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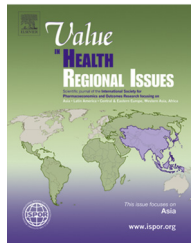

Antiepileptic Drugs and Quality of Life in Patients with Epilepsy: A Tertiary Care Hospital-Based Study

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ABSTRACT

Objectives: The present study evaluated patterns of the use of antiepileptic drugs (AEDs) and their impact on quality of life (QOL) in patients with epilepsy. **Methods:** In this cross-sectional study, patients with epilepsy (age >18 years) receiving AEDs for at least 1 year were enrolled. Demographic, clinical, and treatment parameters were recorded. QOL was measured using the modified Quality of Life in Epilepsy Inventory-10 (QOLIE-10) questionnaire for epilepsy. **Results:** Of 200 patients, 53.5% were males and 60% were younger than 30 years. Seizures were predominantly partial (58%) and of idiopathic origin (61%). Monotherapy to polytherapy ratio was 1:1, with 70% of the patients on one new AED. Clobazam (37%) was used most frequently followed by phenytoin (25.5%), levetiracetam (23%), oxcarbazepine (21.5%), and carbamazepine (21%). Patients on polytherapy experienced a significantly more number of adverse drug reactions than did those on monotherapy ($P < 0.0001$). The mean QOLIE-10 score was 74.58 ± 20.60. There was no significant difference in seizure frequency, number of adverse drug reactions, and QOLIE-10 score among patients receiving old and new AEDs. Multiple linear regression analysis identified increased seizure frequency (standardized β −0.157; $P = 0.003$), more number of AEDs (standardized β 0.107; $P = 0.05$) as well as adverse drug reactions (standardized β −0.692; $P = 0.0001$) as significant predictors of poor QOL. **Conclusions:** Appropriate tools for early detection, selection of rational and safer AED treatment options, and regular monitoring for adverse effects play a crucial role in achieving seizure freedom and optimal QOL in patients with epilepsy.

Keywords: antiepileptic drugs (AEDs), epilepsy, quality of life (QOL).

Introduction

Epilepsy, the second most common neurological condition after headache, is characterized by recurrent seizures of cerebral origin. Fifty million people in the world and an estimated 6 to 10 million people in India suffer from epilepsy [1–3]. It is of concern that the diagnosis and management of epilepsy is often suboptimal in developing countries and in the European region [4,5].

Epilepsy is both a medical diagnosis and a social label [6] because people with epilepsy face many psychosocial challenges (anxiety, social stigma, difficulty in driving, unemployment) that can negatively impact quality of life (QOL). Such growing recognition of the importance of the psychosocial effects of epilepsy has led to the need to quantify QOL in affected individuals. Hence, appropriate antiepileptic drug (AED) use, along with monitoring of adverse effects, and assessment of QOL as an outcome measure are important in the management of epilepsy to achieve optimal seizure control.

The measurement of QOL using validated tools such as Quality of Life in Epilepsy Inventory-31 [7], Quality of Life in Epilepsy Inventory-10 (QOLIE-10) [8], and short-form 36 health survey [9] are popular. The evaluation of QOL is a relatively new measure to assess patient-related outcome of AED treatment for epilepsy. Demographic characteristics, high seizure frequency, and long duration of the disorder have been shown to correlate strongly with poor QOL [10]. Although several new AEDs have been licensed over the last decade, there are limited numbers of studies that have examined the impact of AED pharmacotherapy (type of AED/monotherapy, polytherapy/adverse drug reactions [ADRs]) on QOL [4].

The present study was designed to evaluate patterns of AED use and to examine the impact of factors, namely, demographic, clinical, and pharmacotherapy characteristics, affecting QOL.

Methods

Study Design and Sampling

This was a cross-sectional study conducted over 15 months (January 2011–March 2012) at the Neurology Outpatient Department of St. John's Medical College, Bangalore, India. Institutional Ethical Review Board approval was obtained. To be powered at 90% with 5% alpha error, 92 patients were needed for the study to detect a difference of 10 SD in QOL scores between patients on AED monotherapy and polytherapy. A random sample of 200

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Table 1 – Sociodemographic profile of patients with epilepsy.

