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A Retrospective Study on Drug Utilization Evaluation of Anti-epileptics

Dr Pratyusha Behara[1], S. Hyma Padmavathi[2], P Priyanka[2], S. Asha Sai Durga Kumari [2], Pujitha Mallareddi[2]

[1]PharmD, Assistant Professor, Viswanadha Institute of Pharmaceutical Sciences, Affiliated to JNTUGV, Mindhivanipalem (V) Sontyam(P) Anandapuram (M)Visakhapatnam (Dist) 531 173. [2]Student in doctor of pharmacy, Viswanadha Institute Of Pharmaceutical Sciences, Affiliated to JNTUGV, Mindhivanipalem (V) Sontyam(P) Anandapuram (M)Visakhapatnam (Dist) 531 173.

Abstract

Epilepsy is a chronic neurological & non-communicable disorder of the brain that affects around 50 million people worldwide. It is characterized by recurrent seizures, which are brief episodes of involuntary movement that may involve a part of the body (partial) or the entire body (generalized) and are sometimes accompanied by loss of consciousness and uncontrolled bowel or bladder function. It is estimated in various studies that the overall prevalence in India is 5.59-10 per 1000. Drug Utilization Evaluation (DUE) is an authorized and structured ongoing review of practitioner prescribing, pharmacist dispensing and patient use of medications. The purpose of DUE is to ensure drugs are used appropriately, safely and effectively to improve patient health status.The objective of this study is to identify the most common type of therapy in different types of seizures and to identify the most prescribed drug and combination of drugs in monotherapy and polytherapy respectively. This study suggests the importance of DUE program as a tool for improving clinical care and dynamic role of clinical pharmacist in clinical sector.

Keywords: Drug Utilization Evaluation, Epilepsy, Monotherapy, Polytherapy, Type of seizures

INTRODUCTION

Epilepsy is a neurological disorder of the brain characterized by repeated seizures. A seizure is usually defined as a sudden alteration of behavior due to a temporary change in the electrical functioning of the brain. [1] .
Epilepsy is a chronic noncommunicable disease of the brain that affects around 50 million people worldwide. It is characterized by recurrent seizures, which are brief episodes of involuntary movement that may involve a part of the body (partial) or the entire body (generalized) and are sometimes accompanied by loss of consciousness and control of bowel or bladder function.[2]

The objective of this study is to identify the most common type of therapy in different types of seizures and to identify the most prescribed drug and combination of drugs in monotherapy and polytherapy respectively. This study suggests the importance of DUE program as a tool for improving clinical care and dynamic role of clinical pharmacist in clinical sector.

TYPES OF SEIZURES:

1. Generalized
2. Focal
3. Unknown.

1) Generalized Seizures begin with a widespread electrical discharge that involves both sides of the brain at once.
2) Focal seizures begin with an electrical discharge in one limited area of the brain. These seizures are also called partial seizures.
3) Unknown seizures: When the beginning of a seizure is not known, it's now called an unknown onset seizure.

DRUG UTILIZATION EVALUATION

DUE is an authorized and structured ongoing review of practitioner prescribing, pharmacist dispensing and patient use of medications. The purpose of DUE is to ensure drugs are used appropriately, safely and effectively to improve patient health status. DUE is typically classified in three different categories: prospective, concurrent and retrospective.

1.Prospective DUE: Prospective review involves evaluating a patient's planned drug therapy before a medication is dispensed.This process allows the pharmacist to identify and resolve problems before the patient has received the medication.Issues Commonly addressed by Prospective DUR:

- Clinical abuse/misuse
- Drug-disease contraindications (when a prescribed drug should not be used with certain diseases)
- Drug dosage modification
- Drug-drug interactions (when two or more different drugs interact and alter their intended effects, often causing adverse events)
- Drug-patient precautions (due to age, allergies, gender, pregnancy, etc.)
- Formulary substitutions (e.g., therapeutic interchange, generic substitution)
- Inappropriate duration of drug treatment.

2. Concurrent DUE: Concurrent review is performed during the course of treatment and involves the ongoing monitoring of drug therapy to foster positive patient outcomes. It presents pharmacists with the opportunity to alert prescribers to potential problems and intervene in areas such as drug-drug interactions, duplicate therapy, over or underutilization and excessive or insufficient dosing. This type of review allows therapy for a patient to be altered if necessary.

3.Retrospective DUE: A retrospective DUE review drug therapy after the patient has received the medication.A retrospective review aims to detect patterns in prescribing, dispensing or administering drugs. [3]

PRESCRIBING FREQUENCIES:

Monotherapy: The choice of the first antiepileptic drug for an individual with newly diagnosed seizures is of great importance and should be made taking into account high-quality evidence of how effective the drugs are at controlling seizures and whether they are associated with side effects. It is also important that drugs appropriate for different seizure types are compared to each other. [4]

Polytherapy: With the advent of multiple AEDs in the past 15 years, rational polytherapy, the goal of finding combinations of AEDs that have favourable characteristics, has become of greater importance. [5]

TREATMENT OF EPILEPSY:

- The aim of treatment is to control seizures with the most appropriate antiepileptic drug (AED) without causing any significant side effects.
- Treatment of epilepsy with AEDs should be started after confirming the diagnosis of epilepsy.
- Treatment should be initiated following the occurrence of two or more unprovoked seizures, after discussion about the risks and benefits of treatment with the person with epilepsy and his/her family members.

