



To Study of Drug Utilization Review in Epileptic Patients

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Abstract

Background: *There is an evidence of diverse patterns of drug utilization of antiepileptic drugs in our country. Newer drugs are becoming available now and how these drugs are utilized is very interesting to see. Problems in antiepileptic therapy like use of polytherapy, adverse drug reactions, lack of adherence to medications etc., can be identified and resolved by clinical pharmacist. Considering all these facts we started study with title "To Study of Drug Utilization Review in Epileptic Patients".*

Materials and Methods: *Prospective observational study of 6 months duration was carried out after human ethics research committee approval. All in-patients and outpatients who had epilepsy and prescribed with anti-epileptic drugs in neurology department were selected. Data were collected in customized data collection form after taking patient consent and also from patient case sheets/prescriptions. The data collection tool used for the study was a validated self-prepared questionnaire to assess the Drug Utilization Review and other objectives. Among the people with epilepsy, Data were measured in percentage and frequency using descriptive statistics. Microsoft excel was used to summarize the analysis of data. Chi –square test, t-test and Annova test was used.*

Results: *A total of 100 patients enrolled to study where 197 antiepileptic drugs were prescribed. The majority of patients belonged to age group 11-20 year (34%) followed by the age group 21-30 year (24%) The mean age of the participant was 25yrs. There were 56% male in sample and 44% female. In this study 24% patients with symptomatic epilepsy and idiopathic generalized epilepsy was 12 %. Prescription pattern of drugs showed that clobazam 31% was the most common drug used either as single, dual or in combination with other drugs to treat epilepsy. Mostly dual therapy (56%) was used to treat the patients. (22%) prescriptions for newer compared to older generation antiepileptic's. Variations of Sum-of- squares within the treatment i.e., between mono, dual and poly therapy is much more compare to the variations between the disease types and conditions. Hence, the newer prescribed anti-epileptic drugs shows the remarkable superior variables on account of low ADR compare to older anti-epileptic drugs. Majority of sample were compliant and never miss their medication (73%), only 10 patients was irregular in taking antiepileptic drugs and antiepileptic drug compliance. The study showed that there was no relationship between AED compliance these include patient age, gender, duration of illness, adverse drug reaction, type of therapy, and frequency of take medicine. By chi –square test. A significant relationship was found between age (0.0428), adverse drug reaction (p=0.05). Drug related problems were drug interaction (29.10%) followed by medication error (29%), adverse drug reaction (14%), untreated conditions (13.6), wrong dose (13). We counselled these patients.*

Conclusion: *Very less new antiepileptic drugs were used with high evidence of dual therapy. Clobazam was the most commonly prescribed drug. Clinical pharmacist mediated services helped to identify and reduce drug therapy related problems. Majority of patients found Drug compliance*

Keywords: *Antiepileptic drug, prescribing pattern, polytherapy, drug interaction, Drug compliance.*

Introduction

The subject of the study is the drug utilization review in epileptic patients. Designing a Hospital

based study enabled to interview all the people in the hospital, who were identified to have epilepsy. Drug utilization is outlined by World Health

Organization (WHO) as a think about of the study of systematic , Ongoing, criteria-based evaluation of drug use that will help certify that medicines are used correctly (at the individual patient level). If therapy is deemed to be inappropriate, intervention with provider or patients will be essential to optimize drug therapy is deemed to be inappropriate, interventions with providers or patients will be necessary to optimize drug therapy. A DUE is drug or disease - specific and can be structured so that it will assess the actual process of prescribing, dispensing or administering a drug (Indications, dose, drug interactions, etc.) DUE is the same as Drug utilization review (DUR)

Six types of generalized seizures exist- tonic seizures, absence seizures, tonic seizures, myoclonic seizures, clonic seizures, tonic- clonic seizures. Having seizures at definite times can lead to circumstances that are hazardous are drawing, falling, car accidents, etc. other life frightening obstacles of epilepsy are rare but may occur such as status epilepticus, sudden unexpected death in epilepsy.

