

Addis Ababa University

College of Health Science

School of Medicine

Department of Neurology



Patterns of treatment outcome of epilepsy and associated factors among patients on follow-up at adult neurology clinic at Tikur Anbessa Specialized Teaching Hospital: Hospital based cross sectional study October 1-30, 2020 G.C.

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A Thesis to be submitted to the Department of Neurology, School of Medicine, Addis Ababa University, in partial fulfilment of the Specialty Certificate in Clinical Neurology

December 2020 G.C.

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Abstract

Background: Pattern of treatment outcome can be categorized based on the effect of an intervention on seizure control in relation to occurrence of adverse effects. A minimum of 12 months of seizure freedom from all types of seizure is required to label a treatment outcome as seizure freedom. Predictors of seizure treatment outcome can be utilized to direct resources towards strategies that lead to good seizure outcome. Despite the availability of interventions which can control the seizure frequency to an extent of 70% a large number of epileptic patients continue to have a seizure.

Objective: Patterns of treatment outcome of epilepsy and associated factors among patients on follow-up at adult neurology clinic at Tikur Anbessa Specialized Teaching Hospital: Hospital-based cross-sectional study October 1-30, 2020G.C

Methods: A hospital-based cross-sectional descriptive study is conducted among epileptic patients who have a follow-up at the Neurology department referral clinic, Tikur Anbessa Specialized Hospital, Addis Ababa from Oct 1-30. A convenient sampling method was used. A questionnaire including, sociodemographic status, is used to assess patterns of treatment outcome with associated factors. The data were entered, processed, and analyzed using SPSS 26 window version.

Result: A total of 245 participants were included in the study. More than half 145(59.2%) of patients with epilepsy were in the age range of 15-30. Among participants male gender account for 113(54.3%) and female gender for 112(45.7%). The age of onset of a seizure was below 15 for 115(46.9%) of patients. Generalized onset seizures 154(62.9%) was the commonest type of

seizure diagnosed. Comorbidity is seen in 110(44.9%). Monotherapy 68(27.8%) was commonly used for treatment of seizure. The 166(67.8%) of patients had developed antiepileptic related adverse event. Antiepileptic drugs non adherence seen in 68(27.8%)of patients. In 41(16.7%) of patients there is no seizure attack after initiation of antiepileptic medications.

Seizure freedom was seen in 99(40.4%) of patients. Sex (adjusted odds ratio (AOR)= 3.316, CI=1.044-10.534;p-value=0.042) was predictor of poor seizure control.

Conclusion: In this study, it was found that more than two-thirds of the participants continue to have seizure activity despite being placed on antiepileptic medications. Still, a large proportion of patients are not adherent to the medication prescribed. The older generation of antiepileptic medications utilized and more than half of patients reporting adverse events. Male sex is found to have a three times higher risk of developing poor seizure control. A further multicenter study of different subgroups of treatment is recommended and effect of sex on seizure can be studied further.

Keywords: Pattern of treatment response, Anti-epileptic drugs, Adverse Events

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List of abbreviations and acronym

MOH- Ministry of Health

PWE- People with epilepsy

MTLE- Mesial Temporal lobe Epilepsy

EEG- Electroencephalogram

NRC- Neurology referral clinic

DDD- Defined Daily Dose

WHO- World Health Organization

SUDEP- Sudden Unexpected Death In Epilepsy

ILAE-International League Against Epilepsy

TASH-Tikur Anbessa Specialized Hospital

Chapter one

1. Introduction

1.1 Background

The current definition of epilepsy according to the International League against Epilepsy should meet the following two requirements; at least two unprovoked seizures 24 hours apart or one unprovoked seizure with a probability of recurrence of at least 60% in subsequent 10 years. The current definition of epilepsy by ILAE considers it to be a disease rather than a disorder. (1)

Each diagnosis should incorporate seizure type, epilepsy type, and epilepsy syndrome taking investigations like neuroimaging and electroencephalography along with other investigative modalities into account. At each level of the diagnostic pathway, an etiologic diagnosis should be considered as it has great significance in a treatment plan. (2)

In Ethiopia, epilepsy affects 5.2 per 1000 of the population. Despite being the most common cause of neurological disability only 2-13 % of epileptic patients receive medical therapy. (3) 80-90% treatment gap identified in developing countries is multifactorial. Inadequate infrastructure, medication diagnostic tools, and cultural attitude are among the major reasons causing poor treatment coverage. (4)

There are different patterns of response to medical treatment of epilepsy with AEDs. Pharmacoresponsive means that appropriate antiepileptic therapy will likely control the seizure (2). Pharmacoresistant also referred to as treatment-resistant, medically refractory, and poorly controlled seizure (5). ILAE defines drug resistance seizure as poor control of seizure despite at least two appropriately selected, utilized, and tolerated AEDs. (6) The minimum criteria proposed by ILAE will avoid delay in utilizing non-pharmacologic management options. (7)

1.2. Statement of the problem

Uncontrolled epilepsy imposes a substantial burden at the individual level resulting in a poor quality of life. Such patients have increased physical and psychological co-morbidities. The likelihood of sudden unexplained death in epilepsy is increased. (8)

Severe physical consequences from uncontrolled epilepsy include accidents, drowning and injury. Brain injury with nerve cell death is also a consequence of uncontrolled seizure. Sudden unexplained death in epilepsy patients or SUDEP is a rare but rather serious complication reported 4-7 times higher in people with medically refractory seizures. (9)

There is a significant economic burden in delivering care to people with epilepsy. The economic expenditure can reach half of the household revenue. The cost vary based on disease severity, response to treatment, and pathway taken to reach appropriate medical therapy. (10)

Poor seizure control restricts patients' social interaction, limits involvement in activities including driving, and reduces employment status further worsening the economic burden.(7) Respective surgery is a potential therapeutic option for patients' whose seizure is not controlled with several AED. With the further addition of AED chance of improvement is less than 5%. Selection of candidates for non-medical therapy can reduce the social economic and psychological burden in PWE. (7)

Chapter Two

2.2. Literature Review

Epilepsy accounts for a significant proportion of the world's disease burden, affecting around 50 million people worldwide. (11)

The prevalence of epilepsy ranges from 0.5 to 1% of the population in developed countries and is higher in developing countries. (12) It is a major public health concern for developing countries where 80% of PWE currently live. (10)

The prevalence of epilepsy in Ethiopia is shown to be 5.2/1000 from a community-based study done in rural central Ethiopia where 10% had an occurrence of seizure on daily basis. (13) Prevalence as high as 29.5/1000 was reported in the Zay Society of Ethiopia. A strong family history where 100% of study participants with active seizure had 100% family history, shared genes and environment taught to contribute to a higher prevalence of the disease in this specific community of Ethiopia. (17)

The estimated proportion of the general population with active epilepsy (i.e. continuing seizures or with the need for treatment) at a given time is between 4 and 10 per 1000 people. (11) It is estimated that 75% of those living in resource-limited settings do not receive appropriate medication. (10)

