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Research Article

A PROSPECTIVE STUDY ON IMPACT OF PATIENT COUNSELLING ON QUALITY OF LIFE AND MEDICATION ADHERENCE IN EPILEPTIC PATIENTS

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ABSTRACT

Objective: To study the impact of patient counseling on medication adherence and quality of life (QOL) in epileptic patients and to assess the factors affecting medication adherence.

Methods: This study is a prospective observational study involving 100 patients with an age limit of 8-60 years and those taking Antiepileptic drugs for at least 3 months. The study population received patient counseling during their first visit. The impact of patient counseling on QOL and medication adherence was assessed using self-reported questionnaire QOLIE-31 and MMAS-8 between the first visit and the second visit. Statistical analysis (Paired t-test and Paired Chi-square test) was performed to analyze the impact of patient counseling on QOL and medication adherence in epileptic patients.

Results: A total of 100 patients were included in the study. After providing patient counseling, it was observed that there was a statistically significant ($p<0.05$) improvement in all domains of QOLIE-31 and MMAS-8 scores. Before counseling, mean overall T-score of QOLIE-31 was 44.08±2.07which was changed to 49.14±1.27 after patient counseling with a mean change of 5.06 in overall T-score. In the case of medication adherence, before counseling 77% subjects were nonadherent to therapy, after counseling it was reduced to 41%. The common reasons for medication adherence were forgetfulness, unawareness, therapy related, and economics related. Out of which forgetfulness along with unawareness was the major one.

Conclusion: The study described that patient counseling plays a major role in improving QOL and medication adherence.

Keywords: QOLIE-31, MMAS-8, Epilepsy, Antiepileptic drugs, Patient counseling.

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INTRODUCTION

Epilepsy is said to be a recurrent, usually unprovoked seizure which results from excessive synchronous and abnormal firing patterns of the cerebral cortical neuron. It is a neurological condition that produces seizures and affects a variety of mental and physical function [1]. Having a single seizure does not necessarily mean a person has epilepsy [2]. It affects about 50 million people worldwide and India is home to about 10 million people with epilepsy (prevalence of about 1%), higher in rural as compared with urban area [3]. Broadly epilepsy can be classified into generalized and partial epilepsy (focal). While categorizing epilepsy based on etiological factors, it is as genetics, acquired and unknown. Quality of life (QOL) is a subjective concept based on the subject's perspective and experiences and involves physical, psychological, social and cultural components, all of which contributes to patient's adjustment to his condition and impacts perception in his life [4,5]. The frequency and seizure severity, adverse effects of antiepileptic drugs (AEDs), seizure worry, mood status, physical, cognitive, and psychosocial limitations including dependence of caregivers are determinant aspects frequently assessed by QOL inventories [6]. Medication adherence is the backbone of antiepileptic therapy. Medication adherence can be defined as taking medication on time without fail, not manipulating dosages and following the doctor's advice regarding the daily activities [7]. Relapse of seizure occurs when doses are missed, or medication is taken irregularly [8,9].

METHODS

Study design

A prospective observational study was conducted in a Neurological Department, a Tertiary Care Hospital from November 2015 to April 2016.

Study population

This study was conducted involving 100 patients with an age limit of 8-60 years and those taking AEDs for at least 3 months. Newly diagnosed epileptic patients and those with pseudoseizure were excluded from the study. The study population received patient counseling during their first. This study was approved by the Institutional Ethics Committee, and the informed consent from each patient was collected before enrollment. The study protocol was approved by the hospital authority, and a proper consent was obtained.

Data collection

Design of data entry format (Pro forma) for incorporating patient details was designed which comprises demographic details (age, sex, literacy, and marital status), past medical history (comorbidities), medication history, and seizure details (type, duration, age of onset, last episode, triggers, family history, symptoms, AED, side effects, and aura). The impact of patient counseling on QOL and medication adherence was assessed using self-reported questionnaire QOLIE-31 and MMAS-8 between the first visit and the second visit.

Statistical analysis

Statistical analysis was performed using Microsoft Excel and SPSS (Statistical Package for the Social Sciences) software programme version 23. To describe about the data descriptive statistics frequency analysis, percentage analysis were used for categorical variables and the mean and SD were used for continuous variables. To find the significance difference between the bivariate samples in paired groups the paired sample t-test was used. To find the significant categorical data chi-square test was used. A $p<0.05$ was considered statistically significant in both the statistical tools.