This study plays a key role in serving achieved health care system understand, interpret, evaluate and improve the prescribing, administration and use of medications. All the data pertaining to the study were collected and recorded in a specially designed data collection form. Self-prepared structure questionnaire or data collection form contain five parts- patients demography, patient's disease details, medication detail, drug related problems, drug compliance. All the variables for the study were evaluated. The collected data were thoroughly screened to check the risk factors, prescribing pattern, Safety profiles of different generation of Antiepileptic Drug, Drug compliance and Drug Related Problems. Systematic sampling was done in epilepsy patients after settle on the sample size. Population type (all age group, both male and female) conditions. Data were collected in a well-designed Performa.

Methodology

Aim

To study the drug utilization review in epileptic patients.

Objective

- To assess the management of the epilepsy patients and to compare the safety profiles of antiepileptic drugs.
- To observe the drug compliance and drug related problems experienced during the course of therapy.

Plan of Work

The study of six months duration was perform in the multispecialty healthcare setting and is Distributed into three phases.

Phase I:

- Site of practice
- Design of study
- Criteria's of study
- Literatures survey
- Followed and selection of Performa
- Designing data collection form
- Approval and permission from hospital authority
- Approval and registering the study in the Institutional board

Phase II:

- Data collection

Phase III:

- Analysis and evaluation of collected data's Interpretation of results
- Deriving conclusion
- Limitations if any
- Recommendations.

Sources of Data

All the relevant and necessary data was collected from the following sources-patients consent form, Patients data collection form, Patient record file/prescription Treatment chart. Patient interview, Laboratory reports. Also, Data was achieved from every patient at the initial and consequent out patient's visits, also from past medical records as well as family members.

Sample Size: The study was led on a patient pool of 100 people.

Sampling Technique: Purposive sampling

Study Duration: This study was conducted for a period of 6month.

Study Criteria: Prospective observational study.

Study Site: This study was conducted in both in and outpatient setting of the neurology department at Teerthanker Mahaveer Hospital, Moradabad, Uttar Pradesh. It is a near out 800 bedded multispecialty tertiary care teaching hospital.

Inclusion Criteria

- Patients were included in the study if
- Patients suffering from epilepsy from any cause.
- Both the genders with all age groups.
- Willing to sign informed consent included the study.

Exclusion Criteria

- Patients were excluded in the study if
- Patients who do not fulfill inclusion criteria.
- Patients with incomplete information.
- Pregnant and breast-feeding women.

Method of Data Collection

Patients data such as the type of epilepsy, number of AED prescribed, drug-related problems and drug compliance if any during the therapy and whether drug monitoring was carried out or not was collected from various data sources case sheets, out-patient cards, laboratory reports etc. The follow-up was done based on the next appointment given by treating clinician .The follow-up was done for a period of 6 months.

Statistical Methods: The data were subjected to descriptive statistical analysis using Microsoft Excel. Microsoft word, the collected data were cleared, categorized and analyzed using Microsoft Excel and the results were presented in excel have been used to generate bar graph, pie chart, histogram, and tables

Result and Discussion

The finding of the study were analyzed and arranged under the following sections.

- Distribution of sample according to demographic data.
- Distribution of sample according to disease data.
- Distribution of sample according to medication data.
- Distribution of sample according to drug related problems
- Factors influencing drug compliance

Distribution of Sample According to Demographic Data

Distribution of sample according to age group distribution

The age of the sampled ranged from infants -80 years with a mean age of 25. In figure 1. The Age classifications were made in view of age dispersion of test in order to have a base number under each class .The larger part of patients had a place with age gather 11-20 year (34%).Followed by the age assemble 21-30 year(24%), infants- 10 (13%), 31-40 year (13%), 41-50 year(7%), 51-60year(5%), 61-70year(3%), 71-80(1%)

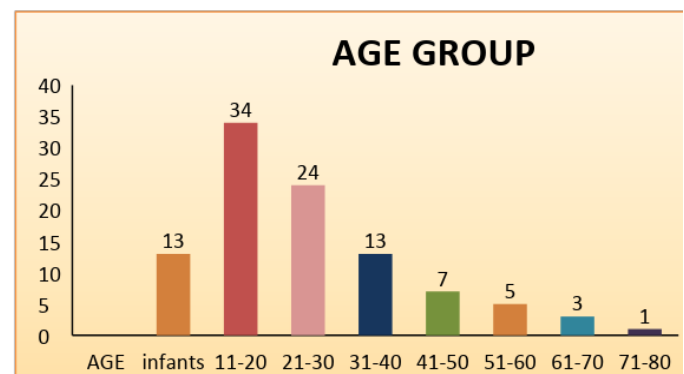


Figure: Column diagram of the sample according to age group distribution.