Treatment of the first unprovoked seizure

Epilepsy should not be diagnosed after a single seizure. The average risk of developing a second seizure following a single unprovoked seizure is about 35-40%. Many individuals with a first seizure if left untreated may not have a second seizure. The risk of a third seizure following two unprovoked seizures is much higher. Generally the first seizure is not treated. The individual and family are explained about the possible risk of

recurrence and need for follow up. Patients with the first seizure may be treated in the following circumstances.
Circumstances in which a single seizure may be treated :

- Prolonged focal seizure.
- First seizure presenting as status epileptics.
- presence of neurological deficit, hemiparesis, mental retardation, cerebral palsy etc.
- Family history of seizures among parents, siblings or children.
- EEG abnormality.
- Abnormality on brain imaging (CT, MRI).
- When the patient might have had a seizure before. This may not have been recognized by the patient and may be brought out only by a careful history.
- High risk jobs (Professional or other activities that may endanger life during a seizure).
- The individual and family do not accept the expected risk of recurrence.

Treatment of newly diagnosed epilepsy

- AED therapy is generally recommended after a second unprovoked epileptic seizure.
- AED therapy should be started only after the diagnosis of epilepsy is confirmed.
- AED treatment may occasionally be deferred under the following circumstances:

✓ Infrequent seizures with extremely long / several years interval between seizures.
✓ Occurrence of brief (and infrequent partial sensory or myoclonic) seizures without underlying structural lesion
✓ Benign epilepsy with centro-temporal spikes (Rolandic epilepsy in children).

Principles of AED treatment

- The decision to start AED treatment should be made after discussion of the risks and benefits of treatment and taking into account the person's seizure type, prognosis, lifestyle and socioeconomic circumstances.
- Treatment should be started with a single conventional antiepileptic drug (AED monotherapy).
- Start with a low dose and gradually increase the dose until seizures are controlled or side-effects occur.
- If the initial treatment is ineffective or poorly tolerated, then monotherapy using another AED can be tried.

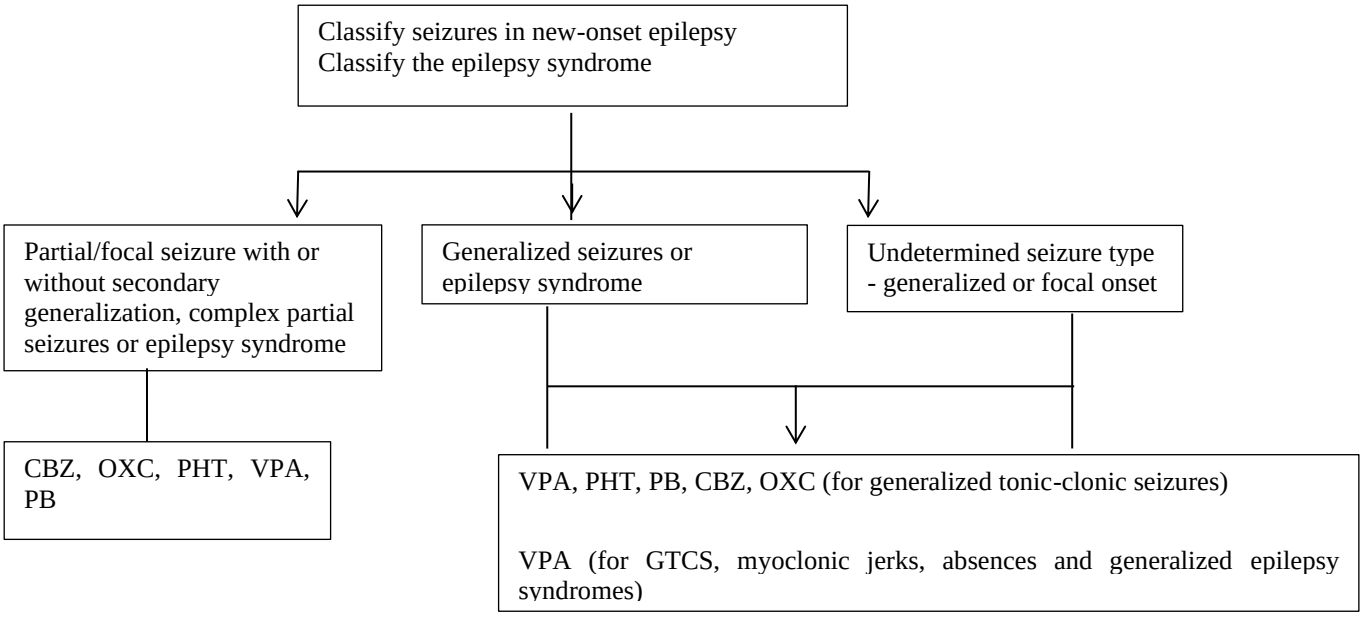
The dose of the second drug is slowly increased until adequate or maximum-tolerated dose is reached. The first drug is then tapered off slowly. If the second drug is also unhelpful, the drug with lesser efficacy or tolerability should be taken off.

- Combination therapy (polytherapy or adjunctive or 'add-on' therapy) can be considered when two attempts at monotherapy with AEDs have not resulted in seizure freedom.If seizures continue despite trial with two AEDs, patient should be referred to a specialist for evaluation.
- The formulation or brand of AED should preferably not be changed (variations in bioavailability or different pharmacokinetic profiles may increase the potential for reduced effect or excessive side effects).
- Modified release formulations offer ease of administration due to less frequent dosing and better compliance. These are costlier than regular formulations.
- Once daily administration of AEDs should be used with caution during pregnancy.

Choice of AEDs

- Phenytoin (PHT), Phenobarbitone (PB), Carbamazepine (CBZ), Oxcarbazepine (OXC), Valproate (VPA) are usually called 'conventional' or 'first line drugs'. The other AEDs are called 'new' or 'second line drugs'.
- It is preferable to use a conventional AED as the initial drug since those are less expensive and the side effects with long-term use are well known.
- The choice of AED is mainly based on the seizure type and epilepsy syndrome. For partial seizures, the initial choice can be CBZ, OXC, PHT, VPA or PB.
- For generalized onset tonic clonic seizures, the initial choice is VPA, PHT, PB, CBZ, OXC. For absence seizures VPA is the drug of choice. For myoclonic jerks, VPA and benzodiazepines are generally used.
- Prior to initiating treatment it is preferable to have baseline blood counts, liver enzymes and renal functions tested.