The mainstay of treatment for seizure control is AED. (8) Currently, available therapies with AEDs can effectively treat the majority of newly diagnosed epileptic patients. (14) The proportion of refractory seizures has unchanged despite the availability of newer antiepileptic drugs on top of older generation AEDs with established efficacy. (8) The initial therapy should always be started with monotherapy. Alternative treatment options in addition to AEDs include surgical resection of the seizure focus, ketogenic diets, vagus nerve stimulators, and implantable brain neurostimulators. (15)

The goal of current treatment options for epilepsy is eliminating seizure episodes with improved quality of life and limited adverse effects. In Ethiopia a hospital-based study done showed a 65.6 % seizure freedom for less than 1 year. (16)

Two most clinically relevant outcome dimensions we need to address seizure control and occurrence of adverse effects. The outcome of treatment can be classified simply as seizure-free or not. Seizure freedom without occurrence of adverse event is the most relevant outcome. (6)

Treatment outcome determination requires documentation of whether AED is applied adequately, details of management utilized, and treatment duration. Adequate dose definition includes documented titration of medication to reach minimum clinically effective dose, minimum utilization of AED for at least 3 months at a dose of 50% of the defined daily dose recommended by WHO.(7)

Seizure freedom is defined as freedom from all seizures, including auras for at least 12 months. Drug-resistant epilepsy considered when trials of two or more AEDs resulting in a ‘treatment failure’ outcome. (6)

Uncontrolled epilepsy is a continued occurrence of an unacceptable quantity of seizures despite reasonable treatment. Control of seizure can have multiple effects on both the individual and societal level. The effects can range from direct physical trauma to significant economic and psychosocial burdens. Multiple factors can predict the control of seizure. (18-22)

An uncontrolled seizure can have a deleterious effect on the brain itself ranging from neuronal death, dysfunctional synapses, and brain volume loss. In addition to the direct effect on the brain, it can cause heavily body injuries, psychological injuries, and social disability including high economic burden. (18, 21-22)

Epilepsy related expense to be high as shown in different studies. Resource implication of epilepsy treatment is higher where both direct medical cost and indirect cost is high. Medication expense and cost of lost productivity is higher in PWE. Seizure frequency is one of the cost-

driving factor in epilepsy. In Germany indirect cost associated with the care of patients with epilepsy is higher and study done in the Democratic Republic of Ghana showed the cost of epilepsy treatment to be higher due to the utilization of expensive traditional medication in addition to modern medicine (21.22)

Quality of life is also impaired in intractable epilepsy and relates to seizure control. Psychosocial disabilities, including lower social interaction with reduced marriage rates, reduced employment levels, reproductive and hormonal disorders are common in both men and women, and stress on the patient's family, caregivers, and support system are a common effect of poor seizure control.(9)

Limitation in simple day to day activities like restricted driving can have multiple consequences including reduced independence and mobility with resulting limited social interaction and employment opportunities.(9) Levels of anxiety and depression, perceived impact of epilepsy, perceived stigma have a clear relationship with the current seizure frequency. (26)

Convulsive uncontrolled seizures and nocturnal seizures are also associated with an increased risk of death including sudden unexpected death in epilepsy. (9)

Determining patients with the likelihood of poor seizure control help in counselling families of PWE and the patient themselves. Selection of patients for further detailed investigation and consideration of early initiation intensive management to an extent of epilepsy surgery can be considered with the use of predictors and factors with a clear association with control of seizure. Further research for the determination of the mechanisms that underlie poor control can be a major goal that can be achieved with the determination of poor prognostic factors. (19)

Seizure type, age at onset, etiology, duration of epilepsy and number of pre-treatment seizures, concomitant morbidity, family history of seizure, febrile seizure, electroencephalographic findings, response to the first drug, and genetics of drug resistance has been considered to affect seizure control. (20)

Several studies have shown response for first AED to have a strong predication for long term outcome in both adults and children. Presence of active seizure with utilization of adequate dose of AED the patient has a lower chance of remission of seizure. On the other hand, patients who tolerated the initial AED have a higher chance of remission. (20)

In addition to early predictors of seizure control, non-adherence to medications contribute to seizure control. Non-adherence to medication is widespread in chronic diseases including epilepsy is a major problem in medical practice. It is estimated non-adherence ranges from 30-50% in epileptic patients. Poor adherence may be the most important cause of poorly controlled epilepsy. (23)

The magnitude of antiepileptic drug non-adherence is ranged from 26% in the United States of America to 67% in Nigeria. As a study done in North Carolina indicated, the prevalence of AEDs non-adherence was 39% and it was higher (43%) in the elderly accompanied by an increased likelihood of hospitalization. A primary care-based study in the United Kingdom showed that the prevalence of antiepileptic drugs non-adherence was 36.4%. (24)

Some patients whose seizures prove difficult to treat could benefit from non-pharmacological strategies, especially epilepsy surgery, which remains one of the most underutilized effective treatment modalities worldwide. Early identification of patients whose seizures are likely to be pharmaco-resistant and have a factor that can be modified would permit them to be offered a referral for epilepsy surgery at the most appropriate juncture (12).

Patient identification, diagnosis, choice of drug treatment, disease and drug information and patient monitoring should always be part of the management of any chronic illness including epilepsy. The five steps represent a feedback loop required for management of epilepsy. Each step should be navigated effectively to achieve optimal outcomes(16)

2.2. Significance of the study

The current study aims to classify patients who have a follow-up at the neurology clinic based on their pattern of response at least into two categories; well controlled and Poor control. The identification of patients and classification helps in allocating appropriate resources and identifying those at risk of being drug-resistant. Specialty care can be diverted to those in need early.

This study will provide baseline line data for the current treatment gap and the pattern of response. It will be a stepping stone for further studies in the same area.

It will identify predictive factors that can be helpful for the management of such patients.

Chapter three

3. Objective

3.1 General objective

- ❖ To assess the patterns of treatment response and associated factors among patients with epilepsy at Neurology referral clinic, Tikur Anbessa Specialized hospital, Addis Ababa from October 1 to October 30,2020 G.C

3.2 Specific objective

- ❖ To assess the sociodemographic characteristics of patients with epilepsy on follow-up at neurology referral clinic, Tikur Anbessa Specialized hospital, Addis Ababa, from October 1 to October 30,2020 G.C
- ❖ To assess the patterns of treatment outcome among patients with epilepsy on follow-up at neurology referral clinic, Tikur Anbessa Specialized hospital, Addis Ababa, from October 1 to October 30,2020 G.C
- ❖ To assess factors associated with treatment outcome among patients with epilepsy on follow-up at neurology referral clinic, Tikur Anbessa Specialized hospital, Addis Ababa, from October 1 to October 30,2020 G.C
- ❖ To assess factors associated with antiepileptic drug utilization including adverse events among patients with epilepsy on follow-up at neurology referral clinic, Tikur Anbessa Specialized hospital, Addis Ababa, from October 1 to October 30,2020 G.C
- ❖ To assess patterns of clinical variables including seizure type among patients with epilepsy on follow-up at neurology referral clinic, Tikur Anbessa Specialized hospital, Addis Ababa, from October 1 to October 30,2020 G.C
- ❖ To assess antiepileptic drug adherence among patients with epilepsy on follow-up at neurology referral clinic, Tikur Anbessa Specialized hospital, Addis Ababa, from October 1 to October 30,2020 G.C

Chapter four

4. Methods

4.1. Study area

Addis Ababa lies 9°1 '48"N latitude and 38 ° 44 '24"E longitudes. The city is located at the heart of the country, at an altitude ranging from 2,100 meters at Akaki in the south to 3,000 (9,800 ft) meters at Entoto Hill in the North.