Distribution of sample according to gender

This shows the distribution of patients according to gender. Out of 100 patients there were 56% male in sample and 44% female. In contrast to our results; T.Badwaik et al., seen females were more than males in their study exposed to antiepileptic drugs, It is however that Murthy NV et al showed males were more frequently attacked with epilepsy than females which complements our result.

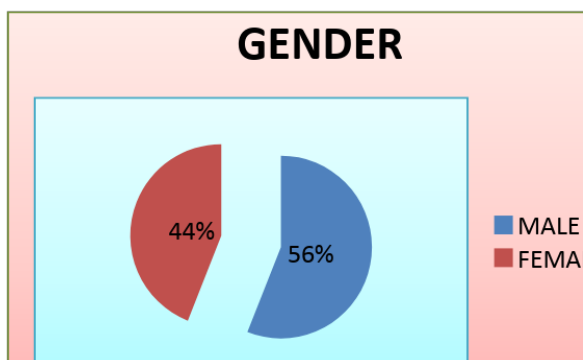


Figure: Pie Diagram of Distribution of sample according to gender

Distribution of sample of patients according to duration of illness

This shows that the majority of sample of patients had fresh episode (37%), followed by 36 % sample of patients had duration of illness 1-5 year .The duration of illness less than 1 year were in 21% of sample of patient only 2% of sample of patients had duration of illness ranged from 6-10 years

Table Distribution of sample of patients according to duration of Illness

| DURATION OF ILLNESS | NO.OF PATEINTS | PERCENTAGE |
|---------------------|----------------|------------|
| FRESH EPISODE | 37 | 37% |
| less than 1 year | 21 | 21% |
| 1-5 year | 36 | 36% |
| 6-10 year | 2 | 2% |
| TOTAL | 100 | 100% |

Distribution of sample of patients according to Type of seizures

This show that majority of sample of patients had symptomatic epilepsy(24%) followed by idiopathic generalized epilepsy (12%), focal epilepsy (11%),complex partial seizure and generalized tonic clonic epilepsy (10%), seizure with mental retardation and cerebral palsy(7%), scar epilepsy (6%), absence and juvenile myoclonic seizure (5%), generalize epilepsy (4%), complex partial seizure(2%),and cryptogenic, status, genetic, chronic alcohol epilepsy 1%were the different type of epilepsy encountered in our hospital.

Table Distribution of sample of patients according to types of epilepsy

| TYPES OF SEIZURE | NO.OF PATINTS | PERCENTAGE |
|--|---------------|------------|
| COMPLEX PARTIAL SEIZURE | 10 | 10% |
| GENERALIZE TONIC CLONIC SEIZURE | 10 | 10% |
| SYMPTOMATIC EPILEPSY | 24 | 24% |
| JUVENILE MYOCLONIC SEIZURE | 5 | 5% |
| IDIOPATHIC GENERALIZED EPILEPSY | 12 | 12% |
| FOCAL EPILEPSY | 11 | 11% |
| SEIZURE WITH MENTAL RETARDATION (CEREBRAL PALSY) | 7 | 7% |
| ABSENCE SEIZURE | 5 | 5% |
| GENERALIZE EPILEPSY | 4 | 4% |
| COMPLEX FEBRILE SEIZURE | 2 | 2% |
| CRYPTOGENIC EPILEPSY | 1 | 1% |
| SCAR EPILEPSY | 6 | 6% |
| CHRONIC ALCOHOL EPILEPSY | 1 | 1% |
| STATUS EPILEPSY | 1 | 1% |
| GENETIC EPILEPSY | 1 | 1% |
| TOTAL | 100 | 100% |

Distribution of sample of patients according to number of antiepileptic drugs per prescription

It table showed that majority of cases, antiepileptic drugs were as dual therapy other than monotherapy and polytherapy. Over all 56 % patients treated by dual therapy i.e. 2 antiepileptic drugs and 24% patients treated by monotherapy i.e. 1 antiepileptic drug and 20% patients treated by polytherapy i.e. more than 2 antiepileptic drugs treatment.