❖ **Algorithm for choice of AED among new-onset epilepsy patients**



Initial and maintenance daily doses and important side effects of commonly used AEDs

AED	**Starting dose in average adults**	**Maintenance dose in average adults (mg/day)**	**Important side effects**
Carbamazepine(CBZ)	100mg BD	400 – 1000	Sedation, dizziness, ataxia, skin rash (occasionally Steven-Johnson syndrome), hyponatremia, weight gain, seizure worsening in some epilepsy syndromes
Clobazam(CLB)	10mg OD (HS)	10-30	Sedation, ataxia, somnolence, irritability, depression, weight gain, tolerance (reduced anti-epileptic effect)
Lamotrigine(LTG)	25mg OD (HS) lower dose with VPA	100-300	Sedation, ataxia, dizziness, skin rash (occasionally Steven-Johnson syndrome)
Levetiracetam(LEV)	250mg BD	1000-3000	Somnolence, dizziness, cognitive slowing, Psychosis
Oxcarbazepine(OXC)	150mg BD	600-1800	Sedation, dizziness, ataxia, headache, hyponatremia, skin rash
Phenobarbitone(PB)	60-90mg OD (HS)	60-180	Sedation, ataxia, depression, memory problems, skin rash, hyperactivity in children
Phenytoin(PHT)	200-300mg OD (HS)	200-400	Ataxia, sedation, gum hyperplasia, coarsening of facial features, hirsutism, memory problems, osteomalacia and bone loss, skin rash
Topiramate(TPM)	25mg OD	100-400	Sedation, somnolence, cognitive problems, weight loss, word-finding difficulty, renal stones, seizure worsening

Valproate(VPA)	200mg BD	500-2000	Anorexia, weight gain, nausea, vomiting, tremors, hair loss, polycystic ovarian syndrome, thrombocytopenia
Zonisamide(ZNS)	50mg OD (HS)	200-500	Sedation, anorexia, renal stones, forgetfulness, skin rash, weight loss, distal parasthesiae

Table 1: Initial and maintenance daily doses and important side effects of commonly used AED

Role of newer AEDs

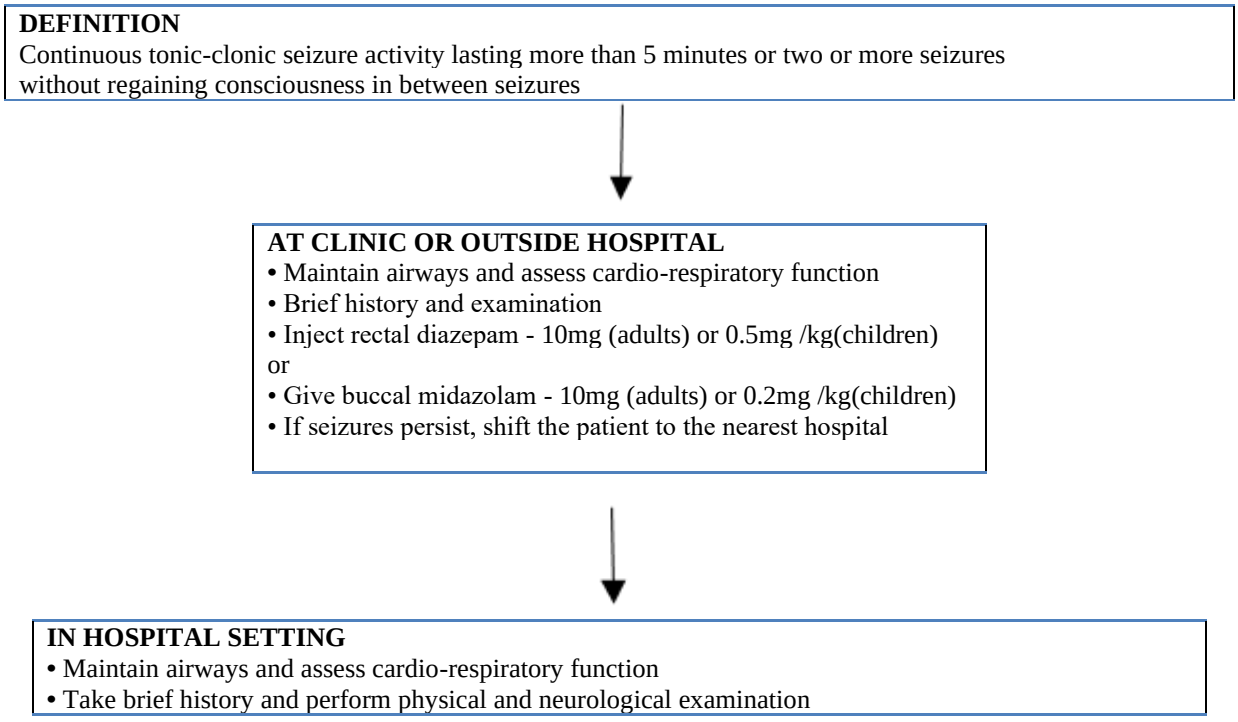
- The newer AEDs (Gabapentin, Lamotrigine, Levetiracetam, Tiagabine, Topiramate, Vigabatrin and Zonisamide) are recommended for the management of epilepsy in people who have not benefited from treatment with the conventional AEDs or for whom the older AEDs are unsuitable because of intolerable adverse events.
- The new AEDS are almost as effective as the conventional drugs but do add significantly to the cost.
- The newer AEDS can also be used when:

