

Epilepsy Treatment Outcome, Adherence to Anti-seizure Medications and Predicting Factors at the Chronic Care Facility in Jimma University Medical Center, Jimma, Southwest Ethiopia: Cross-sectional Study

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Abstract

The aim of this study was to assess epilepsy treatment outcome, adherence to Anti-seizure medication (ASM), and its predictors among epileptic patients on follow-up at the chronic care unit of Jimma University Medical Center with a total of 168 epileptic patients enrolled in the study. Data was collected by data collectors using data abstraction formats, then entered and analyzed using SPSS version 26.0. Multiple logistic regression analysis was performed to identify the association between dependent and independent variable. In this study, 132(78.6%) patients were adherent to their ASMs. Seizure recurrence was identified in 120(71.4%) patients. Rural residence (AOR=6.42, 95% CI: 1.32, 31.28, P=0.02), chronic ASM therapy for above five years (AOR=20.86, 95% CI: 2.66, 163.77, P=0.00), and complaint of ASM-associated undesirable effect (AOR=13.51, 95% CI: 2.72, 67.26, P=0.00) significantly increased the probability of seizure recurrence. On the other hand, the presence of seizure triggering factors (AOR=0.12, 95% CI: 0.02, 0.64, P=0.01) decreased the probability of seizure recurrence by 88%.

Keywords: Epilepsy • Anti-seizure medication • Treatment outcome • Jimma University Medical Center • Ethiopia

Introduction

Epidemiologically, epilepsy is one of the most common neurological diseases affecting about 50 million people globally. Low- and middle-income countries take the lion share were nearly 80% of people live with epilepsy [1]. According to the 2017 report from the Global Burden of Disease Study, the prevalence of epilepsy in Ethiopia was estimated to be 0.38% causing a 0.68% sudden death [2].

Seizure control is the main outcome measure of treatment in patients with epilepsy, and this can be realized in an estimated 70% of the patients with proper diagnosis and treatment. However, three-quarters of people with epilepsy in low-income countries suffer from seizure recurrence due to different reasons [1]. In various studies conducted in Ethiopia, seizure recurrences were reported in more than half of epilepsy patients with medical treatment. Number of drugs, adherence to Anti-seizure medication (AEM), presence of comorbidities, multiple ASMs, side effect, and educational levels were among the factors mentioned to affect seizure recurrence [3-7].

As one of the determinant factor affecting seizure recurrence, adherence to ASM is strictly recommended in epilepsy patients. However reports indicated that up to 75% of people with epilepsy fail to adhere to ASM regimens. This negatively affects the benefit that could be derived from

ASMs leading to seizure recurrence and decreased quality of life [8]. One systematic review and meta-analysis conducted in Ethiopia had also reported a high pooled prevalence (39.77%) of ASM non-adherence [9]. Marital status, level of education, epilepsy treatment duration, side effects and absence of co-morbidity were among the determinants affecting adherence to ASMs reported in various studies [3,4,10-13]. Given the availability of limited studies in Ethiopia, epilepsy is still an area to be addressed further. Therefore, this study is aimed to assess adherence to ASM, seizure control status, and its predictors among epilepsy patients on follow-up at the chronic care unit of (JUMC).

Methods

Study area and period

This study was conducted at the chronic care unit of JUMC from March 20 to June 30, 2022. JUMC is a tertiary teaching hospital in Ethiopia, located in Jimma town, southwest region of the country and found 346 km from Addis Ababa, the capital city of Ethiopia. JUMC serves for a Catchment's population of 15,000,000. There are inpatient, and outpatient services in the chronic illness follow-up clinics including epilepsy treatment service [14].

Study design

A Hospital-based cross-sectional study was employed.

Study population

Eligible epileptic patients (n=168) who visited the chronic care unit of JUMC for follow-up during the study period were included.

Sample size determination and sampling method

The sample size was determined using a single population proportion formula. From related studies conducted in Ethiopia, a proportion (P) of the uncontrolled seizure (44.7%) which gave a higher sample size was taken [6]. Thus, considering the total source population of N=254, P=0.447, a confidence interval of 95% ($\alpha=0.05$) and d=0.05, after using the correction

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formula and including a 10% contingency, the sample size was $n=168$. During the data collection, eligible epileptic patients were included on their visit to the chronic care unit for follow-up until the estimated sample size reached. Systematic random sampling was carried out to conduct the study.