Table According to number of antiepileptic drugs per prescription

| THERAPY | NO. OF PATEINTS | PERCENTAGE |
|--------------|-----------------|------------|
| MONO-THERAPY | 24 | 24% |
| DUAL THERAPY | 56 | 56% |
| POLYTHERAPY | 20 | 20% |
| TOTAL | 100 | 100% |

Distribution of sample of patients for extent of antiepileptic drug utilization

This Table showed 11 different types of antiepileptic. In 100 prescriptions these drugs were prescribed 197 times. Number of drug per prescription was 197/100 i.e. 1.97 .extent of utilization of individual drugs were Clobazam 31% followed by Phenytoin 19.70%, Levetiracetam 19.20%, Oxcarbazepine 11%, Sodium Valproate 8.12%, Clonazepam and Locasamide 3%,Lamotrigine and Carbamazepine

1.01%, lorazepam 0.50% .Following was the utilization pattern of these drugs presented numerically. There are above 20 antiepileptic drugs which are available for clinical use today. In our hospital, only 11 different antiepileptic drugs were used, however. This study highlighted that Clobazam was the most commonly prescribed antiepileptic drug in both cases of monotherapy and adjuvant therapy a similar study by Mathur et al., reported that clobazam is a well-tolerated, safe and very effective antiepileptic drug.

Table Distribution of sample of patients for extent of antiepileptic drug utilization

| ANTIEPILEPTIC DRUG PRESCRIBED | NO. OF PATIENTS | PERCENTAGE |
|-------------------------------|-----------------|------------|
| CLOBAZAM | 62 | 31% |
| CLONAZEPAM | 6 | 3% |
| LAMOTRIGINE | 2 | 1.01% |
| OXCARBAZEPINE | 22 | 11% |
| PHENOBARBITAL | 3 | 1.50% |
| PHENYTOIN | 39 | 19.70% |
| SODIUM VALPROATE | 16 | 8.12% |
| LEVETIRACETAM | 38 | 19.20% |
| LOCASAMIDE | 6 | 3% |
| CARBAZEPINE | 2 | 1.01% |
| LORAZEPAM | 1 | 0.50% |
| TOTAL | 197 | 100% |

Distribution of sample of patients for extent of class of antiepileptic drugs

This showed the extent of class of antiepileptic drugs .7 different type of class of antiepileptic .in 100 prescription these class of antiepileptic were prescribed 197 times .extent of utilization of class of drugs were benzodiazepines 35.02%, newer drugs 22.33%,hydantoin 19.70%,iminostilbene 12.18%, aliphatic carboxylic acid 8.10%, barbiturates 1.52 %, phenyltriazine 1.01%.

Table Extent of class of antiepileptic

| CLASS OF ANTIEPILEPTIC DRUGS | NO. OF PATIENTS | PERCENTAGE |
|------------------------------|-----------------|------------|
| HYDANTOIN | 39 | 19.70% |
| BARBITURATE | 3 | 1.52% |
| IMINOSTILBENE | 24 | 12.18% |
| ALIPHATIC CARBOXYLIC ACID | 16 | 8.10% |
| BENZODIAZEPINES | 69 | 35.02% |
| PHENYLTRIAZINE | 2 | 1.01% |
| NEWER DRUG | 44 | 22.33% |
| TOTAL | 197 | 100% |

Distribution of sample according to adverse drug reaction

In our study group this table 18 shows that 70 patients developed 24 ADR’s of various types. (The most ADR’s mostly causes Ataxia 5(20%), dizziness3(12.5%), headache3(12.5%), vertigo 2(8.33%), gumhypertrophy1(4.16%), rashes1 (8.33%), nausea/vomiting2(8.33%), pain in abdomen1(4.166), constipation1(4.16%), severe hairfall1(4.16%), Stephenjonsons syndrome1 (4.16), memory cognition (4.16%), urine intolerance(4.16%), drowsiness(4.16%) .The most common drugs causes for ADR’s were Phenytoin (16%), clobazam (16.64%), and Oxcarbazepine (4.16 %%), Levetiracetam (16.6 %%), valproic acid (8.33%), The ADR’s assessed by using WHO probability scale and Naranjo’s algorithm respectively. Majorly probable causality assessment in both case Naranjo and WHO Causality assessment scale.