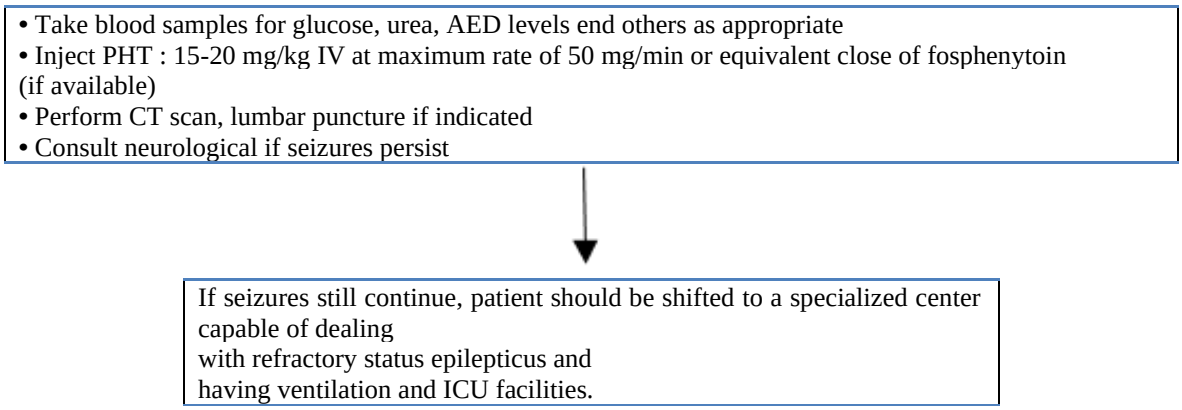
➢ There are contraindications to the first line drugs due to coexisting illnesses.
➢ The first line drugs interact with other drugs the person is taking (notably oral contraceptives, anticoagulants, anti-retrovirals or immunosuppressants).
➢ Always consider factors such as cost and continued availability of medicines before starting newer AEDs.

How to withdraw AEDs

- AEDs are usually withdrawn gradually over several months (at least 3-6 months or longer). There is possibility of seizure recurrence during and after withdrawal.
- The tapering may be performed at a slower rate for benzodiazepines (6 months or longer). Withdraw one drug at a time in those patients who are on multiple AEDs.
- If seizure recurs during or after AED withdrawal, the person may be advised to revert to their AED dose before reduction and seek medical help.

Algorithm for treatment of convulsive status epilepticus





Algorithm 2: Algorithm for treatment of convulsive status epilepticus.[7]

Materials and methods
MATERIALS:
Patient Informed Consent Form (ICF)
Adult consent form
Pediatric consent form
Clinical data form (drug utilization evaluation)
Patient information Sheet

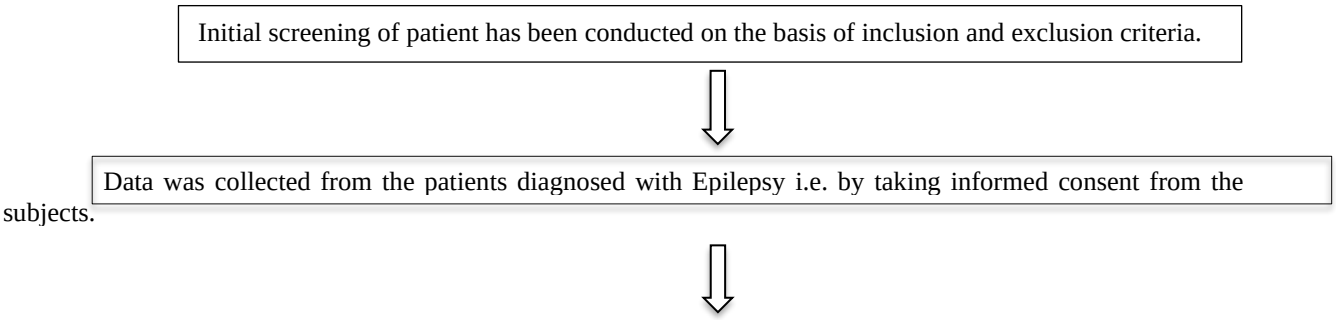
Study Design: A Retrospective Study.
Study Population: 150 cases of patients with Epilepsy.

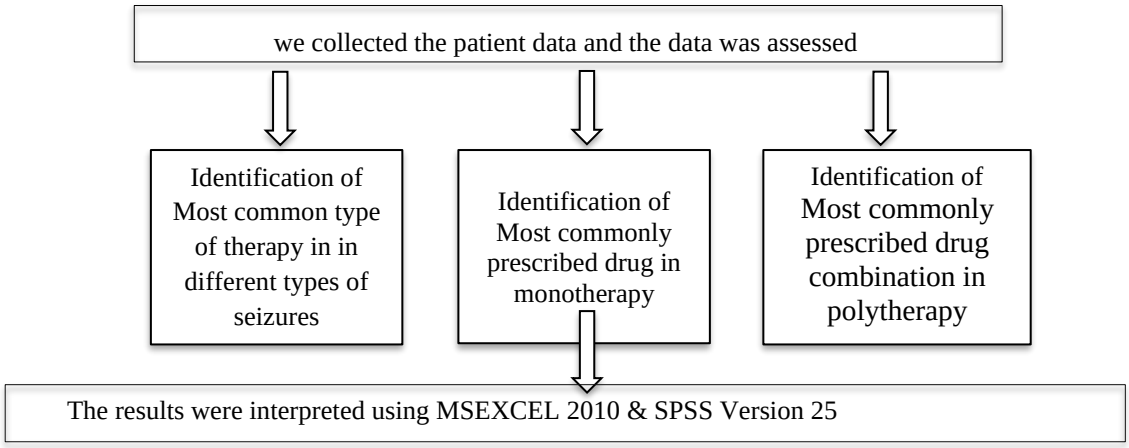
Study site: The study has been conducted in Gayatri Vidya Parishad Institute of Health Care & Medical Technology, Vijayasri Hospital and other Neuroclinics in and around Visakhapatnam.
Study period: The study was conducted for a period of 6 months.