Eligibility criteria

Epileptic patients whose age was ≥ 15 years, who had been on ASM therapy and on follow-up at the chronic care unit of JUMC for at least one-year duration were included in the study. Mentally unstable (epileptic patients with aggressive psychiatric manifestations) or critically ill patients (epileptic patients with worsened seizure and/or serious comorbid condition (s) to be admitted for treatment in the ward) were considered ineligible.

Study variables

Treatment outcome status (good, poor) and adherence to ASMs were considered as the dependent variable. Patient-related factors (age, sex, place of residence, religion, educational level, occupation, monthly income, marital status, and pregnancy status), drug-related factors (ASM, number of ASM, undesirable effects of ASM, and adherence to ASM), and disease-related Factors (seizure triggering factors, comorbidity, number of comorbidities, time since seizure is diagnosed, types of seizure diagnosed, follow-up, frequency of seizure attack before ASM, presence of brain injury, and presence of neurologic disturbances) were the independent variables.

Instrument and data collection technique

The data abstraction format was developed after an in-depth literature review. The abstraction format is comprised of both adopted and standard questions. The standard tool, Morisky medication adherence scale-8 (MMAS-8) was used to assess the adherence level of patients to ASM. It is a widely used and validated self-reported questionnaire for assessing medication adherence in chronic illness. The tool contains eight questions with a total score ranging from 0 to 8 points. Medication adherence was considered as low, medium, and high if the total score is >2 , 1 to 2, and 0 points, respectively. In this study, patients having medium and high adherence to ASM were considered adherent, whereas patients with a low adherence were categorized as non-adherent. Patient interviews and medical chart reviews were employed to collect the data. Prior to the data collection, training was provided to the data collectors (two Clinical Pharmacy students) on the data collection format and data collection procedure. Then, the data collection format was pre-tested.

Data quality control

Completeness and accuracy of the collected data were checked on a daily basis to ensure and maintain the quality of the collected data.

Data processing, analysis, and presentation

SPSS version 26.0 was used for data entry and analysis. Descriptive statistics such as frequency and percentage were employed to summarize the findings of the study variables. Binary logistic regression was conducted and variables with a $p \leq 0.25$ were considered a candidate for multiple logistic regression analysis. Multiple logistic regression analysis was performed to identify predictors of seizure recurrences. Text, tables, and figures were employed for data presentation.

Definitions of terms

Seizure recurrence was defined as experience of one or more seizure attacks in the last one year before the study period. Seizure triggers are situations that can result on a seizure in people with epilepsy. The most common triggers include tiredness and lack of sleep, stress, alcohol, and not taking medication [15]. Brain injury is an injury resulting from an external force on the head, such as sudden and violent hitting an object, an object piercing the skull and entering brain tissue, and others. Brain injury has

a potential to cause seizures [16]. Neurologic disturbance/deficit is any cognitive, verbal, visual and other related disturbances as diagnosed and recorded by the treating physician in the patient chart.

Results

Socio-demographic characteristics of study participants

The study involved a total of 168 eligible epilepsy patients. Of the total, 88 (52.4%) of them were male. The majority of the study participants were <45 years old 136 (81%) (Table 1).

Table 1. Sociodemographic characteristics of the study participants.

Socio-Demographic Characteristics	Frequency (%)
Age, Years	
15-30	68 (40.5)
31-45	68 (40.5)
46-60	21 (12.5)
>60	11 (6.5)
Sex	
Male	88 (52.4)
Female	80 (47.6)
Residence	
Urban	68 (40.5)
Rural	100 (59.5)
Religion	
Muslim	103 (61.3)
Orthodox	47 (28.0)
Protestant	15 (8.9)
Others (Catholic, Wakefata)	3 (1.8)
Marital status	
Single	60 (35.7)
Married	91 (54.2)
Divorced	11 (6.5)
Widowed	6 (3.6)
Education level	
No formal education	106 (63.1)
Primary (1-8)	44 (26.2)
Secondary	13 (7.7)
College/University	5 (3.0)
Occupation	
Farmer	75 (44.6)
Daily labor	35 (20.8)
Merchant	30 (17.9)
Student	10 (6.0)
Government employee	8 (4.8)
Others	10 (6.0)
Monthly income, in ETB	
<1000	126 (75.0)
1000-2000	25 (14.9)
2001-3000	8 (4.8)
3001-4000	6 (3.6)

>4000	5 (3.0)
Pregnancy	
Yes	14 (8.3)
No	66 (39.3)

Clinical characteristics of the study participants

Generalized tonic-clonic seizure (GTCS) was the most common type of seizure, 127 (75.6%), diagnosed. Brain injury was recorded in 46 (27.4%) study participants. Seizure triggering factors were reported in 88 (52.6%) of the study participants, and missing medication, 67 (76.1%), was the predominantly mentioned reason. There was evidence of neurologic disturbance in 152 (90.5%) study participants (Table 2).