Tikur Anbessa Specialized hospital is the largest referral hospital in the Ethiopia with 1025 beds. It is an institution where specialized clinical services are rendered to the whole nation. It is the only center in the country where neurology speciality is undertaken.

There is neurology clinic that runs five times per week with separate epilepsy clinic carried out once per week. Overall a total of 1100 adult patients are evaluated at TASH with diagnosis of Epilepsy. Among the 1100 patients a total of 250-350 patients are seen each week at adult epilepsy clinic, TASH.

4.2. Study period

The study was conducted from October 1 to October 30, 2020 G.C.

4.3. Study design

A hospital based cross-sectional study was conducted among adult epileptic patients with follow up at adult neurology referral clinic of Tikur Anbessa Specialized Hospital (TASH).

4.4. Source population

All patients with Epilepsy who have follow up in adult neurology referral clinic in Tikur Anbessa Specialized Hospital, Addis Ababa.

4.5. Study Population

Patients with epilepsy on follow-up at neurology referral clinic whose phone number is registered on electronic medical records of TASH were included in the study.

4.5.1. Inclusion and exclusion criteria

4.5.1.1. Inclusion criteria

1. All patients who are 14 years of age and older.

❖ Follow-up at adult neurology clinic starts at age 14.

2. Patients who fulfil the definition of Epilepsy as per the ILAE 2017 G.C definition.

3. Patients who have follow-up for more than one year.- In order to asses treatment outcome patient must be followed for at least one year.

4.5.1.2. Exclusion criteria

1. Incomplete medical records.

2. Whenever patient or caregivers could not give the required information

4.6. Sampling method

Sample size was determined with single proportion formula.

Convenient sampling method was utilized.

n =,

Where n = the desired sample size

Z= value at α alpha risk express in z-score 0.05 = 1.96

P = estimated level of uncontrolled seizure

q = 1-p and

d = margin of error (5%).

n= = 322 when corrected for a population size of less than 10000 total sample size becomes 243

4.7. Variables

4.7.1. Dependent variables

The following variable is considered as dependent variable

1. Outcome of seizure management
2. Frequency of seizure

4.7.2. Independent variables

-Independent variables considered for this study include

1. Sex
2. Age
3. Economic status of the patient
4. Type of seizure
5. Number of medication
6. Co-morbidity

4.8. Data collection method

Data was collected from volunteer patients with registered phone number on the electronic medical records and patients seen at seizure clinic, TASH. Patients with registered phone number on electronic medical records were interviewed over phone. Patients' data were collected through interview and data retrieved from electronic medical recordings. Data regarding neuroimaging finding, EEG result and co morbidities were taken from electronic medical recordings.

Because of the current pandemic of COVID-19 the number of patients seen at regular clinic has reduced. In order to overcome the reduction in patients available for data collection data was also collected over phone.

Data was collected by second year medical students after receiving training.

4.9 Data analysis and quality assurance

Data analysis was done using SPSS version 26. The data was coded so that the confidentiality was not breached. The quality of data was assessed at each level of data entry. Median with IQR range and mean with SD was used for continuous variables, tproportion for categorical variables, bivariate and multivariate analysis was done for multiple factors

4.10. Ethical considerations

Official ethical clearance was secured from the Ethical Review Committee of the Department of Neurology, TASH. A written consent was translated to Amharic language and the purpose of study was explained to the study participant. Participants who were volunteer to participate in the study were included. Participants were free to decline giving information at any time without any justification and prejudice. Informed verbal consent was obtained before proceeding with data collection

4.11. Dissemination of the result

The findings of the study will be shared with relevant stakeholders such as the school of Medicine, Department of neurology, policy makers, candidates in the management of epilepsy and NGO'S who work on epilepsy.

4.12. Operational definition

- ❖ Treatment outcome-Effect of an intervention as categorized by seizure control
 - Classified into well control and poor control.
- ❖ Well controlled seizure/seizure freedom- absence of all seizure activity for at least one year period.
- ❖ Poor control of seizure-presence of one or more seizure attack in one year period.
- ❖ Adverse events related to AEDs- Unintended effect of the AEDs perceived by patient.
- ❖ Adherence- Utilization of prescribed AEDs with amount mentioned on prescription and on prescribed time

Chapter Five

5. Results

5.1. Socio-demographic Characteristics of the Study Subjects.

A total of 245 patients were interviewed and electronic medical records were reviewed in this study.

The number of male participants were 133 (54.3%) and female 112 (45.7%) respectively. A total of 145(59.2%) participants were between the age 15- 30 and 64(26.1%) of the participants were in the 31-45 age group. Only 18(7.3%) participants have no formal education. More than half (58%) of participants have never been married. Among the participants 160(65.3%) were employed.

Table 1: Sociodemographic characteristics of Patients with epilepsy at adult NRC,TASH , Oct 1-30,2020 G.C

		Count (n-245)	%
Sex	Male	133	54.3%
	Female	112	45.7%
Level of Education	No formal education	18	7.3%
	Primary school	63	25.7%
	Secondary school	80	32.7%
	More than secondary school	84	34.3%
Occupation	Unemployed	160	65.3%
	Employed	85	34.75%
Marital Status	Never Married	142	58%
	Married	92	37.6%
	Living together	0	0
	Separated/Divorced	10	4.1%
	Widowed	1	0.4%
	Never Married	142	58%