INCLUSION CRITERIA:
- Patients who are willing to sign the ICF.
- Patients of all age groups are considered.
- Patients who are on monotherapy and polytherapy of antiepileptic drugs.

EXCLUSION CRITERIA:
- Patients who are not willing to sign the ICF.
- Pregnant women.
- Lactating women.

METHODOLOGY FLOW CHART:





Algorithm 3: Methodology flow chart

RESULTS & DISCUSSION

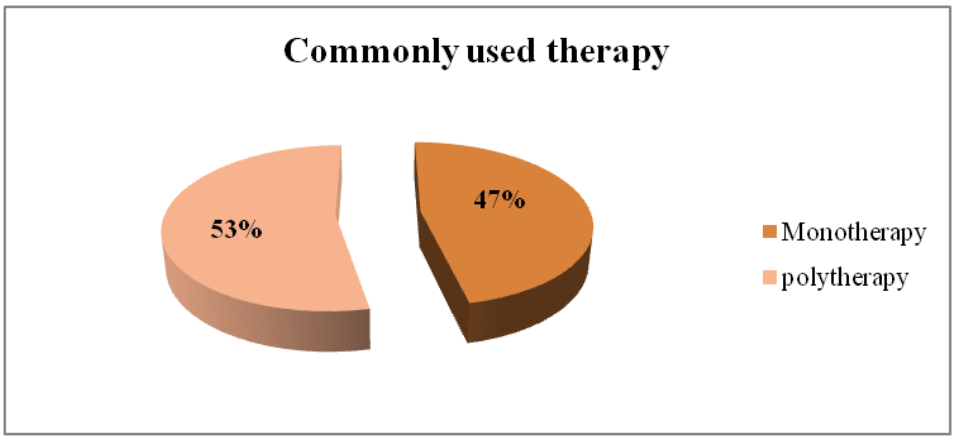
A total of 150 epilepsy patients were included and assessed in our study.
Several parameters were considered and assessed. The results were produced with emphasis on drug utilization evaluation based on type of therapy, drug utilization evaluation based on type of seizures, prescribing frequencies based on therapy.

1. Drug Utilization Evaluation

In our study conducted over a period of 6 months involving 150 subjects with AED Medication 70 subjects were on monotherapy comprising 47% and 80 subjects were on polytherapy comprising 53%.

Type of therapy	
Monotherapy	**Polytherapy**
70	80

Table 2: Drug Utilization Evaluation



Graph 1: Drug Utilization Evaluation

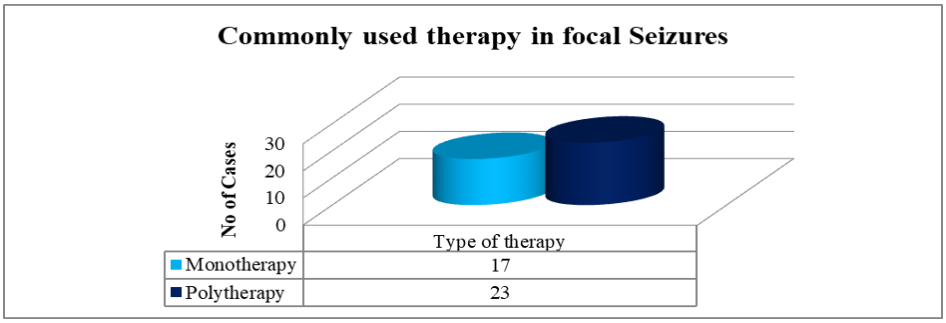
2.Drug utilization based on type of seizure:

A) Focal

Out of 40 subjects diagnosed with focal type of seizures 17 subjects were on monotherapy and 23 subjects on polytherapy.

Focal	Monotherapy	Polytherapy
40	17	23

Table 3: Commonly used therapy in focal seizures



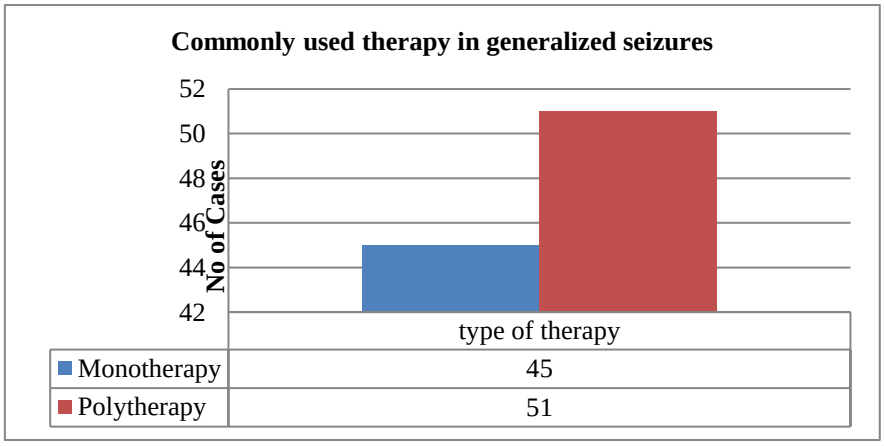
Graph 2:Commonly used therapy in focal seizure

B) Generalized

Out of 96 subjects diagnosed with generalized type of seizures 45 subjects were on monotherapy and 51 subjects on polytherapy.