Table 2. Clinical characteristics of the study participants.

Clinical Characteristics	Frequency (%)
Age of the patients at diagnosis, Years	
< 15	7 (4.2)
15–30	76 (45.2)
31–45	60 (35.7)
46–60	14 (8.3)
>60	11 (6.5)
Duration on follow-up, Years	
1–5	81 (48.2)
5–10	63 (37.5)
>10	24 (14.3)
Comorbid condition	
Yes	26 (15.5)
No	142 (84.5)
Type of comorbid condition	
Diabetes mellitus	1 (3.8)
Hypertension	8 (30.8)
Chronic Heart Failure	1 (3.8)
Urinary tract infection	4 (15.4)
Peripheral neuropathy	2 (7.7)
Pneumonia	2 (7.7)
Others (Asthma, CKD, and trauma)	8 (30.8)
Brain injury	
Yes	46 (27.4)
No	122 (72.6)
Time of brain injury occurrence	
Before seizure	35 (76.1)
After seizure	11 (23.9)
Triggering factors	
Yes	88 (52.4)
No	80 (47.6)
Type of seizure triggering factors	
Missing medication	67 (76.1)
Sleep deprivation	14 (15.9)
Emotional stress	7 (8.0)
Types of seizure diagnosed	

GTCS	127 (76)
Unclassified	41 (24.0)
Frequency of seizure attack before ASM	
1–5	155 (92.3)
6–10	13 (7.7)
Frequency of seizure attack in the previous one year before the study period	
0	120 (71.4)
1–5	46 (27.4)
>5	2 (1.2)
Neurologic disturbances/deficit	
Yes	152 (90.5)
No	16 (9.5)

Anti-seizure medication therapy and related factors

More than half (55.4%) of the patients were on combination ASM. Phenobarbitone, 66 (39.3%), was the most commonly prescribed monotherapy, whereas the most commonly prescribed combination ASM was Phenytoin plus Phenobarbitone, in 68 (40.5%) patients (Figure 1).

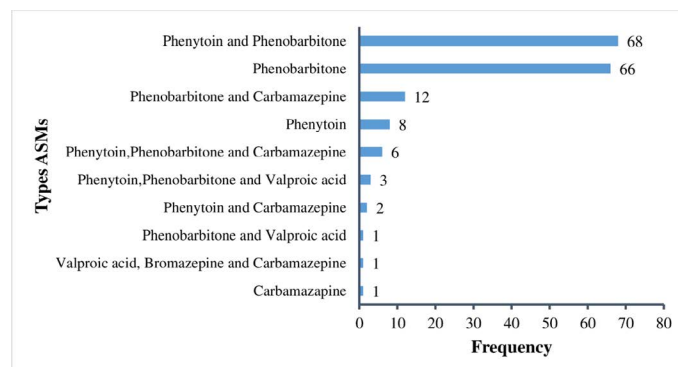


Figure 1. Types of ASMs taken by the epilepsy patients

Most of the epileptic patients, 132(78.6%), were adherent to their ASMs. Undesirable effects of ASMs were recorded in 49 (29.2%) patients (Table 3).

Table 3. Anti-seizure medication therapy and related factors

ASM related factors		Frequency (%)
Mode of management	Monotherapy	75 (44.6)
	Combination therapy	93 (55.4)
The most frequent monotherapy	Phenobarbitone	66 (39.3)
The most frequent combination therapy	Phenytoin plus phenobarbitone	68 (40.5)
Duration on ASM, years	1 to 5	81 (48.2)
	5 to 10	63 (37.5)
	Above 10	24 (14.3)
Adherence to ASM		
	Adherent	132 (78.6)
	Non-adherent	36 (21.4)
Complaint of ASM- associated undesirable effects		
	Yes	49 (29.2)

	No	119 (70.8)
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Seizure control status

Seizure recurrence was identified in 120 (71.4%) patients. Of those patients who had no seizure recurrence, 28 (16.7%) of them had seizure-free periods of 1-2 years.

