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Subjective Complaints and Quality of Life in Patients Receiving Antiepileptic Therapy: A Cross Sectional Study



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ABSTRACT

Epilepsy is a common neurological disorder with significant morbidity and social impact. The primary goal of antiepileptic therapy is to restore normal health-related quality of life (HRQOL). AED treatment is usually associated with a high risk of side effects. Some patients may put up with their side effects if their seizure is under control. So, side effects are highly subjective in nature. Quality of life assessments are very important in knowing how patients live with a treatable but chronic condition like epilepsy. Our aim was to assess the severity and prevalence of subjective complaints and quality of life in patients taking anti epileptic drug and their correlation with other determinants such as their social background. We conducted a prospective observational study. The patients who were considered well controlled with AEDs taking medication for greater than 6 months were included in the study of 103 patients included. Severe complaints were reported by 23% patients and about 76% reported moderate complaints. Mostly reported complaints were behavioral, cognitive, headache and CNS complaints. QOL showed significant lower values in patients on polytherapy ($p=.000$), Age and duration of treatment were good predictors of QOL and SIDAED score. QOL was low in patients with higher SIDAED score ($r=-.755, p=.000$). This study reveals that systemic questionnaires may be used at specified intervals to assess them. The assessment of subjective complaints and QOL are key indicators towards the patients' benefit and satisfaction from the treatment.



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INTRODUCTION

Epilepsy is a common neurological disorder with significant morbidity and social impact¹. The primary goal of antiepileptic therapy is to restore normal health related quality of life (HRQOL), which is dependent on achievement of seizure-free life without any significant adverse drug effect (Jacoby et al.,2007)². There are about 20 different AEDs available, yet people with epilepsy fail to become seizure-free on pharmacologic treatment (Kwan & Brodie, 2000)⁶. AED treatment is usually associated with a high risk of side effects^{3,7}. Some patients may put up with their side effects if their seizure is under control. So side effects are highly subjective in nature Thus they can be called as subjective complaints. Subjective complaints start insidiously and patients may not associate their complaints with the medication, especially when patients are well controlled with AEDs⁹. Previous studies have shown that even the patients who seem to be well controlled reported side effects^{4,5,7,8,9}. These side effects have shown to be associated with a high AED(Antiepileptic drug) burden (poly therapy) and other personality traits in many earlier studies ^{4,5,7,8,9}. Quality of life assessments are very important in knowing how patients live with a treatable but chronic condition like epilepsy. Health-related quality of life (HRQoL) is impaired in patients with epilepsy compared to people of the same age and gender in the general population^{10,11,12}. Studies have shown that of many chronic conditions patients with epilepsy have shown low quality of life¹³ Several studies have demonstrated the negative impact DRUG RELATED FACTORS AND PERSONALITY TRAITS on the quality of life of patients with epilepsy (PWEs) (Gilliam¹⁴; Cramer et al.¹⁵; Jesso George et.al.¹⁶; Rod. S. Taylor et.al.¹⁷). Common side effects of antiepileptic drugs include general CNS effects (drowsiness, tiredness, difficulty in concentration etc.), cognitive, depression etc. may seriously affect their social and academic life adversely. Which in turn effect their quality of life.

Based on the preceding background, a reappraisal of the comparative AEs and their association with the drug related factors and personality factors appears to be desirable. Quality of life being a good indicator on how the patients live with a potentially debilitating condition. Assessing them would be beneficial in knowing the present social condition of patients with epilepsy. We aimed to access the severity and prevalence of subjective complaints and quality of life in patients taking anti epileptic drug and their correlation with other determinants. Unlike previous studies we wish to find the association of the severity of subjective complaints and state of quality of life in patients with their social background also.

MATERIALS AND METHODS

We conducted a cross-sectional observational study. The patients who were considered well controlled with AEDs taking medication for greater than 6 months attending the outpatient department of neurology in medical college Calicut, Kerala were recruited to the study. Patients who were able to fill up the questionnaires were selected. Patients taking anti epileptic therapy with any neurodegenerative or psychiatric condition were excluded from the study.

Data Collection

Patients' age, sex, marital status, educational qualification, occupation, duration of disease, duration of treatment, comorbidities, current AED Treatment, time since last seizure were collected in a data documentation form.