Generalized	Monotherapy	Polytherapy
96	45	51

Table 4:Commonly used therapy in generalized seizures



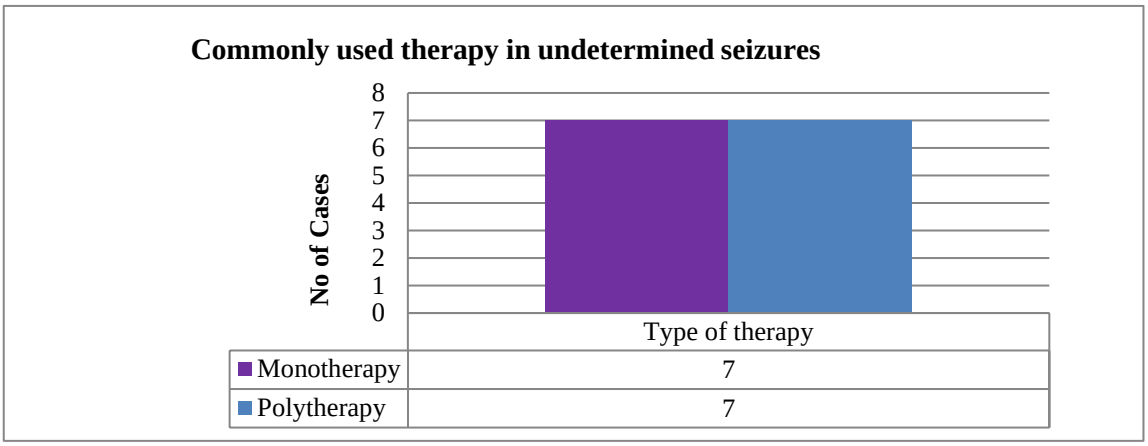
Graph 3: Commonly used therapy in generalized seizures

C) Undetermined

Out of 14 subjects diagnosed with undetermined type of seizures 7 subjects were on monotherapy and 7 subjects on polytherapy.

Undetermined	Monotherapy	Polytherapy
14	**7**	**7**

Table 5: Commonly used therapy in undetermined seizures



Graph 4:Commonly used therapy in undetermined seizures

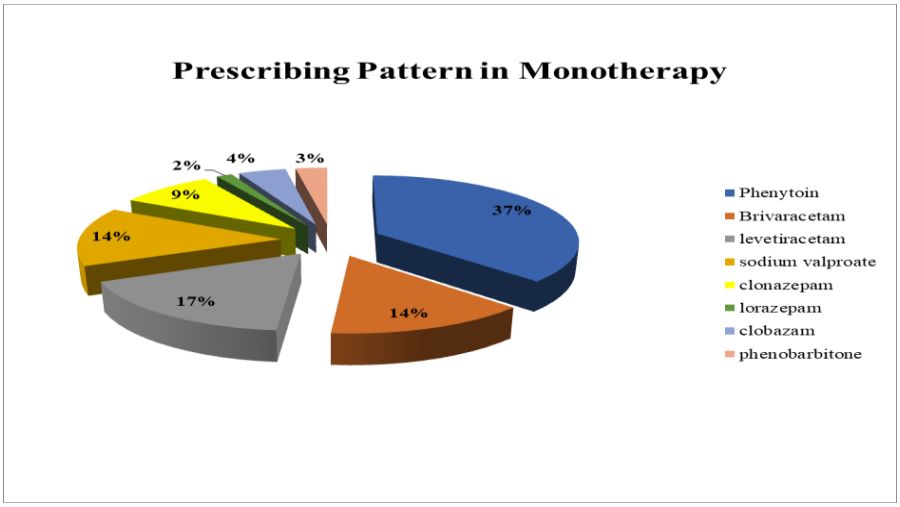
3.Prescribing Frequencies of drugs:

a) Monotherapy

Phenytoin constituted a paramount section in monotherapy comprising 37%, sequenced by levetiracetam, brivaracetam, sodium valproate, clonazepam, clobazam and phenobarbitone comprising 17%, 14%, 14%, 9%, 4% and 3% respectively. Among different AED used in monotherapy lorazepam constituted least section with 2%.

Drug	No of patients
Phenytoin	26
Brivaracetam	10
Levetiracetam	12
sodium valproate	10
Clonazepam	6
Lorazepam	1
Clobazam	3
Phenobarbitone	2