Table: Distribution of sample according to adverse drug reaction.

| ADVERSE DRUG REACTION | suspected drug | CAUSALITY RELATIONSHIP naranjo | WHO |
|--------------------------|------------------|--------------------------------|-------------|
| drowsiness | 1 PHENYTOIN | POSSIBLE | POSSIBLE |
| urine intolerance | 1 CLOBAZAM | PROBABLE | POSSIBLE |
| dizziness | 2 CLOBAZAM | PROBABLE | probable |
| ataxia | 5 PHENYTOIN | PROBABLE | PROBABLE |
| memory cognition | 1 OXCARBAZEPINE | POSSIBLE | POSSIBLE |
| rashes | 1 PHENYTOIN | PROBABLE | PROBABLE |
| headache | LEVETIRACETAM | POSSIBLE | CONDITIONAL |
| vomiting | PHENYTOIN | PROBABLE | CONDITIONAL |
| stephen jonsons syndrome | PHENYTOIN | PROBABLE | PROBABLE |
| severe hairfall | VALPROIC ACID | probABLE | PROBABLE |
| headache | PHEYTOIN | POSSIBLE | CONDITIONAL |
| dizziness | CLOBAZAM | POSSIBLE | POSSIBLE |
| constipation | PHENYTOIN | UNLIKELY | CONDITIONAL |
| pain in abdomen | SODIUM VALPROATE | PROBABLE | POSSIBLE |
| NAUSEA | PHENYTOIN | UNLIKELY | CONDITIONAL |
| rashes | CLOBAZAM | PROBABLE | PROBABLE |
| headache | LEVETIRACETAM | POSSIBLE | PROBABLE |
| gum hypertrophy | 1 PHEYTOIN | PROBABLE | PROBABLE |
| vertigo | LEVETIRACETAM | PROBABLE | PROBABLE |
| vertigo | LEVETIRACETAM | PROBABLE | PROBABLE |

Type of drug related problems identified

Majority identified drug related problems were drug interaction (29.10%) followed by medication error (29%), adverse drug reaction (14%), untreated conditions (13.6), wrong dose (13). Drug-related problems can be potential and actual. Potential are those which will happen in near future but the actual drug-related problem are those which was already happened.

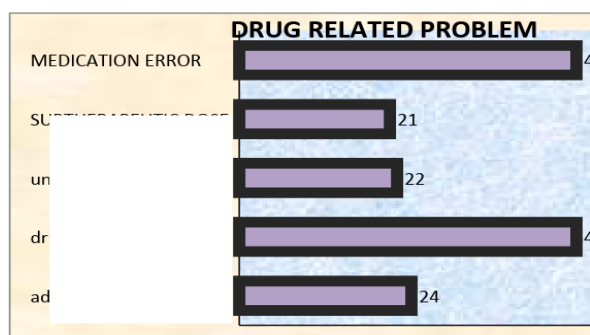


Figure: Bar diagram Type of drug related problems

Factors influencing drug compliance

This table shows relation between selected background variable and antiepileptic drug compliance. These include patient age, gender, marital status, place of living, duration of illness, adverse drug reaction, family history, type of therapy, and frequency of take medicine. by chi – square test. There was no relation between antiepileptic drug compliance and place of living (p=0.192), duration of illness (p=0.08), gender (p=0.055) marital status (p=0.49), family history (p=0.49), type of therapy (p=0.19), frequency of take drug (p=0.307) however a significant relationship was found between age (0.0428), adverse drug reaction (p=0.05) This study provides the insights of the current trend of antiepileptic drug utilization pattern in epileptic patients.