Parameters	Category	N = 200, n (%)
Sex	Male	107 (53.5)
	Female	93 (46.5)
Age (y)	Mean age ± SD/ median	31.46 ± 12.834/26
Marital status	Married	118 (59)
	Unmarried	82 (41)
Residence	Urban	115 (57.5)
	Semiurban	62 (31)
	Rural	23 (11.5)
Education	Primary school and below	40 (20)
	High school to PUC	94 (47)
	Degree and professionals	66 (33)
Employment	Employed	96 (48)
	Unemployed	72 (36)
	Student	32 (16)
Per-capita income (INR)	10,000–50,000	69 (34.5)
	>50,000	5 (2.5)

INR, Indian rupee; PUC, pre-university college.

patients who met the inclusion criteria was recruited, which was deemed adequate to detect a clinically meaningful difference in QOL scores (10–11 points) across other variables [11].

Selection Criteria and Data Collection

Patients with epilepsy (PWE) aged 18 years or older receiving AEDs for at least 1 year and consenting to participate were included. The International League Against Epilepsy classification of seizures and epileptic syndromes was followed [12]. Patients with significant disability, major psychiatric disorders, severe medical comorbidity confounding QOL assessment, and an AED change in the last 1 month were excluded.

A structured case record form was used to collect data on sociodemographic, clinical, and treatment parameters. Seizure burden was scored according to the Engel system [13] for seizure frequency and burden in a quasi-logarithmic scale ranging from 0 to 12. Scores less than 5 were considered as no seizures. A score of 5 denotes one to three seizures per year, and a score of 6 indicates 4 to 11 seizures per year. Seizure frequency of one per month was scored as 7 to 12. Persons were said to be seizure free if there was absence of disabling seizures for more than 12 months. Treatment data included generic names, daily dose, duration, and adverse reaction profile after the administration of AEDs.

The QOLIE-10, an abbreviated questionnaire consisting seven domains and 10 items derived from the QOLIE-31, was used to assess QOL [8,14]. The overall score ranged from 0 to 100, with higher scores representing better QOL. We used the English version of the QOLIE-10, and the question on driving was modified to suit the Indian scenario. Patients conversant in English completed the questionnaire, and the remaining patients in the multilingual patient population were explained the questions in their respective languages and responses were recorded.

Statistical Analysis

Data were analyzed using SPSS version 20. Descriptive data were expressed as mean ± SD, median, interquartile range, and percentages. The QOLIE-10 scores were expressed as mean ± SD with 95% confidence intervals. Categorical variables were compared using the chi-square test. Continuous variables were analyzed using the unpaired *t* test and analysis of variance (parametric), the Mann-Whitney *U* test, the Kruskal-Wallis test (nonparametric), and the Spearman correlation coefficient. The significant variables in univariate analysis were entered into a stepwise multiple linear regression model to identify the significant predictors of poor QOL. Statistical significance was set at $P < 0.05$.

Results

Demographic and Clinical Characteristics

A total of 200 patients who were recruited into the study fulfilled the eligibility criteria. The majority were males (53.5%) and 60% of patients were between 18-30 years. Type of seizure was partial in 116 (58%), generalized in 84 (42%), and 122 (61%) patients had an idiopathic or cryptogenic origin for seizures. The common attributable etiologies for seizures were central nervous system infections (neurocysticercosis), vascular, degenerative disorders, and head injury. Median age at onset of epilepsy was 18 years and duration was 7.5 years. Seizure frequency was one to three per year (Engel score 5) in 47% of the patients, and 30% were seizure free for more than 12 months (Tables 1 and 2).

AED Treatment Profile

AED monotherapy was received by 100 patients, dual therapy by 69 patients, triple therapy by 24 patients, four AEDs by 4 patients, and five AEDs by 3 patients. There were 21 types of two-drug combinations and 17 types of three-drug combinations. The mean number of AEDs/person was 1.7 ± 0.9, with 30% on old,

Table 2 – Clinical characteristics of seizures among patients on AED monotherapy and polytherapy.

Variables	Monotherapy (n = 100)	Polytherapy (n = 100)	Significance level* (χ^2 test)
Seizure frequency			
1 and above per month	9	14	$P = 0.003$
4–11 per year	4	19	
1–3 per year	51	43	
Absent	36	24	
Percentage of patients who reported ADR	47	75	$P = 0.0001$
Generalized seizures	49	35	$P = 0.062$
Partial seizures	51	65	

AED, antiepileptic drug; ADR, adverse drug reaction.
* $P < 0.05$.