Table 6: Prescribing Pattern in Monotherapy



Graph 5: Prescribing Pattern in Monotherapy

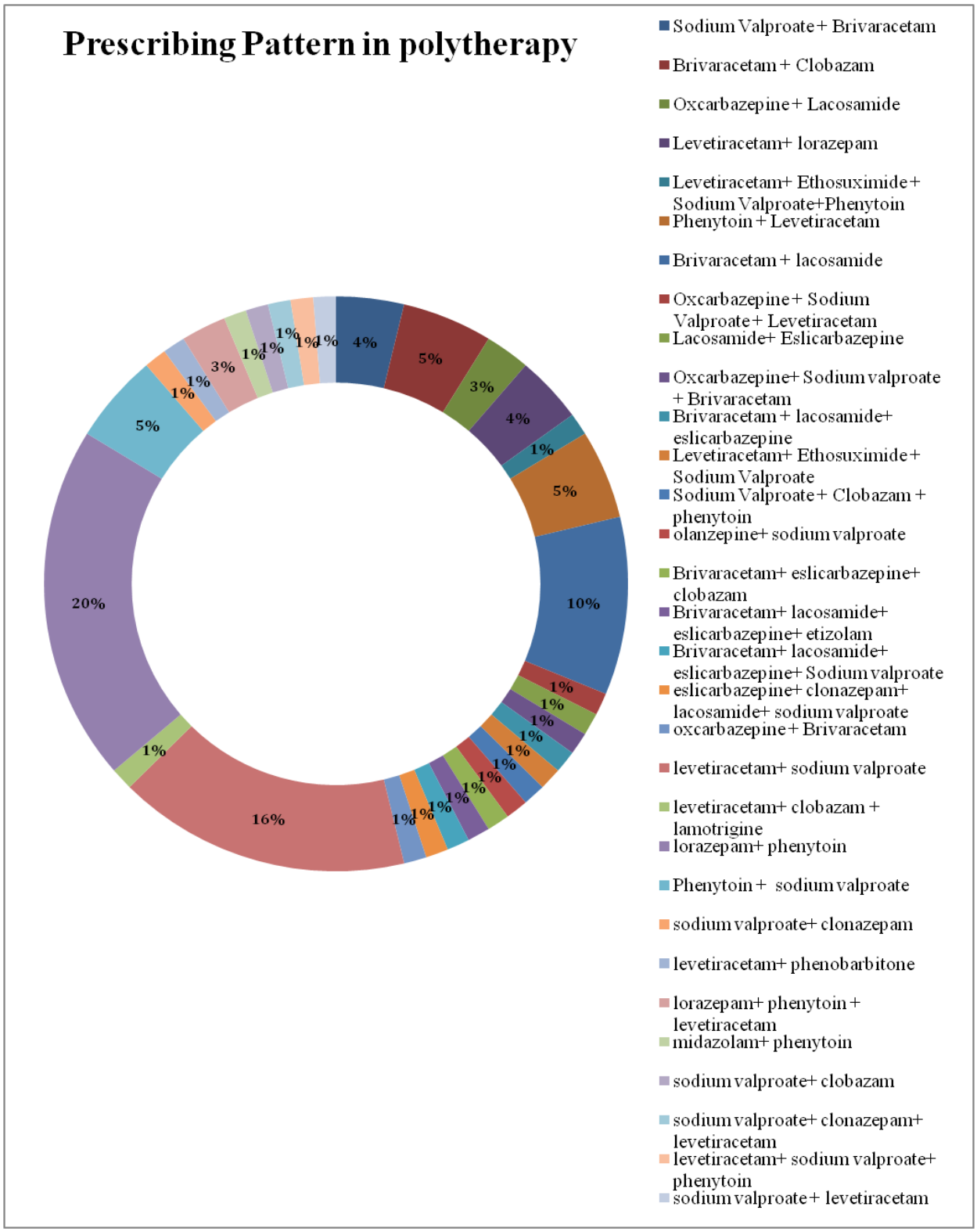
B) Polytherapy

Lorazepam + phenytoin constituted a prime section amid the different combination that we be observed in our study comprising 20%, sequenced by levetiracetam + sodium valproate with 16%, followed by brivaracetam+ lacosamide , Brivaracetam + Clobazam, Phenytoin + Levetiracetam, Phenytoin + sodium valproate, Sodium Valproate + Brivaracetam, Levetiracetam+ lorazepam, Oxcarbazepine + Lacosamide and lorazepam+ phenytoin + levetiracetam comprising 10%, 5%, 5%, 5%, 4%, 4% and 3% respectively. The least combination of polytherapy used in our study was observed to be Levetiracetam+ Ethosuximide + Sodium Valproate + Phenytoin,Oxcarbazepine + Sodium Valproate + Levetiracetam, Lacosamide+ Eslicarbazepine, Oxcarbazepine+ Sodium valproate + brivaracetam, brivaracetam + lacosamide+ eslicarbazepine, Levetiracetam+ Ethosuximide + Sodium Valproate, Sodium Valproate + Clobazam + phenytoin, olanzepine + sodium valproate, brivaracetam + eslicarbazepine + clobazam, brivaracetam + lacosamide + eslicarbazepine + etizolam, brivaracetam + lacosamide + eslicarbazepine + Sodium valproate, eslicarbazepine + clonazepam + lacosamide + sodium valproate, oxcarbazepine + brivaracetam, levetiracetam + clobazam + lamotrigine,sodium valproate + clonazepam, levetiracetam + phenobarbitone, midazolam + phenytoin, sodium valproate + clobazam, sodium valproate + clonazepam + levetiracetam, levetiracetam + sodium valproate + phenytoin and sodium valproate + levetiracetam comprising 1% each.

Drug	**Combination of drugs**
Sodium Valproate + Brivaracetam	3
Brivaracetam + Clobazam	4
Oxcarbazepine + Lacosamide	2
Levetiracetam+ lorazepam	3
Levetiracetam + Ethosuximide + Sodium Valproate + Phenytoin	1
Phenytoin + Levetiracetam	4
Brivaracetam + lacosamide	8

Oxcarbazepine + Sodium Valproate + Levetiracetam	1
Lacosamide+ Eslicarbazepine	1
Oxcarbazepine+ Sodium valproate + Brivaracetam	1
Brivaracetam + lacosamide + eslicarbazepine	1
Levetiracetam + Ethosuximide + Sodium Valproate	1
Sodium Valproate + Clobazam + phenytoin	1
Olanzapine + sodium valproate	1
Brivaracetam + eslicarbazepine + clobazam	1
Brivaracetam + lacosamide + eslicarbazepine + etizolam	1
Brivaracetam + lacosamide + eslicarbazepine + Sodium valproate	1
Eslicarbazepine + clonazepam + lacosamide + sodium valproate	1
oxcarbazepine + Brivaracetam	1
Levetiracetam + sodium valproate	13
Levetiracetam + clobazam + lamotrigine	1
Lorazepam + phenytoin	16
Phenytoin + sodium valproate	4
sodium valproate + clonazepam	1
Levetiracetam + phenobarbitone	1
Lorazepam + phenytoin + levetiracetam	2
Midazolam + phenytoin	1
sodium valproate + clobazam	1
sodium valproate + clonazepam + levetiracetam	1
Levetiracetam + sodium valproate + phenytoin	1
sodium valproate + levetiracetam	1

Table 7: Prescribing Frequencies in polytherapy



Graph 6: Prescribing Pattern in Polytherapy

STATISTICAL ANALYSIS (SPSS)

Descriptive Analysis

A total of 150 Subjects were included in our Statistical Analysis. Using SPSS software we had conducted the descriptive Statistical Analysis for type of therapy.