RESULTS AND DISCUSSION

Patients, who were included in the study, were in the age range of 8-60. 27% of study population comes under age group of 11-20. 26% of patients were between 21-30 years of age. 13% were in 31-40 years of age. 10% in 41-50 and 24% of patients belongs to 51-60 range of age (Table 1).

Among the 100 patients who were analyzed during the study an equal distribution of male and female ratio was obtained. 50 were male (50%) and the rest were female (Table 2).

More than half of the subjects were married that is 55%. 42% of patients were unmarried and among this 27 of them did not attain the age for marriage and remaining were unmarried due to the stigmatization of the disease. 3 patients were married but divorced due to disease conditions (Table 3).

The study comprises 67 subjects who were literate, out of these 20 are students. 33 subjects were illiterate (Table 4).

In this study, 70 out of 100 patients were having no comorbidities (Table 5).

Among all the seizure types, CPS was found to be more predominant among the study population that is 36% out of 100 (Table 9). This is followed by Generalized seizures 27%> other seizure types such as febrile, remote, cold water, default, postpartum, and late onset 22%> simple partial seizures 15% (Table 6).

The majority of subjects 28% experienced 2-10 episodes (>1) of seizure per month and 27% of them had 1 seizure episode per year. 19 of them had 1 seizure attack per month, 18 of them had seizure episodes >1 per year, and 8 of them experience occasional episodes of seizure (>10 per month) (Fig. 1 and Table 8).

In this study, a large number of subjects 79% had seizures lasting for <10 minutes (Table 7).

Most commonly reported problem related to AEDs was sedation (18%). 42% patients had no complaints while the following therapy (Table 10).

The mean overall T-score of QOLIE 31 before counseling was 44.08±2.07. The lowest mean T-score was obtained for the subscale QOL (37.03±4.56). The corresponding T-scores of each domain as per the study was as follows: QOL (37.03±4.56) <cognitive function (43.57±5.163) <social function (43.74±1.80) <seizure worry (44.77±6.36) <emotional wellbeing (45.56±4.43) <medication effect (46.17±4.46) <energy/fatigue (47.60±5.92) (Fig. 2). There was a statistically significant difference ($p<0.05$) in T-scores corresponding to overall scores of QOLIE-31 between before (44.08±2.07) and after (49.14±1.27) provision of patient counseling in the 6 months study (Table 11). While checking the T-scores before and after counseling each domain showed (Fig.3) significant difference $p<0.05$.

Statistical analysis of adherence before and after counseling using Pearson Chi-square test showed (Table 12) a significant difference ($p<0.05$).

Table 1: Age wise distribution

S. No.	Age group	Frequency (%)
1	11-20	27 (27)
2	21-30	26 (26)
3	31-40	13 (13)
4	41-50	10 (10)
5	51-60	24 (240
6	Total	100 (100)

Table 2: Gender wise distribution

Gender	Number of patients (n=100) (%)
Male	50 (50)
Female	50 (50)

Table 3: Marital status based segregation

S. No.	Marital status	Frequency (%)
1	Married	55 (55)
2	Divorced	3 (3)
3	Unmarried	42 (42)
4	Total	100 (100)

Table 4: Literacy based segregation

S. No.	Literacy	Frequency (%)
1	Literate	67 (67)
2	Illiterate	33 (33)
3	Total	100 (100)

Table 5: Based on comorbidities

S. No.	Comorbidities	Frequency (%)
1	Comorbidities present	30 (30)
2	Comorbidities absent	70 (70)
3	Total	100 (100)

Table 6: Categorization according to seizure type

S. No.	Seizure type	Frequency (%)
1	Generalized seizure	27 (27)
2	Complex partial seizure	36 (36)
3	Simple Partial Seizure	15 (15)
4	Others	22 (22)
5	Total	100 (100)

Table 7: Categorization based on duration of seizure episode

S. No.	Duration (minutes)	Frequency (%)
1	0-9	79 (79)
2	10-19	17 (17)
3	20-29	4 (4)
4	Total	100 (100)

Table 8: Based on last episode of seizure

S. No.	Last episode of seizure	Frequency (%)
1	Last week	33 (33)
2	Last month	25 (25)
3	More than 1 month	36 (36)
4	More than 1 year	6 (6)
5	Total	100 (100)