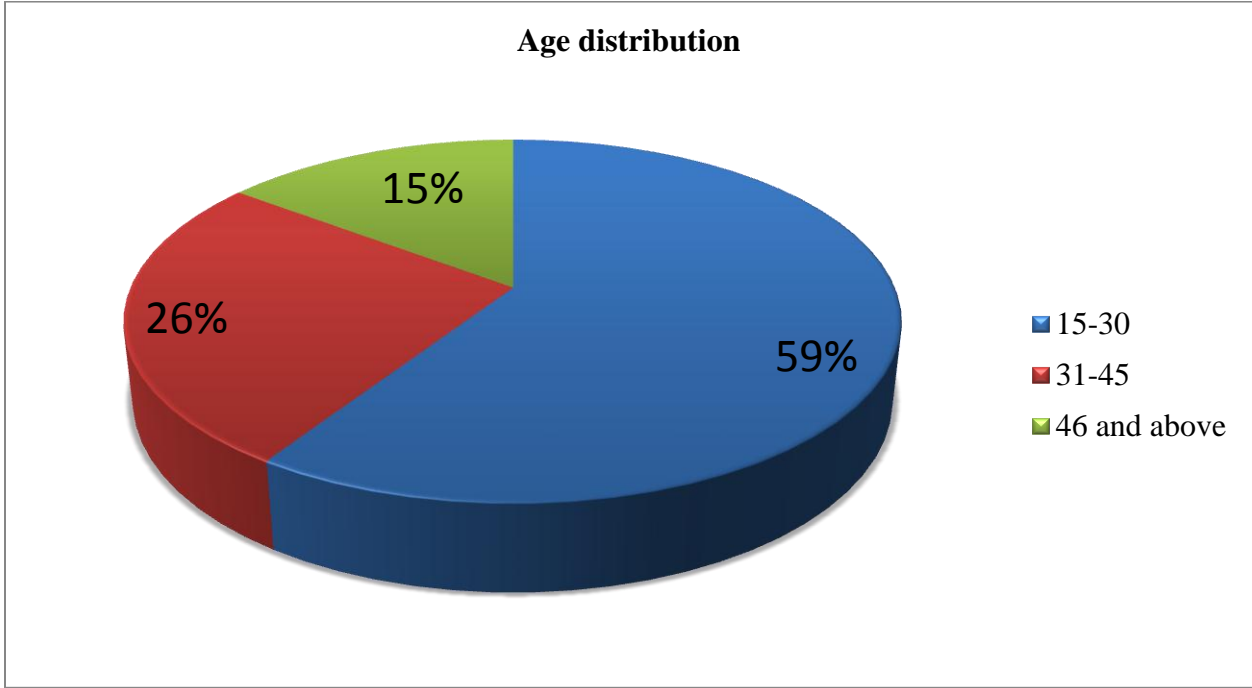


Fig 1: Age distribution of Patients with epilepsy at adult NRC, TASH, Oct 1-30, 2020 G.C

5.2. Clinical and laboratory data Information

The age of onset of seizure for participants was below 15 years for 115(46.9%) of participants. (Fig 2). The mean frequency of seizure was 2 with 54(21.1%) having more than 2 episodes of seizure in the past year.

More than half 172 (70.2%) of the patients had generalized onset seizure with 154(62.9%) having a generalized tonic-clonic seizure and 61(24.9%) of participants had focal onset seizure (Table 3).

Presence of comorbidity was reported in 110(44.9%) of participants. Psychiatric disorders account for highest proportion of comorbidities.

Positive family history of seizures was found in 29(11.8%) participants. There is a positive history of aura among 134(54.7%).

Imaging was done for 161(65.7%) participants. Abnormal imaging finding was found in 47(19.2%). EEG was done for 210(85.7%) patients where 78(31.8%) of participants had documented EEG results. Normal EEG was reported in 42(17.1%) of the cases where EEG was performed.

Table 2: Clinical Variables and laboratory findings of Patients with epilepsy at adult NRC, TASH, Oct 1-30,2020 G.C

		Count (n-245)	%
Type of Seizure	Generalized onset	172	70.2
	Focal onset	61	24.9
	Unclassified	10	4.1
	Unknown onset	2	0.8
Aura	Yes	134	54.7
	No	111	45.3
Any Comorbid Condition	Yes	110	44.9
	No	135	55.1
EEG	Yes	210	85.7
	No	35	14.3
Brain Imaging	Yes	161	65.7
	No	84	34.3
Family History of Seizure	Yes	29	11.8
	No	216	88.2

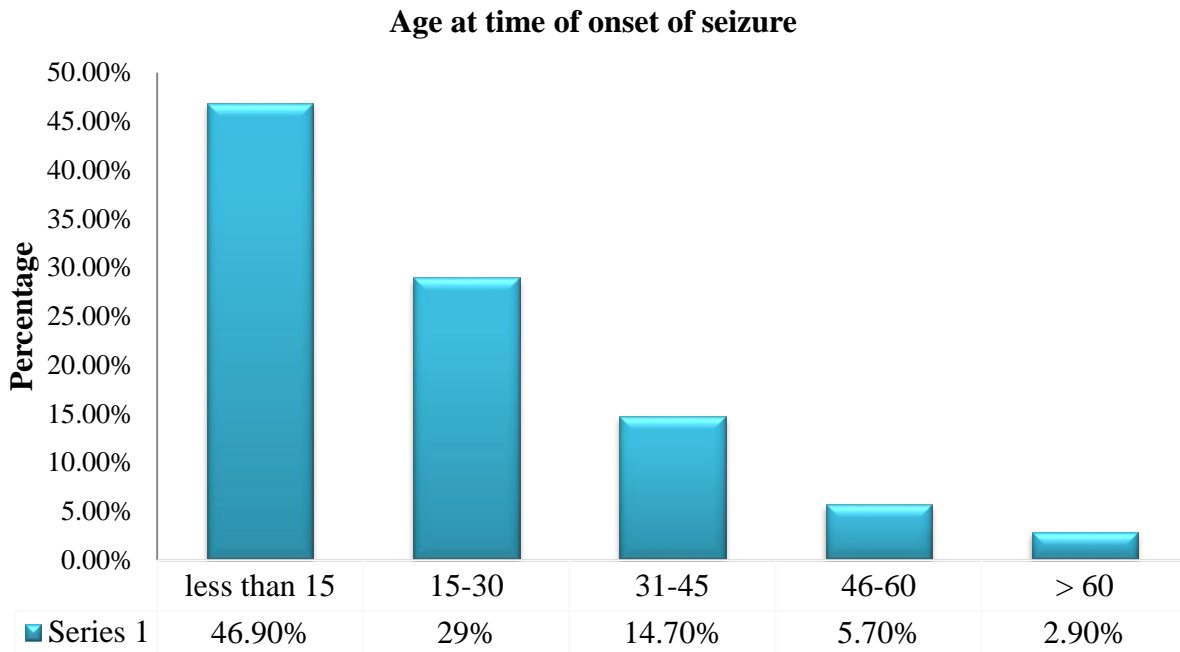


Fig 2: Age at time of seizure diagnosis of Patients with epilepsy at adult NRC, TASH, Oct 1-30,2020 G.C

5.3. Patterns of seizure control and AED associated factors

Reduction in seizure frequency, duration, and severity after initiation of AEDs was reported by 187(76.3%) of the participants (Figure 3) and 41(16.7%) had no seizure attack after initiation of AEDs. Reduction in seizure frequency and no seizure attack after initiation of AEDs accounts for a total of 228(93.1%) of patients treatment outcome. Among patients with no seizure after initiation of AEDs 41(16.7%) (Fig 6), 25 of them have reported adverse events related to AED utilization. Within the past one year 99(40.4%) of the participants having no seizure attack.

Participants placed on monotherapy were 68(27.8 %). Most commonly prescribed medications were Phenobarbital taken by 88(35.9%) participants, Carbamazepine was taken by 85(34%) of participants, and Phenytoin is taken by 72(29.45) of the participants.