Factors associated with anti-seizure medication adherence

On the binary logistic regression analysis, ten variables had a P<0.25 and recruited for multiple logistic regression analysis. Of the ten recruited variables, age category from 31-45 years (COR=0.41, 95% CI: 0.18, 0.97, p=0.04), being government employee (COR=4.77, 95% CI:1.05, 21.58, p=0.04), being primary (COR=2.63, 95% CI:1.15, 6.01, p=0.02) or secondary (COR: 3.52, 95% CI: 1.02, 12.12, p=0.04) schooled, history of brain injury (COR: 3.18, 95% CI:1.47, 6.89, p=0.00), presence of seizure triggering factors (COR: 2.49, 95% CI: 1.13, 5.47, p=0.02), multiple ASMs use [use of two ASM (COR:2.84, 95% CI:1.17, 6.87, p=0.02), use of three ASM (COR: 19.54, 95% CI:4.20, 91.01, p=0.00)], complaint of ASM-related undesirable effects (COR: 2.40, 95% CI:1.12, 5.17, p=0.03), and presence of seizure recurrence (COR:0.29, 95% CI:0.14, 0.64, p=0.00) were significantly associated with adherence status. Running multiple logistic regression analysis identified no predictors for non-adherence (Table 4).

Table 4. Binary logistic regression analysis for identifying factors associated with adherence.

Variables	Adherent, n (%)	Non-adherent, n (%)	COR (95% CI)	P-value
Age				
15-30	48 (36.4)	20 (55.6)	1	
31-45	58 (43.9)	10 (27.8)	0.41 (0.18, 0.97)	0.04
46-60	17 (12.9)	4 (11.1)	0.57 (0.17, 1.89)	0.35
>60	9 (6.8)	2 (5.6)	0.53 (0.11, 2.69)	0.45
Occupation				
Farmer	62 (47.0)	13 (36.1)	1	1
Merchant	25 (18.9)	5 (13.9)	0.95 (0.31, 2.96)	0.94
Student	7 (5.3)	3 (8.3)	2.04 (0.47, 8.97)	0.34
Government employee	4 (3.0)	4 (11.1)	4.77 (1.05, 21.58)	0.04
Daily labor	27 (20.5)	8 (22.2)	1.41 (0.53, 3.80)	0.49
Others	7 (5.3)	3 (8.3)	2.04 (0.47, 8.97)	0.34
Educational level				
No formal education	90 (68.2)	16 (44.4)	1	1
Primary	30 (22.7)	14 (38.9)	2.63 (1.15, 6.01)	0.02
Secondary	8 (6.1)	5 (13.9)	3.52 (1.02, 12.12)	0.04

College/ University	4 (3.0)	1 (2.8)	1.41 (0.15, 13.41)	0.77
Pregnancy				
Yes	8 (13.3)	6 (30.0)	2.79 (0.83, 9.36)	0.09
No	52 (86.7)	14 (70.0)	1	1
Brain injury				
Yes	29 (22.0)	17 (47.2)	3.18 (1.47, 6.89)	0.00
No	103 (78.0)	19 (52.8)	1	
Merchant	Merchant	Merchant	Merchant	Merchant
Triggering factors				
Yes	63 (47.7)	25 (69.4)	2.49 (1.13, 5.47)	0.02
No	69 (52.3)	11 (30.6)	1	
Neurologic disturbance				
Yes	117 (88.6)	35 (97.2)	04.49 (0.57, 35.18)	0.15
No	15 (11.4)	1 (2.8)	1	
Number of prescribed ASM				
One	67 (50.8)	8 (22.2)	1	1
Two	62 (47.0)	21 (58.3)	2.84 (1.17, 6.87)	0.02
Three	3 (2.3)	7 (19.4)	19.54 (4.20, 91.01)	0.00
Complaint of ASM-associated undesirable effects				
Yes	33 (25.0)	16 (44.4)	2.40 (1.12, 5.17)	0.03
No	99 (75.0)	20 (55.6)	1	
Seizure recurrence				
Recurrence	102 (77.3)	18 (50.0)	0.29 (0.14, 0.64)	0.00
No recurrence	30 (22.7)	18 (50.0)	1	

Predictors of seizure recurrence

In the binary logistic regression, eleven variables had a P<0.25 and were recruited for multiple logistic regression. Of the eleven candidate variables: Duration on ASM, duration of follow-up, brain injury, presence of triggering factors, complaint of ASM-associated undesirable effect, and level of adherence were significantly associated with seizure control status (Table 5).