1) TYPE OF THERAPY:

Polytherapy was prescribed at greater percent (53.3%) when compared to monotherapy (44.7%) amid the total population involved in the study.

Monotherapy had shown mean of 23.93 with standard error (SE) of 2.133 followed by median, variance, std. deviation, minimum, maximum & range are 22, 318.473, 17.846, 1, 65 & 64 respectively.

Polytherapy had shown mean of 27.56 with standard error of 2.408 followed by median,variance, std. deviation, minimum, maximum & range are 24, 463.996, 21.541, 1, 79, & 78 respectively.

Total therapy had shown mean of 25.87 with standard error of 1.626 followed by median,variance, std. deviation, minimum, maximum & range are 22, 396.801, 19.920, 1, 79, & 78 respectively

Type of therapy					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Monotherapy	70	46.7	46.7	46.7
	Polytherapy	80	53.3	53.3	100.0
	Total	150	100.0	100.0	

Table8: Type of therapy

Type of therapy	**Mean**	N	Std. Deviation	Median	Min	ax	Grouped Median	Std. Error of Mean	Range	Variance
Monotherapy	**23.93**	70	17.846	22.00	1	65	21.75	2.133	64	318.473
Polytherapy	**27.56**	80	21.541	24.00	1	79	23.00	2.408	78	463.996
Total	25.87	150	19.920	22.00	1	79	22.20	1.626	78	396.801

Table 9: Type of Therapy - Descriptive

T- TEST

We divided entire sample size (150) into 7 different age groups which are then organized into two different sets (< 3, >= 3).

The age groups involved in < 3 set are group 1 (0-9 years) & group 2 (10-19 years).

The age groups involved in >= 3 set are group 3 (20-29 years), group 4 (30-39 years), group 5 (40-49 years), group 6 (50-59 years) & group 7 (above 60 years).

1. AGE GROUPS – MONOTHERAPY

Hypothesis:

● **H_0 (Null Hypothesis):** There is no significant difference between the two set of age groups for the drug given in monotherapy.

● **H_1 (Alternative Hypothesis):** There is a significant difference between the two set of age groups for the drug given in monotherapy.

Group Statistics					
	Age	N	**Mean**	Std. Deviation	Std. Error Mean
Levetiracetam (Lev)	>= 3	5	**.80**	.837	.374
	< 3	2	**4.00**	.000	.000

Table 10: Group Statistics

Independent Samples Test										
		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	T	Df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
Lev	**Equal variances assumed**	**3.891**	**.106**	**-5.111**	**5**	**.004**	**-3.200**	**.626**	**-4.809**	**-1.591**
	Equal variances not assumed			-8.552	4.00	.001	-3.200	.374	-4.239	-2.161

Table 11: Independent Sample Test

At degrees of freedom (df) 5 & level of significance (α) 0.05 the table t-value is 2.5706.

Interpretation:

We observed a clear difference between the mean of 2 set of age groups for the drug used in monotherapy in table 10.

The calculated t-value (5.111) is greater than table t-value (2.5706). So we have to reject null hypothesis and accept alternative hypothesis.

Therefore there is a significant difference between the two set of age groups for the Levetiracetam (Lev) given in monotherapy.

2. AGE GROUPS – POLYTHERAPY

Hypothesis:

● **H_0 (Null Hypothesis):** There is no significant difference between the two set of age groups for the combination of drugs given in polytherapy.

● **H_1 (Alternative Hypothesis):** There is a significant difference between the two set of age groups for the combination drugs given in polytherapy.

Group Statistics					
	Age	N	**Mean**	Std. Deviation	Std. Error Mean
Brivaracetam + Clobazam (BC)	>= 3	5	**.60**	.894	.400
	< 3	2	**.50**	.707	.500

Table 12: Group Statistics

Independent Samples Test										
		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	T	Df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
BC	**Equal variances assumed**	**.569**	**.485**	**.139**	**5**	**.895**	**.100**	**.720**	**-1.750**	**1.950**
	Equal variances not assumed			.156	2.440	.888	.100	.640	-2.230	2.430

Table 13: Independent Sample Test

At degrees of freedom (df) 5 & level of significance (α) 0.05 the table t-value is 2.5706.

Interpretation:

We observed a negligible difference between the mean of 2 set of age groups for the combination of drug used in polytherapy in table 12 .

The calculated t-value (0.139) is less than table t-value (2.5706). So we have to accept null hypothesis and reject alternative hypothesis.

Therefore there is no significant difference between the two set of age groups for the Brivaracetam + Clobazam (BC) of drugs given in polytherapy.

Hence our data is statistically significant.

CONCLUSION

Polytherapy was the most common type of therapy prescribed when compared to monotherapy due to lower success rate of monotherapy in control of seizures. We observe the same trend in each type of seizures expect that of undetermined, we observe a equal percentage. Amidst all the AED in monotherapy phenytoin is the most commonly prescribed drug and among combination therapy the frequently prescribed combination is lorazepam and phenytoin.The occurrence of seizures can be controlled by avoiding stress in adults which is the prevailing factor. Similarly febrile seizure can be minimized by consulting physician at early occurrence of fever.

By conducting statistical analysis using SPSS our data is observed to be statistically significant as the visualization of mean between sets in each category had shown the same result as statistically interpreted data.

As epilepsy is a chronic disorder it needs lifelong medical therapy, we conducted a study on drug utilization which helps to determine effective and rational combination of drugs used in epilepsy.Our study also suggests the dynamic role of a clinical pharmacist in the review of drug use in hospitals and the importance of DUE program as tool for improving clinical care rather than a budget plan.

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Conflict of interest

Nil

Ethics committee

The institutional Ethics committee GVPIHCMT had approved for project title "A prospective cross-sectional study on risk factor assessment of epilepsy".
Approval Number: GVIHCMT/ICE/20221003/02

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