One episode of seizure attack per week was reported by 125(51%) of participants before the initiation of medication. Only 16(5.7%) of participants had less than 5 episodes of seizure throughout their life before the initiation of medication.

Adverse events associated with AEDs were reported by 166(67.8%) the most commonly reported adverse event being sedation.

Among respondents, 68(27.8%) were not adherent to medication. Forgetfulness was reported among 24(9.8%) of the patients who do not take medication as prescribed.

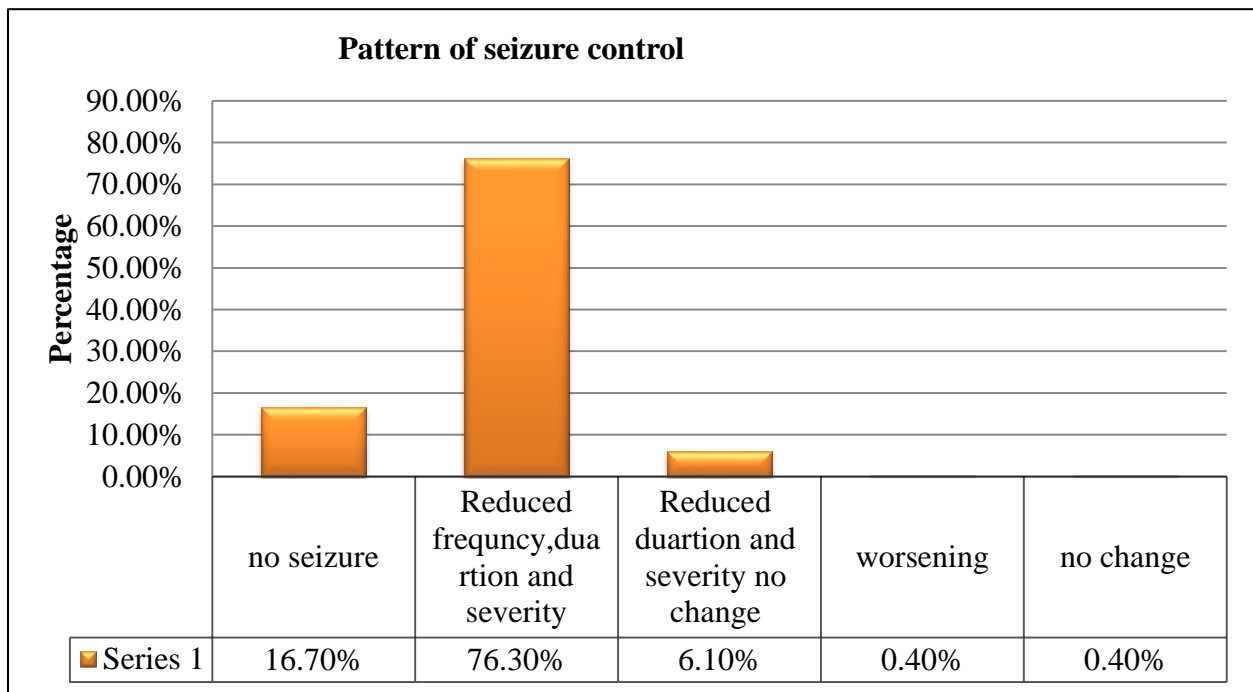


Fig 3: Pattern of seizure control after AED initiation of Patients with epilepsy at adult NRC, TASH, Oct 1-30, 2020 G.C

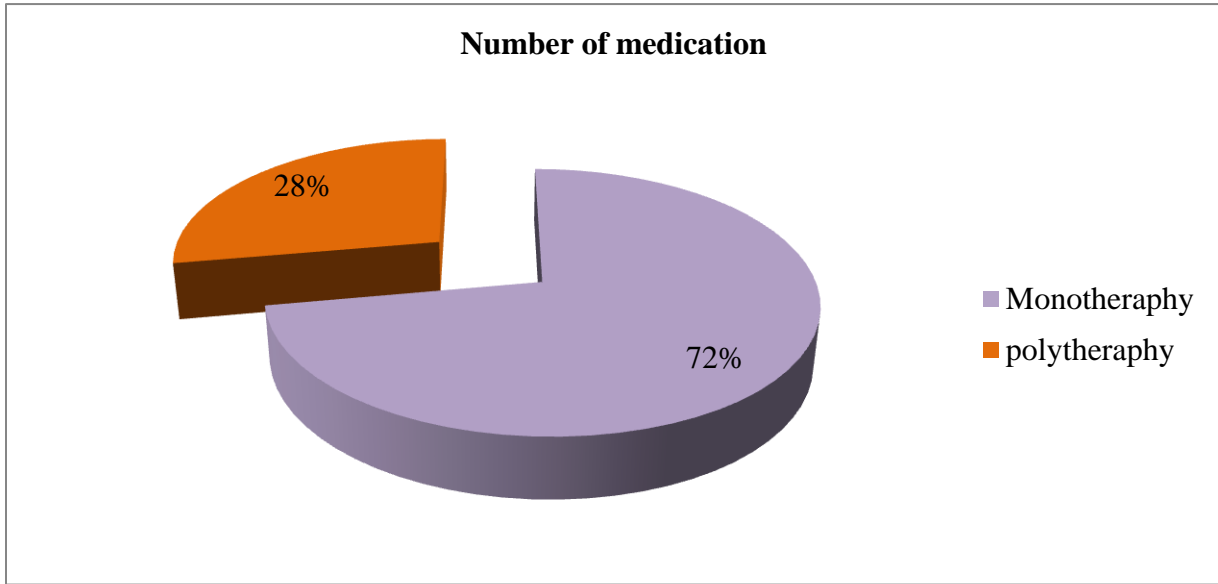


Fig 4: Monotherapy and Polytherapy utilization of Patients with epilepsy at adult NRC, TASH, Oct 1-30,2020 G.C