Table 9: Based on type of therapy

S. No.	Type of therapy	Frequency (%)
1	Monotherapy	54 (54)
2	Polytherapy (2 drugs)	34 (34)
3	Polytherapy (3 drugs)	12 (12)
4	Total	100 (100)

In this study population, 77 were nonadherent to medication. Forgetfulness, therapy related problems (adverse drug reactions [ADR], polytherapy, long-term therapy), economics unawareness, seizure control, and combination of these like forgetfulness+unawareness were the reasons for nonadherence. The major reason for non-adherence was found to be forgetfulness+unawareness (32.46%) (Table 13) [11].

DISCUSSION

There are many evidence that people with epilepsy have a number of psychosocial difficulties which impact greatly on their QOL [10]. In this study, we aim to assess the impact of patient counseling on QOL and medication adherence in epileptic patients. Seizures affect males and females equally. Based on gender, here we found that half of the patients were female and the other half were male. This result is supported by CDC 2007, Thomas *et al.* [10] and Ahmad *et al.* [9].

Incidence of epilepsy can occur at any age with a peak in the first two decades and the second peak in the late life (>60 years). This study revealed that more than half of the study population (53%) was within the range of 10-30 years of age which is corresponded with Ahmad *et al.* who reported that majority of the patients were within the range of 18-30 years of age [9]. Jenkis (2008) found that incidence of epilepsy was highest among youth patients [11].

Table 10: Based on problem related to AEDS

S. No.	Problems related to AEDs	Frequency (%)
1	Nil	42 (42)
2	Weight gain	10 (10)
3	Loss of memory	6 (6)
4	Sedation	18 (18)
5	Anger	9 (9)
6	Loss of memory+tiredness	4 (4)
7	Abdominal discomfort+loss of memory+anger	9 (9)
8	Others	2 (2)
9	Total	100 (1000)

AEDs: Antiepileptic drugs

Table 11: BASED on adherence before and after counseling (n=100)

Adherence 1 (before counseling)	Adherence 2 (after counseling)		
	High	Medium	Low
High 23 (23)	20	1	2
Medium 27 (27)	22	5	0
Low 50 (50)	17	28	5
Total 100 (100)	59	34	7

Table 12: Statistical analysis of adherence before and after counseling using Pearson Chi-square test (n=100)

Test	Value	Significance (2-tailed)
Pearson Chi-square association number of valid cases	28.252[a]	0.0005
Likelihood ratio	33	0.0005
Linear-by-linear association	15	0.0005
Number of valid cases	100	0.0005

[a]3 cells (33.3%) have expected count<5. The minimum expected count is 1.61

Table 13: Reasons for nonadherence in epilepsy patients

Reasons for nonadherence	Frequency (%)
Forgetfulness	13 (16.88)
Therapy related problems	18 (23.37)
Economic related problems	4 (5.19)
Unawareness	9 (11.68)
Forgetfulness+unawareness	25 (32.46)
Forgetfulness+seizure control	8 (10.38)
Total	77 (100.0)