Upon performing multiple logistic regression, four variables were identified as predictors of seizure control status. Accordingly, the probability of seizure recurrence was above six times (AOR=6.42, 95% CI: 1.32, 31.28, P=0.02) higher in those epilepsy patients from rural residence as compared to the urban. The probability of seizure recurrence was also found to be approximately twenty-one times (AOR=20.86, 95% CI: 2.66, 163.77, P=0.00) higher in those epilepsy patients who were on chronic ASM for above five years. Furthermore, those patients who complained ASM-associated undesirable effects were approximately 14 times (AOR=13.51, 95% CI: 2.72, 67.26, P=0.00) at higher risk of seizure recurrence than those who didn't. Finally, the probability of seizure recurrence was found 88% less in those epilepsy patients with recorded seizure triggering factors (AOR=0.12, 95% CI: 0.02, 0.64, P=0.01) as compared to those who don't have (Table 6).

Table 5. Binary logistic regression for identifying candidate variables for the multiple logistic regression

Variables	No seizure recurrence, n (%)	Seizure recurrence, n (%)	COR (95% CI)	P-value
Gender				
Male	21 (43.75)	67(55.8)	1	
Female	27 (56.25)	53 (44.2)	0.62 (0.31, 1.21)	0.16
Residence place				
Urban	16 (33.3)	52 (43.3)	1	1
Rural	32 (66.7)	68 (56.7)	0.575 (0.283, 1.167)	0.13
Pregnancy				
Yes	7 (25.9)	7 (13.2)	2.30 (0.71, 7.42)	0.16
No	20 (74.1)	46 (86.8)	1	1
Age at the time of diagnosis, in years				
<15	1 (2.1)	6 (5)	1	
15-30	29 (60.4)	47 (39.2)	3.70 (0.42, 32.32)	0.24
31-45	14 (29.2)	46 (38.3)	1.50 (0.17, 13.67)	0.72
46-60	2 (4.2)	12 (10)	1.64 (0.14, 19.39)	0.70
>60	2 (4.2)	9 (7.5)	2.25 (0.19, 27.37)	0.53
Duration on ASM, Years				
1-5	14 (29.2)	67 (55.8)	1	
Above 5	34 (70.8)	53 (44.2)	0.33 (0.16, 0.67)	0.00
Duration of follow-up in the clinic, Years				
1-5	14 (29.2)	67 (55.8)	1	1
6-10	23 (47.9)	40 (33.4)	2.75 (1.27, 5.95)	0.01
>10	11 (22.9)	13 (10.8)	4.05 (1.51, 10.88)	0.00
Brain injury				
Yes	24 (50.0)	22 (18.3)	4.46 (2.15, 9.25)	0.00
No	24 (50.0)	98 (81.7)	1	
Time of brain injury Occurrence				
Before seizure	17 (70.8)	18 (81.8)	1	
After seizure	7 (29.2)	4 (18.2)	1.85 (0.46, 7.48)	0.39
Neurologic deficits				
Yes	45 (93.8)	107 (89.2)	1.82 (0.49, 6.71)	0.37
No	3 (6.3)	13 (10.8)	1	
Seizure triggering factors				
Yes	32 (66.7)	56 (46.7)	2.29 (1.14, 4.60)	0.02
No	16 (33.3)	64 (53.3)	1	
Types of seizure Diagnosed				
GTCS	40 (83.3)	87 (72.5)	1.90 (0.80, 4.48)	0.14
Unclassified seizure	8 (16.7)	33 (27.5)	1	
Seizure frequency before ASM initiation				
1-5 times	47 (97.9)	108 (90)	1	1
Above 5 times	1 (2.1)	12 (10)	1.19 (0.02, 1.52)	0.12
Compliant of ASM-associated undesirable effect				
Yes	26 (54.2)	23 (19.2)	4.98 (2.41, 10.32)	0.00
No	22 (45.8)	97 (80.2)	1	
Level of adherence				
Adherent	30 (62.5)	102 (85.0)	1	
Non-adherent	18 (37.5)	18 (15.0)	3.40 (1.58, 7.34)	0.00

Table 6. Multiple logistic regression for identifying predictors of seizure recurrence.