Table: Factors influencing drug compliance

| variables | category | compliant frequency(%) | non-compliant frequency(%) | total (%) | p-value |
|----------------------------|------------------|------------------------|----------------------------|-----------|---------|
| age | >25 | 30(63.8) | 17(36.17) | 47(100) | 0.0428 |
| | <25 | 43(81.13) | 10(18.86) | 53(100) | |
| place | urban | 36(78.2) | 10(21.7) | 46(100) | 0.192 |
| | rural | 37(68.51) | 17(31) | 54(100) | |
| duration of illness | FRESH EPISODE | 33(86.8) | 5(13.15) | 38(100) | 0.08 |
| | less than 1 year | 12(63) | 7(36.8) | 19(100) | |
| | 1-5 year | 23(67.64) | 11(32.35) | 34(100) | |
| | 6-10 year | 5(55.5) | 4(44.4) | 9(100) | |
| adverse drug reaction | present | 14(58.33) | 10(41.6) | 24(100) | 0.055 |
| | absent | 59(77.63) | 17(22.36) | 76(100) | |
| gender | male | 37(67.27) | 18(32.7) | 55(100) | 0.1151 |
| | female | 36(80) | 9(20) | 45(100) | |
| marital status | married | 27(72.97) | 10(27.02) | 37(100) | 0.49 |
| | un married | 46(73) | 17(26.98) | 63(100) | |
| family h/o epilepsy | present | 10(76.92) | 3(23) | 13(100) | 0.497 |
| | absent | 63(72.41) | 24(27.5) | 87(100) | |
| type of therapy | monotherapy | 17(89.47) | 2(10.52) | 19(100) | 0.0389 |
| | dual therapy | 44(74) | 15(25.42) | 59(100) | |
| | polytherapy | 12(54.54) | 10(45.45) | 22(100) | |
| frequency of take medicine | one in a day | 4(100) | 0 | 4(100) | 0.307 |
| | twice in a day | 61(73.49) | 22(26.50) | 83(100) | |
| | thrice in a day | 8(61.53) | 5(38.46) | 13(100) | |

Summary

A prospective observational study was carried out for 6 months in 100 patients who were admitted and come for follow up in the neurology department of Teerthankar Mahaveer hospital, Moradabad.

- 56% male in sample and 44% female and the majority of patients belonged to age group 11-20 year (34%) followed by the age group 21-30 year(24%) majority of the sample of patients.
- Symptomatic epilepsy(24%) was the most common type of epilepsy followed by idiopathic generalized epilepsy 12%, focal epilepsy 11%,complex partial seizure and generalized tonic-clonic epilepsy 10%, seizure with mental retardation and cerebral palsy7%, scar epilepsy 6% ,absence and juvenile myoclonic seizure 5%,generalize epilepsy 4%,complex partial seizure 2%,and cryptogenic, status ,genetic ,chronic alcohol epilepsy 1% .
- Most commonly prescribed drug was clobazam 31% followed by phenytoin 19.70%, levetiracetam 19.20%, oxcarbazepine 11%, sodium valproate 8.12%,clonazepam and Lacosamide 3%,lamotrigine and carbamazepine 1.01%, lorazepam 0.50%.
- Very less number of newer antiepileptic (22%) agents was used in compared to older ones (78%). Two drugs namely Levetiracetam and Lacosamide are only used as adjunct therapy but not as monotherapy only levetiracetam used as monotherapy in some cases.
- Out of 70 patient exposed to Antiepileptic, we found 24 adverse drug reaction majorly due to phenytoin.
- Prevalence of dual therapy is high (56 %) compared to monotherapy and polytherapy.
- In this study out of 100 patients 73% had good compliance level; they never miss their medication at any time. 27(27%) of patients occasionally miss their medication and irregular take their drugs

Limitation

- ❖ The study can be conducted in a large population in multiple centers.
- ❖ Pregnant/lactating women were not included in this study.
- ❖ The study requires the longer duration of followings with more number of prescriptions
- ❖ The patient not admitted to the hospital and soothe communication may difficult in the outpatient department.
- ❖ Many Patients not willing to answer the questionnaires were included in exclusion criteria.

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