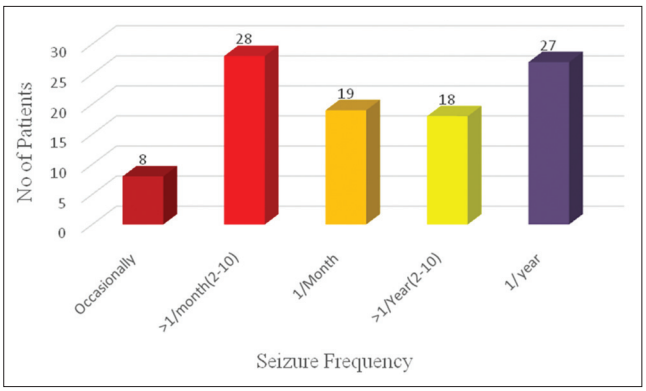

Fig. 1: Categorization based on seizure frequency

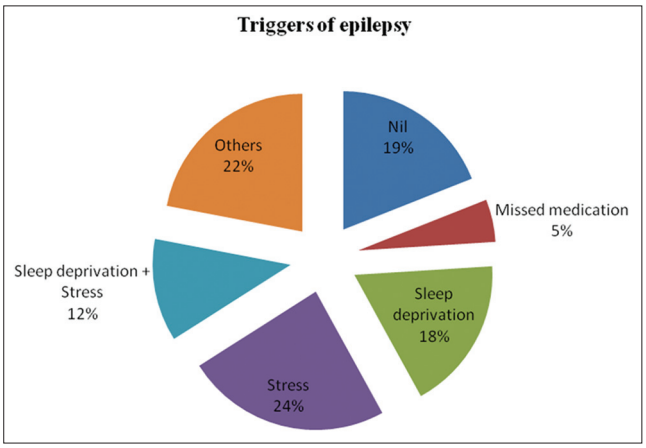

Fig. 2: Comparison of triggers of epilepsy among study population

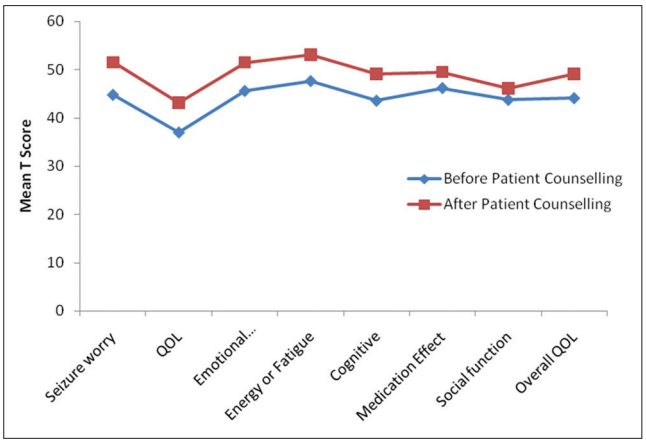

Fig. 3: Statistical analysis of quality of life before and after counseling using paired t-test

Marital status and education are major concerns in epilepsy patients because of social stigma. In our study, 55% of the study populations are married. This result was in agreement with Hovinga *et al.* [12]. More than half of the population (67%) were literate as in the study conducted by Ashjazadeh *et al.* [13] and Hovinga *et al.* [12]. However, many other studies revealed that a high percentage of epilepsy patients were illiterate (Moneer *et al.* 2008). Comorbidities play an important role in QOL of epileptic patients. 30% of patients in the current study had at least one other comorbidity present. Similar results were obtained from Ahmad *et al.* in which 28.8% had other comorbidities [9].

Among all the type of epilepsies, CPS was found to be the predominant in our study (35.4%). Camacho *et al.* (2014) reported that majority of patients had focal seizures (52.2%) [14]. Contradictory results were found in Nabukenya *et al.* says that majority of the respondents were having generalized epilepsy (84%) [15]. Control of seizure frequency is the main objective in the management of epilepsy. The majority of the patients experienced greater than one seizure attack per month (28%) in the current study, and supporting evidence was obtained from Ahmad *et al.* [9]. But in a study by Gabr and Shams (2015) frequency of seizure episode was found to be less than one per month [4].

The seizure episode may be triggered by several factors such as sleep deprivation, missed medication, stress, alcohol, menstruation, and flickering light[16]. In this study, stress (24%) is the major triggering factor. According to the type of epilepsy the duration of seizure episode may differ. In our study, the majority of the patients experienced seizure lasting for less than ten minutes. The last episode of seizure is an important factor in determining the QOL and medication adherence in epileptic patients. In our study, most of the patients had the last episode of seizure before 1 month.

Monotherapy has been the primary therapy for the management of epilepsy as it has minimal adverse effects and low cost. Here, 54% of the study populations were on monotherapy. A result corresponding to this was found in Ahmad *et al.* and 51.9% patients were given monotherapy [9]. The AED commonly used in our study was found to be sodium valproate in the case of monotherapy and sodium valproate+levetiracetam for polytherapy with two drugs and carbamazepine+clobazam+lacosamide for polytherapy with three drugs. Sodium valproate is the chiefly used AED as it can be used in all kinds of epilepsy including generalized epilepsy, partial epilepsy, and epilepsies difficult to classify. Major problems related to therapy reported in our study include sedation, anger, abdominal discomfort, and memory related problems. Out of these, sedation was the major one, which is a common CNS side effect of AEDs. Martin *et al.* observed drowsiness as the major problem related to AED therapy [17].