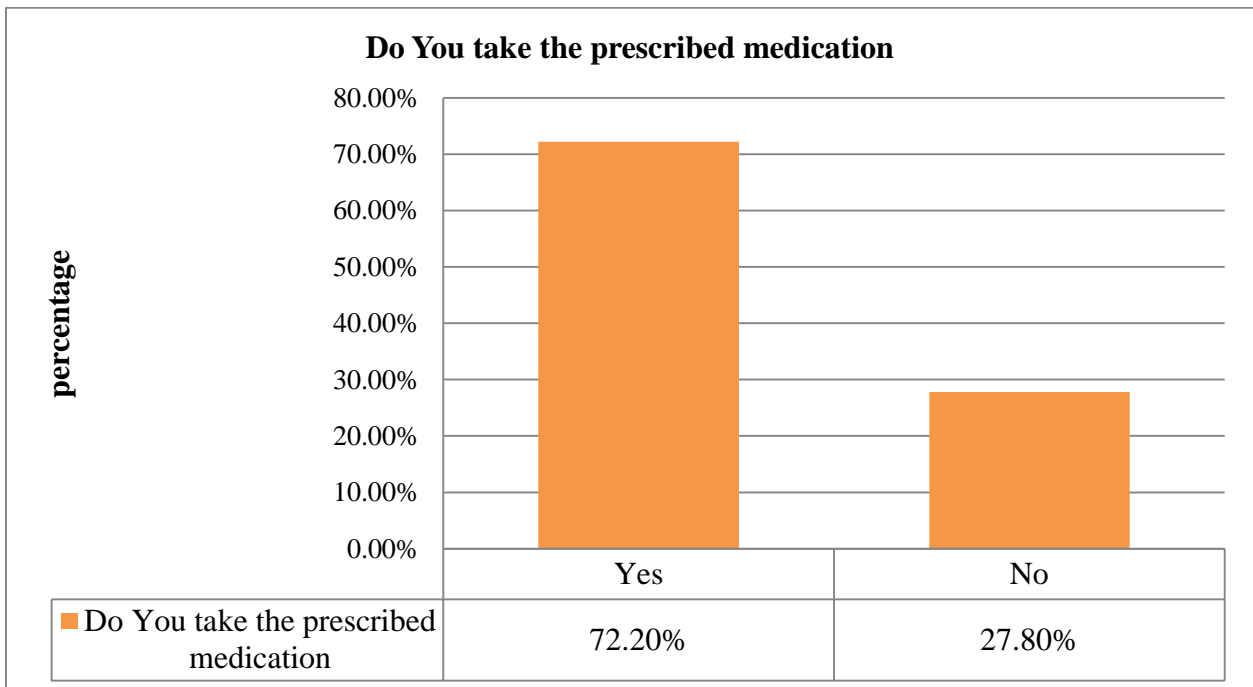


Fig 5: AED adherence pattern of Patients with epilepsy at adult NRC, TASH, Oct 1-30,2020 G.C

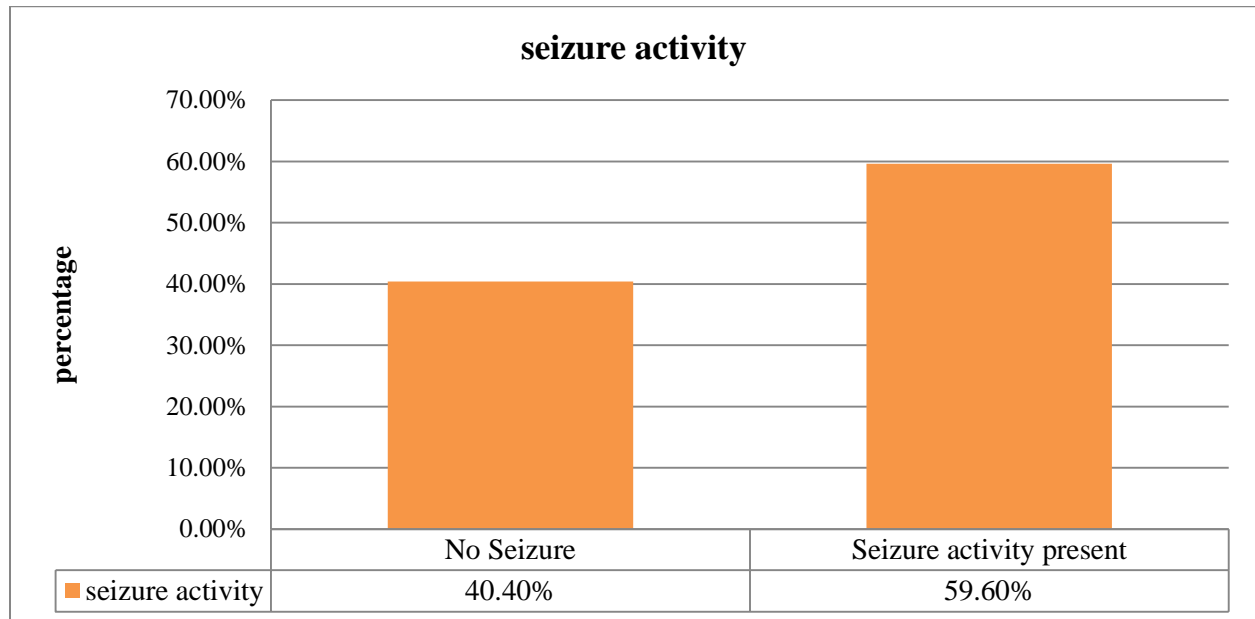


Fig 6: Seizure activity in the past one year of patients with epilepsy at adult NRC, TASH, Oct 1-30,2020 G.C.

5.4. Factors associated with seizure control

From the bivariate analysis: sex, number of medication, adverse reaction, presence of triggering factors, adherence status, presence of aura and EEG findings were associated with the pattern of seizure control at p-value <0.3 and entered into multivariate analysis.

From the multivariate analysis sex (AOR = 3.316, CI: 1.044,10.534) is the only factor with significant association with pattern of seizure control at a p-value <0.05 indicating male sex is associated with seizure activity with risk of seizure three times higher than female counter part.

Table 3: Factors associated with pattern of treatment response (bivariate and multivariate) analysis, of Patients with epilepsy at adult NRC, TASH, Oct 1-30,2020 G.C (n=245)

Variables	COR (CI)	AOR(CI)	P-value
Sex	1.821(1.087-3.051)	3.316(1.044-10.534)	0.042

Monotherapy vs Polytheraphy	0.281(0.145-0.542)	0.124(0.021-0.733)	0.214
Adverse reaction	0.735(0.422-1.279)	0.197(0.048-0.810)	0.247
Triggering factor	2.420(1.328-4.410)	2.323(0.446-12.093)	0.317
Adherence	0.470(0.256-0.863)	0.362(0.100-1.307)	0.121
Aura	1.422(0.851-2.375)	1.934(0.536-6.972)	0.314
EEG findings	1.625(0.659-4.007)	2.386(0.730-7.798)	0.150

Chapter 6

6. Discussion and Conclusion

6.1. Discussion

This current study assessed patterns of seizure control and associated factors control among 245 patients who have a follow-up at the TASH Adult Neurology referral clinic.

The number of male patients who have follow-up is male 133(54.3%). Comparable results studies done in a Bangladesh teaching hospital where 55% of patients were male, study done on Gondor showed 55% of patients were male and study done in Uganda showed 54% of participants were male. (4,31,32)

According to the result, the most common type of seizure is generalized onset seizure specifically generalized tonic-clonic seizure. Generalized tonic-clonic seizures tend to have an aggressive clinical presentation including the presence of loss of consciousness which to both the patient and a bystander are worrisome therefore increasing the tendency to visit a health facility. A similar finding was reported by other studies done in Ethiopia showing 77.6% of patients in mizan tepi and 72.9% in Gondor had a generalized tonic-clonic seizure. (4,14) The current study has not shown the effect of presence of generalized tonic-clonic seizure on treatment outcome. A study done at Shiraz University of Medical Sciences Iran has shown a similar finding. (27) On the contrary Focal onset, seizures tend to have minimal clinical presentation as compared to the generalized onset ones which is clearly apparent to a health professional, patients, and caregivers.