Variables	AOR (95% CI)	P-value
Residence		
Urban	1	
Rural	6.42 (1.32, 31.28)	0.02
Duration on ASM, Years		
1-5	1	
Above 5	20.86 (2.66, 163.77)	0.00
Seizure triggering factors		
Yes	0.12 (0.02, 0.64)	0.01
No	1	
Compliant of ASM-associated undesirable effects		
Yes	13.51 (2.72, 67.26)	0.00
No	1	

Discussion

This ambidirectional cross-sectional study involved a total of 168 eligible epilepsy patients. Of the total participants, 132 (78.6%) patients were adherent to their ASMs. Similarly, a high adherence level was reported in studies done by Gizachew Kassahun (65.9%) [12], Tefera Abula (70%) [17], and Melak Gedamu [4] in Ethiopia. Collin A. Hovinga et al. from United States (71%) [18], and Sunday O. Ogundele from Lagos (64.7%) [11], had also reported similar finding. However, other studies from Ethiopia (36.5.4%) [19] and Nigeria (32.6%) [20], reported a relatively lower proportion of adherence. This variation of the result may be due to difference in the data collection method or sample size employed.

Among factors assessed for association with the level of ASM adherence in this study, age, occupation, educational level, history of brain injury, presence of seizure triggering factors, multiple ASM use, complaint of ASM-related undesirable effects, and presence of seizure recurrence were significantly associated with adherence. Similar studies from Ethiopia [4,12,13], and a study by Sunday O. Ogundele from Lagos [11], reported educational level as one of the factors associated with the level of ASM adherence. The reason why educational status was associated with adherence might be due to the fact that 63.1% of the patients in this study had no formal education. The association of adherence with complaint of ASM-associated undesirable effects may also be explained by the fact that 70.8% of participant were not complained the effect. Similar finding was reported by studies from Ethiopia [4,12], and other study from Sudan [10].

The other significant association was observed between adherence and multiple ASM use. This finding is corroborated by results of the studies from Ethiopia [3,4], and other study conducted in Sudan [10]. This association could be explained in terms of reluctance to take drugs properly as the number of drugs increased. Moreover, patients may experience more adverse drug events with increased number of medications which can also negatively affect the adherence rate.

In patients with epilepsy, proper diagnoses and treatment can make an estimated 70% of them seizure-free. Despite this, about three-quarters of epilepsy people in low-income countries do not get the treatment needed [1]. In our study, seizure recurrence was identified in 71.4% of the epilepsy patients. Similar previous studies from Tikur Anbessa Specialized Hospital [3], Mizan-Tepi University Teaching Hospital [7], Ambo hospital [6], and Ayder comprehensive specialized hospital [5] reported seizure recurrence in 65.6%, 60.8%, 44.7%, and 53.4% of patients, respectively. The higher proportion of seizure recurrence seen in the region could be due to poor community knowledge and awareness [21], lack of health care professionals

training to recognize, diagnose and treat epilepsy, and problems with the availability of ASMs in the region [1].

In the management of epilepsy, ASM-associated undesirable events frequently hinder adequate seizure control and cause other disastrous impacts on the patient [22]. This had also been corroborated by the findings of our study in which higher probability of seizure recurrence was seen in those epilepsy patients complained ASM-associated undesirable events than those who didn't complain. This could potentially be related to the patients' tendency to stop taking ASMs because of the undesirable effects they experience. The presence of seizure triggering factors is also another reason affecting seizure threshold in epilepsy [23,24]. Avoiding or modifying these factors could allow ASM therapy to work better resulting in seizure control.

On the contrary, our study identified a lower likelihood of seizure recurrence in those epilepsy patients with triggering factors as compared to their counterparts. This could be related to potential underreporting of triggering factors in those who didn't reported due to fear of being blamed or could be due to other factors raising the seizure threshold in those epilepsy who reported and vice versa in those who didn't report. Furthermore, the increased probability of seizure recurrence identified in those epilepsy patients from rural residence as compared to the urban in our study may be associated with poor access to health care facility and no ready access to ASM [25]. The increased probability of seizure recurrence seen in those epilepsy patients who were on ASM for more than five years observed in the study may be due to chronic therapy associated potential miss of ASM dose with time.

Conclusion

This study revealed a higher proportion of ASM adherence. Seizure recurrence was identified in more than two-thirds of the patients. Potential missing of ASM dose from chronic therapy and ASM-associated undesirable effect, and factors like, difficulty of access to healthcare in rural residents may be contributing to seizure recurrence.

Acknowledgment

Not applicable.

Conflict of Interest

The authors declare that they have no competing interests.

Declarations

The study was approved by the ethics committee of Jimma University, School of Pharmacy (Ref.: SP/131/19). Prior to data collection, informed consent was obtained from the study participants. Each patient was informed about the objective of the study, procedures of selection, and assurance of confidentiality. Confidentiality was ensured during patient interviews and the review of charts. Patient name was not recorded in the data abstraction formats. We confirm that all methods were carried out in accordance with relevant guidelines and regulations.

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