Health-related QOL (HRQOL) is considered as the major one to assess the patient outcome and an important measure of clinical and physician interventions. Patients with epilepsy tend to have a poor QOL compared to general population. In this study, the overall T-score is found to be 44.08±2.07. Low T-scores are obtained for the subscales QOL (37.03±4.56), social function (43.74±1.80) and emotional wellbeing (45.56±4.43). Nabukenya *et al.* reported that physical functioning and emotional well-being are the mostly affected HRQOL domains in people with epilepsy [15]. Martin *et al.* described that seizure worry, medication effects, energy, or fatigue showed the greatest impact on QOL [17]. The main reasons for the low scores of social function, emotional well-being, and QOL are stigma among the public and lack of knowledge about epilepsy.

Medication adherence is a major challenge in the management of epilepsy. Poor medication adherence is noted as one of the major causes of non-responsiveness to AED therapy. Therefore, identifying level of adherence is an important factor in epilepsy. 77% patients were nonadherent to the therapy in our study. On the other hand, Sweileh *et al.* found that 64% of the patients were nonadherent [18]. While 38.3% were nonadherent reported by Gabr and Shams in 2014 [16]. WHO in 2007 reported that satisfactory adherence among the patients ranges from 30% to 45%.

Complex treatment regimen is believed to threaten patient's medication adherence. Approximately, 46% of patients in our study were on polytherapy. There was a significant difference in adherence between patients on mono and polytherapy. This was in agreement with Sweileh *et al.* [18]. Other factors such as patient gender, age, marital status, education, comorbidities, type of epilepsy[19], age of onset, seizure frequency, last episode, and problems related to therapy did not significantly affect patient medication adherence. This is in agreement with Gabr and Shams (2014) [4]. Medication adherence is a major factor influencing the QOL of the epileptic patients. High medication adherence will result in seizure control which in turn positively affects patients QOL. In our study, a significant correlation between QOL and medication adherence was obtained which is in agreement with the study conducted by Ahmad *et al.* [9].

Poor medication adherence may be due to patient-related factors, (forgetfulness, stigmatization) therapy related factors, (complexity, long duration, and ADR) and socioeconomic factors. In our study, forgetfulness, unawareness, therapy related factors, seizure control, and economic background are the main reasons for poor medication adherence in which forgetfulness+unawareness was the predominant one. The main therapy related factors in our study include complexity of medication and problems related to therapy like sedation, weight gain, anger, etc. This result was in agreement with Johnbull *et al.* who reported that forgetfulness and drug induced fatigue were the major reasons for poor adherence [6].

Educating patients about the disease, treatment, need of adherence, and strategies to improve both QOL and medication adherence is important in epilepsy management [20]. In our study, 77% subjects were nonadherent before counseling which is reduced to 41% after counseling. Statistical analysis of medication adherence revealed a significant result ($p<0.05$). In the case of HRQOL, the overall T-score mean of sample population was found to be 44.08±2.07 and after giving patient counseling it was found to be 49.14±1.27. An increase of 5.06 showed a statistical significance. Thus, we can say that patient counseling has higher impact on QOL of epileptic patient.

CONCLUSION

This study was performed to assess the impact of patient counseling on medication adherence and QOL in epileptic patients. Results showed that patients with epilepsy had poor medication adherence and QOL. The major factors affecting medication adherence were forgetfulness, unawareness, therapy related factors, seizure control, and economic related factors. A significant association was found between medication adherence and QOL, as medication adherence increased QOL also improved. This study proved that patient counseling can improve medication adherence and QOL. Hence, it is concluded that patient counseling has a significant impact on medication adherence and QOL in epilepsy patients. Assessing medication adherence and QOL and providing patient education should be a routine part of the epilepsy management.

LIMITATIONS OF THE STUDY

Since the study is purely based on self-report which had not included any diagnostic procedures, there are high chances of bias. The number of patients and the study duration (6 months) were limited. Potentially large sample size and long duration was required for the study so as to get more significant results. As there is no control group selected in this study, there are chances of bias. The study is performed in a tertiary care hospital, and the results obtained may not be generalizable to all epileptic patients in the community.