The majority of patients were on monotherapy and Phenobarbital is the most prescribed medication as part of monotherapy or polytherapy. This is in line with hospital-based studies done in Gondor teaching hospital, Ethiopia showing 80.35 % of the patients were on monotherapy. (4) Similar results were reported from studies done in Mizan Tepi teaching hospital, Ethiopia. (14) Phenobarbital was utilized in 35.9% of patients despite being the leading prescription in number the percentage is lower to similar studies done in other parts of Ethiopia probably be attributed to the study area being located in the capital city whereby different selections of AEDs are available and the fact that clinical service is rendered by neurologists .

Despite being on AED only 41 (16.7%) of patients had no seizure after initiation of AEDs. reported reduction in seizure frequency, duration, and severity was 187(76.3%). On the other hand, 99(40.4%) of the patients had no seizure in the last one year period. The standard care given with AEDs is estimated to make 70% of PWE seizure-free. The expected seizure freedom depends on multiple factors including appropriate drug selection for each specific seizure type, making the right diagnosis, adherence to medication, and drug-drug interaction, intrinsic factors associated with drug metabolism. Some of these variables are beyond the scope of this study.

Despite not attaining seizure freedom the proportion of patients with more than 1 per week seizure have an improvement in seizure control were 187(76.3) have a reduction in seizure frequency.

Comorbid illness was present in 110(44.9%) of patients which is comparable to results seen in hospital based studies Mizan Tepi, Teaching Hospital (28%) and Mekele, Ayder comprehensive teaching centers (39%). Lower percentage seen hospital based study done in Wollo, dessie referral hospital and 6.2% in northwest Ethiopia(Debre Markos Referral Hospital and Finote Selam District Hospital).(14,24,28,33)

The most commonly diagnosed comorbid condition reported is a psychiatric condition that is consistent with findings globally as well as locally from different parts of Ethiopia including Mekelle, Mizan Tepi, and Gondor. (4,14,33)

Adverse effects of antiepileptic drugs have emerged as one of the strongest predictors of impaired health-related quality of life, independent of seizure outcome and adverse events seem unavoidable complicating seizure control and adherence. (29-30) The reported adverse effect was 68.8% in the current study. A study was done in Mezian-Tepi showed comparable adverse events(72.2%). A study done in Russia showed adverse event in only 6.1%.(34) The differences in different setups might be due to the follow-up for adverse events during each clinic visit with a concomitant determination of serum drug level and subsequent intervention like drug dosage adjustment and also shifting medication.

In this study, it is showed that 27.8% of patients were not adherent to medication or were not taking medication during prescribed time forgetfulness being the major reason for non-adherence. A cross-sectional study done in Debre Markos Referral Hospital and Finote Selam District Hospital showed AEDs non-adherence level of 37.8%.(24). Another hospital-based cross-sectional study done in southern Wollo showed a non-adherence level to AEDs of 34.1% and a major reason for missing medication being forgetfulness (53.5%). (28)

There is association between male sex and increase seizure activity shown in the current study adjusted odds ratio (AOR)= 3.316, CI=1.044-10.534;p-value=0.042). There is no prior study showing a realtion ship between sex and seizure control. But multiple hospital based studies in Ethiopia have shown slightly increased male patients with epilepsy at followup clinic including this study.

6.2. Conclusion

Based on the current study the number of patients still having a seizure is high more than 2/3rdof patients still experiencing seizure despite being placed on AEDs. In this study, sex was

associated with treatment outcome. Further study on each specific pattern of treatment outcome can be assessed in further studies. There is no prior studies linking the increased tendency of Male patients to have poor seizure control. The increment could be multifactorial including presence of preceding trauma.

6.3. Limitation of study

The major limitation of this study is it is conducted in one of the highest tertiary hospitals with a separate neurology department running the seizure follow-up clinic which makes a majority of the patients seen to have different clinical presentations making generalization for other setups difficult. And the cross-sectional nature of the study can not clearly conclude the cause and effect relation between the patterns of seizure especially poor seizure control and the predictors mentioned.

Due to multiple factors, the level of adherence and adverse events might be biased. Recall bias can affect our report, especially when assessing the level of seizure freedom. Major findings like EEG results and Imaging which might have an impact on seizure control have a large portion of data missing making our conclusion regarding the two topics difficult.

6.4 Recommendation

The study showed a significant proportion of patients continue to have seizure attacks. Even though there is no associated predictor of treatment outcome in the current study further study dedicated to each specific treatment outcome should be done.

Regarding the completeness of data, every stakeholder involved in the management of such patients should document relevant information regarding each specific illness.

Epilepsy continued to have a still significant burden on patients and society which should get emphasis starting from the ministry level.

To address the pattern of treatment outcome further multisystem study should be done. And further study regarding each pattern of treatment outcome should be done.

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Annexs

Annex 1: Declaration

I, the undersigned, declare that this postgraduate thesis is my original work, has not been presented for a degree in this or any other university and that all sources of material used for the thesis have been duly acknowledged.

Postgraduate Candidate: Paulos Efrem (MD, Internal Medicine Resident)

Signature:.....

Date of Submission: December 29, 2020

This thesis has been submitted with my approval as advisor.

Advisor: Getahun Tarekegn (MD, Internist, Endocrinologist)

Signature:

Date:

Place: Addis Ababa, Ethiopia

ANNEX 2

Participant Information Sheet: English version

I am a 3rd year neurology resident at Addis Ababa University, School of Medicine, Department of Neurology. I am inviting you to participate in a study that will examine the Pattern and associated factors of treatment response in epileptic patients who have follow -up at the neurology referral clinic at TASH. Individuals who have epilepsy and have been on treatment at the neurology referral clinic for at least one year will be recruited for this study. There is no risk in participating in this study. There is no intended monetary compensation involved for participating in this study. The potential reward of knowing that the participant has contributed to a knowledge base that will help individuals with epilepsy receiving the appropriate and standard services in the future is the only benefit. The confidentiality of the participants will be protected. After receiving your consent the data gathered will only be accessible to researchers of this study. The data collected from you will be documented and analyzed anonymously. Your name will not be mentioned in the study. Although your input would be greatly appreciated, your participation in this study is absolutely voluntary. You may withdraw from this study at any point in time when you believe to do so.

Are you willing to participate?

