwaik et al.[2] A drug utilization study of antiepileptic drugs use in a tertiary care hospital of central india (2015)" where they have reported that 66.4% of the patients were identified as GTCS and it is similar to our study that 66.1% patients were identified as GTCS.

We distinguished patients based on their etiology in which we found 18 (27.6%) unknown cause of seizures majorly affected followed by 16 (24.6%) due to stress. According to the etiological classification of seizures both males and females for unknown cause of seizures were 16 (30.7%) and 2 (15.3%) followed by 14 (26.9%) and 2 (15.3%) respectively. Our study had been contrast By "Pharmaco-Epidemiological And Pharmaco-Economic Analysis Of Antiepileptic Drugs At A Tertiary Level Health Care Centre - A Crosssectional Prospective Study (2016)" where they have reported that 16% of the patients were infectious disease and it is not similar to our study that 23% patients.

We categorized the patients based on drug utilization of various AED's therapy, both males and females was prescribed with Phenytoin 20 (38.4%) and 4 (30.7%) followed by carbamazepine 4 (7.6%) and 1 (7.6%) respectively. Our study had been supported by "juny sebastian et al.[4] Assessment of antiepileptic drugs usage in a south indian tertiary care teaching hospital (2013)" where they have reported that 42.1% of the patients were received Phenytoin and it is similar to our study that 36.9% patients.

We categorized formulations of AEDs which showed 76 (72.3%) were oral and 29 (27.6%) were Parentral formulations. In our study, majorly 76 (72.3%) oral formulations were administered in 65 study patients and 29 (27.6%) injectable formulations were prescribed.

We categorized Drug Related Problems in both males and females which showed that 5 (50%) and 3 (37.5%) have medication errors, followed by 3 (30%) and 4 (50%) with ADR's, 2 (20%) and 1 (12.5%) with drug-drug interactions. Interventions were done to all Drug related problems. In our study, we identified more Medications errors i.e. 8 (44.4%) in 65 patients.

In our study 65 patients with 7 Adverse Drug Reactions were screened, from these 38.8% with ADR's and total of 11%. It was contrast to the observation done by "shobhana mathur et

al.[6] "utilization pattern of antiepileptic drugs and their adverse effects, in a teaching hospital (2010)" where they have to reported that 4.67% ADR's were identified.

In our study, Clinical pharmacist interventions were 18 (27%) patients.

CONCLUSION

In the present study we made an attempt to do Drug utilization evaluation of anti-epileptic drugs in a tertiary care hospital. In that we found generalized seizures were the most prominent seizure encountered and monotherapy was the most frequently used treatment in all types of epileptic seizures. The Selection of the AEDs corresponds almost well with the known efficacy profile for specific epileptic seizures. The most commonly prescribed AED was Phenytoin, followed by sodium valproate, carbamazepine and the new generation AED, levetiracetam. Our data indicate that unknown cause and stress is main offender of symptomatic epilepsy. In our study we found that rural area population was affected more when compared to urban people. Most epileptics were managed with the conventional oral AEDs. There was inappropriate usage of AEDs which comprises drug interaction, inappropriate duration of treatment and incorrect dosage regimen which we found in this study.

Furthermore, we observed that some prescribers are not prescribing drugs based on the guidelines of epilepsy treatment. Hence, it is important for the health care professionals to practice good medical and drug history taking and record maintenance, as well as providing correct treatment based on the disease condition/symptoms.

Patient improvement in Knowledge regarding complications and preventive measures during epilepsy had attained after providing drug utilization evaluation and patient counseling by the clinical pharmacist.

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