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REFERENCES

1. Haut SR, Velísková J, Moshé SL. Susceptibility of immature and adult brains to seizure effects. Lancet Neurol 2004;3(10):608-17.
2. About Epilepsy. US Department of Veterans Affairs; 2015. Available from: http://www.VA/healthcare/epilepsy centers of excellence/about epilepsy. [Last cited on 2015 Jun 3].
3. Schachter CS. Epilepsy Foundation. Available from: http://www.epilepsy. com/learn/types-seizures.
4. Gabr WM, Shams ME. Adherence to medication among outpatient adolescents with epilepsy. Saudi Pharm J 2015;23(1):33-40.
5. Martins HH, Alonso BN, Guilho FF, Guaranha BS, Yacubian TM. Adherence to treatment in patients with juvenile myoclonic epilepsy: Correlation with QOL and ADR of medication. J Epilepsy Clin Neurophysiol 2009;15(4):192-6.
6. Johnbull OS, Farounbi B, Adeleye AO, Ogunrin O, Uche AP. Evaluation of factors influencing medication adherence in Kaduna state Nigeria. Neurosci Med 2011;2(4):299-305.
7. Study: What Affects Quality of Life in Patients with Epilepsy? Available from: https://www.freshsciencenews.wordpress.com/2015/06/12/study-what-affects-quality-of-life-in-patients-with-epilepsy/. [Last updated on 2014 Jun 23].
8. Berto P. Quality of life in patients with epilepsy and impact of treatments. Pharmacoeconomics 2002;20(15):1039-59.
9. Ahmad N, Othaman NI, Islahudin F. Medication adherence and quality of life in epilepsy patients. Int J Pharm Pharm Sci 2013;5(2):401-4.
10. McCagh J, Fisk JE, Baker GA. Epilepsy, psychosocial and cognitive functioning. Epilepsy Res 2009;86(1):1-14.
11. Kerr MP, The impact of epilepsy on patients'lives. Acta Neurol Scand Suppl.2012;(194):1-9. DOI: 10.1111/ane.12014.
12. Hovinga CA, Asato MR, Manjunath R, Wheless JW, Phelps SJ, Sheth RD, *et al.* Association of non-adherence to antiepileptic drugs and seizures, quality of life, and productivity: Survey of patients with epilepsy and physicians. Epilepsy Behav 2008;13(2):316-22.
13. Ashjazadeh N, Yadollahikhales G, Ayoobzadehshirazi A, Sadraii N, Hadi N. Comparison of the health-related quality of life between epileptic patients with partial and generalized seizure. Iran J Neurol 2014;13(2):94-100.
14. Garnett WR. Antiepileptic drug treatment: Outcomes and adherence. Pharmacotherapy 2000;20(8):191S-9.
15. Nabukenya AM, Matovu JK, Wabwire-Mangen F, Wanyenze RK, Makumbi F. Health-related quality of life in epilepsy patients receiving anti-epileptic drugs at National Referral Hospitals in Uganda: A cross-sectional study. Health Qual Life Outcomes 2014;12:49.
16. Balamurugan E, Aggarwal M, Lamba A, Dang N, Tripathi M, Perceived trigger factors of seizures in persons with epilepsy, Seizure 2013;22:743-47.
17. Brusturean BE, Coada CA, Buzoianu AD, Dumbrava LP. Assessment of quality of life in patients with epilepsy. Int J Bioflux Soc 2013;5(3):82-7.
18. Sweileh WM, Ihbesheh MS, Jarar IS, Taha AS, Sawalha AF, Zyoud SH, *et al.* Self-reported medication adherence and treatment satisfaction in patients with epilepsy. Epilepsy Behav 2011;21(3):301-5.
19. Dourado MV, Alonso NB, Martins HH, Oliveira AR, Vancini RL, de Lima C, *et al*. Quality of life and self - Perception impact of epilepsy in three different epilepsy types. J Epilepsy Clin Neurophysiol 2007;13(4):191-6.
20. Shanmukhi S, SitaJayalakshmi S, Anand. B. Factors associated with quality of life in adult epilepsy patients: A hospital based study from South India, Res Neurol Int J 2015;2015:Article ID: 766328, DOI: 10.5171/2015.766328.