A) Yes B) No

For any issues related with this study, please contact

Principal investigator: Hilina Dagnachew

Phone number: - 0966823193 Email: - hilina29dag@gmail.com

የተሳታፊዎች መረጃ

የ መረጃ መሻ ጫ ስምምነት ቅጽ ወይም ወል

ሰላም ! ስሜ ህሊና ዳናች ወይ ባላል እኔ በአዲስ አበባ ዩኒቨርሲቲ የጠፍሳይንስ በኒ ወሮሎጂ ትምህርት ክፍል የድህረ መመሪያ ጽሑፍ በመሻራት ላይ እገኛለሁ። የመመሪያ ጽሑፍ የሚገልጽ በሽታ ያለባቸው ታካሚዎች ላይ በተያያዥ ጉዳዮች ላይ ያተኮረ ሲሆን ከዚህ በተያያዘ እንዳንድ ጥያቄዎችን ቅጽ ማሙላት አለብን። :

ይህ ጥናት ለጠፍሳይ ምኞት እና ለመንግስት መረጃ በመስጠት የሚገልጽ በሽታ ያለባቸው ታካሚዎች እንዲገኙ ጥራት ያላቸውን ዲቫሽን ያደርጋል። ጥያቄዎችን ለመሙላት ስብዘት ሰላሳ ደቂቃ ለውስጥ ድይቻ ላይ። ማለትም በትክክል ይሙሉት ለትክክል ይሙሉት። በጥናቱ ላይ የእርሶ ስም ይጠቀስ ማለት ማለትም ጃክ ዘህ ጥናት አላማ ወይን ሌላ አካል ተላልፎ አይሰጥም። ማህበራዊነት የተጠበቀ ወ። በዚህ ጥናት ላይ በመሳተፍ ለጤና ጊዜ ወይም ለሌላ ማህበራዊ ጥያቄ ስለሌላ ጉዳት ምሆን ጥቅም አይኖርም። :

በዚህ ጥናት መሳተፍ ምኞት ካልሆኑ በመጠይቁ ማለት ጥክፈላ ጉወይ ምህላ ስለሚፈልጉት ጥያቄ ሲኖር የሚታወቅ ጥሙር ማለት እንዳለ ምኞት ልገ ልገ ልገ ወዳለሁ። በጥናቱ ላይ መሳተፍ የእርሶ ትብብር እና ፍቃድ ነፃነት በጉዳዩ ላይ የሚሰጥ ስትግሮችን ለመላ የትእጅግ ጠቃሚ ስህተት በጥናቱ ላይ ፍቃድ ነፃነት እንዲሰጥ ትህትና እጠይቃለሁ። :

ከላይ በተሰጠው መረጃ መሻሻል ትብብር ጥናት ላይ ለመሳተፍ

ፍቃድ ነፃነት ማስጠበቅ ለሁም

የጥናቱ ስራ ስለሚከናወን

መጠን ቅጽ ማሙላት ወይም ልገ ልገ ልገ ነፃ ስር ካለ ከታች በተጠቀሰው አድራሻ ማግኘት ይቻላል። :

የጥናቱ አድራሻ ወስን

ስልክ ቁጥር 0966823193

ኢ.ሜል hilina29dag@gmail.com

Annex 3: Questionnaire (English)

I care no-

1.Socio demographic

1.1 Age

1.2 Sex A. Male B. Female

1.3 Level of education

- A. No formal education
 - Can read and write
 - Can't read and write
- B. Primary school (grade 1-8)
- C. Secondary school (grade 9-12)
- D. More than secondary

1.4 Marital status

- A. Never Married
- B. Married
- C. Living together
- D. Separated/Divorced
- E. Widowed

1.5 Living palace A. Urban B. Rural

1.6 Occupation

- A. Unemployed
 - I. Housewife
 - II. Retired
 - III. Out of job
 - IV. Student
 - V. Other
- B. Employed
 - I. Professional/ technical/managerial
 - II. Clerical
 - III. Skilled manual
 - IV. Agriculture
 - V. Other

1.7 Age at the time of seizure

- a. less than 15
- b. 16-30
- c. 31-45
- d. 46-6
- e. Greater than 60

2. Types of seizure

Types of seizure			
Older classification		Newer classification	
A.Generalized seizure			
I. Tonic clonic			
II. Tonic			
III. Clonic			
IV. Myoclonic			
V. Absence			
VI. Other			
B. Partial seizure			
I. Simple seizure			
II. complex seizure			
III. Focal with secondary generalization			
C.Unclassified			

3. Type of medication

Mono therapy

Phenytoin

Phenobarbital

Lamotrigine

Carbamazepine

Valproate

Other

4. Time on anti- epileptic medications ----

5. Duration of treatment in Tikur Anbessa Specialized Hospital for the epilepsy---

6. Frequency of attack per week before initiation of treatment

a. Adverse reactions of medicine (make X sign on the appropriate adverse effect)

Adverse effect

Mark here

headache

Constipation

Vomiting

Gingival hypertrophy

Psychomotor impairment

Gastric stress

Hypersomina

Skin rash

Joint pain

dizziness

Hepatotoxicity

Shortness of breath

Sedation

Fatigue

Hypoglycemia

Other : specify

Strong necessity belief

Low necessity belief

Medication necessity belief

Medication concern belief

Overall medication belief

7. What is the pattern of seizure control?

- A. Complete seizure control(no seizure)
- B. Reduced seizure frequency, severity and duration
- C. Reduced seizure and duration but no change in frequency

8. If it's poorly controlled what is the Frequency of seizure during the last one year

- A. none
- B. 1-5 times
- C. 6-10 times
- D. greater than 10 times

9. Are there any EEG done after treatment is started? A. Yes B. No

10. What is the finding of the EEG Result?

- A. Normal EEG
- B. Abnormal EEG other than epileptiform discharge
- C. Epileptiform discharge

11. Are there Any Co-morbid conditions?

A. Yes B. No

If yes what are the co-morbid conditions

- A. Hypertension
- B. Diabetic mellitus
- C. Heart failure
- D. Psychiatric conditions
- E. HIV
- F. Space occupying lesion except tuberculoma
- G. Tuberculoma
- H. Stroke
- I. Headache
- J. Systemic malignancy
- K. other specify _____

12. Have you taken any medication other than anti-epileptic medicine? A. Yes B. No

13. Possible medication taken in the last one month. Retrieve data from patient card or by asking directly the patient

14. Is there any triggering factor for the seizure to occur? A. Yes B. No

If yes what is the triggering factor?

- a. Emotional stress
- b. Sleep deprivation
- c. Missing medication
- d. Heavy alcohol use
- e. hunger
- f. High temperature
- g. Headache
- h. Fatigue
- i. Menstruation
- j. Other specify

15. Do you take your medication in the prescribed time? A. Yes B. No

If no select the most appropriate reason for not taking your medication

- a. Cannot afford to buy the medication
- b. Forgetting to take medication
- c. Medication related side effect
- d. My working condition makes it impossible
- e. Misunderstanding of instruction about how to take the medications
- f. Lack free medicine supply

- g. Lack of understanding with physicians
- h. Duration and previous treatment failure
- i. Long distance from treatment facility
- j. Cost of medication

17. Do you have family history of seizure

Yes no

18 .Do you have aura

Yes no

If yes

Visual aura

Auditory aura

Olfactory aura

Sensory aura

19. Imaging done during followup

Yes no

If yes what is the finding

1. Normal

2. Space occupying lesion

3. Hippocampal scleriosis

4. MTLE

5. Stroke

6. others

Thank you so much for committing your time for participating in this research!!!