SIDAED questionnaire

It is 46 item questionnaire used to assess the subjective complaints. The complaints in 10 categories were assessed CNS complaints, behavior (increased irritability), depressive symptoms, cognitive function, motor problems and coordination, visual complaints, head ache, cosmetic and dermatological complaints, gastrointestinal complaints and sexuality and menses. The patients were asked to rate the severity of their complaints ranging from no complaints to severe on a four point Likert scale 0-no problem,1- mild,2- moderate, 3-serious problem.⁹

QOLIE 10

The QOLIE-10 is a self-administered questionnaire, designed for completion by patients alone. It is an epilepsy specific questionnaire. The QOLIE-10 is a 10-item questionnaire, with two domains: 'daily activities and treatment impact' and 'mental health'. The overall score ranges from 0 to 100, the higher score the better HRQoL. The period to which the questions refer to is "during the last four weeks" .it includes a question about their seizure worry which was separately analyzed. A greater value of "seizure worry" score interprets the patients are less worried about seizure occurrence.^{21,22, 23}

Duration of study

The study was carried out for a duration of 6 months from February to July 2015.

Statistically analysis

The data was analysed for correlation by determining the Pearson correlation coefficient. Mean and standard deviation for each demographic data, SIDAED score and QOL score was calculated. Statistical significance was evaluated by the use of t- test. One way analysis of variance (ANNOVA) was used to test the difference between the groups to evaluate whether the means were significantly different from each other. P values below 0.05 were considered significant.

RESULTS

A total of 103 patients were recruited in to this study patient characteristics are shown in the table 1 Mean age of the subjects was 31.24 ± 15.469 of which 57.3% (n= 103) were females, 49.5% patients were unmarried and 8.7 % were divorced. Most of the subjects reported to have underlying generalized tonic clonic seizures (GTCS). One third (30.1%) of the subjects were students and 23.4 % were unemployed. Mean duration of treatment was 10.11 ± 8.015 years. Less than half of the subjects (46.6%) were on monotherapy for maintenance (Table1). Carbimazepine was the mostly used drug and, mostly prescribed combination drugs consist of carbamazepine and clobazam.

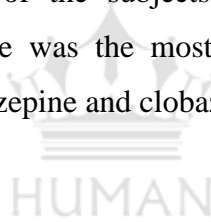


Table 1 show the sociodemographic factors of the subjects with underlying epilepsy (n=103)

Patient characteristics	range	mean
Age	9-76 yr	31.24(±1.4695)
Duration of treatment	1-40 yr	10.49(±7)
Sex	Female -57.3% Male - 42.7%	
Occupation	Daily wages	23.30%
	Govt. employee	2.91%
	Student	30.09%
	House wife	21.35%
	Unemployed	22.33%
Education	Primary	6.7%
	Pre matriculation	27.18%
	Matriculation	27.18%
	Pre degree	20.38%
	Degree	14.56%
	Professional	3.8%
Marital status	Married	42.71%
	Unmarried	60.91%
	divorced	6.79%
Type of epilepsy	GTCS -45.6 CPS- 6.8% myoclonic-6.8%	
Type of therapy	Monotherapy	47.57
	polytherapy	52.42

SIDAED SCORE

The SIDAED score ranged from 6 -87, mean SIDAED score was 54.82(±13.6).

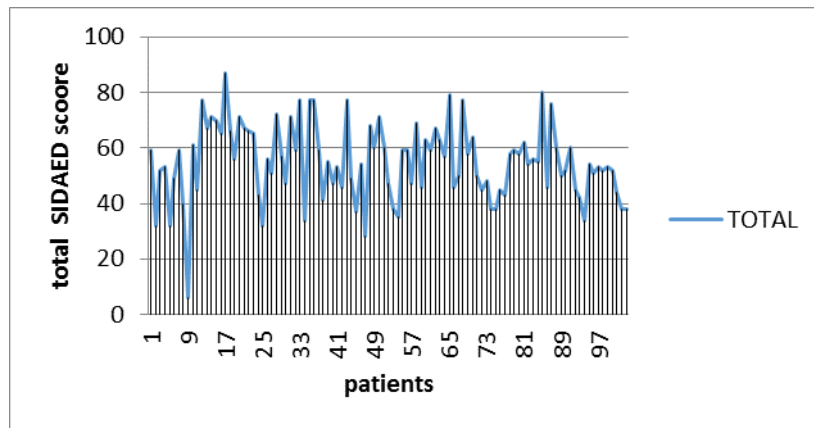


Figure 1: showing SIDAED score of each patient

Reported severe complaints were in these categories: behavioural (increased irritability) (in 76% of patients), head ache (91% of patients), cognitive problems (72% of patients) depressive (83% of patients) and general CNS (93% of patients).

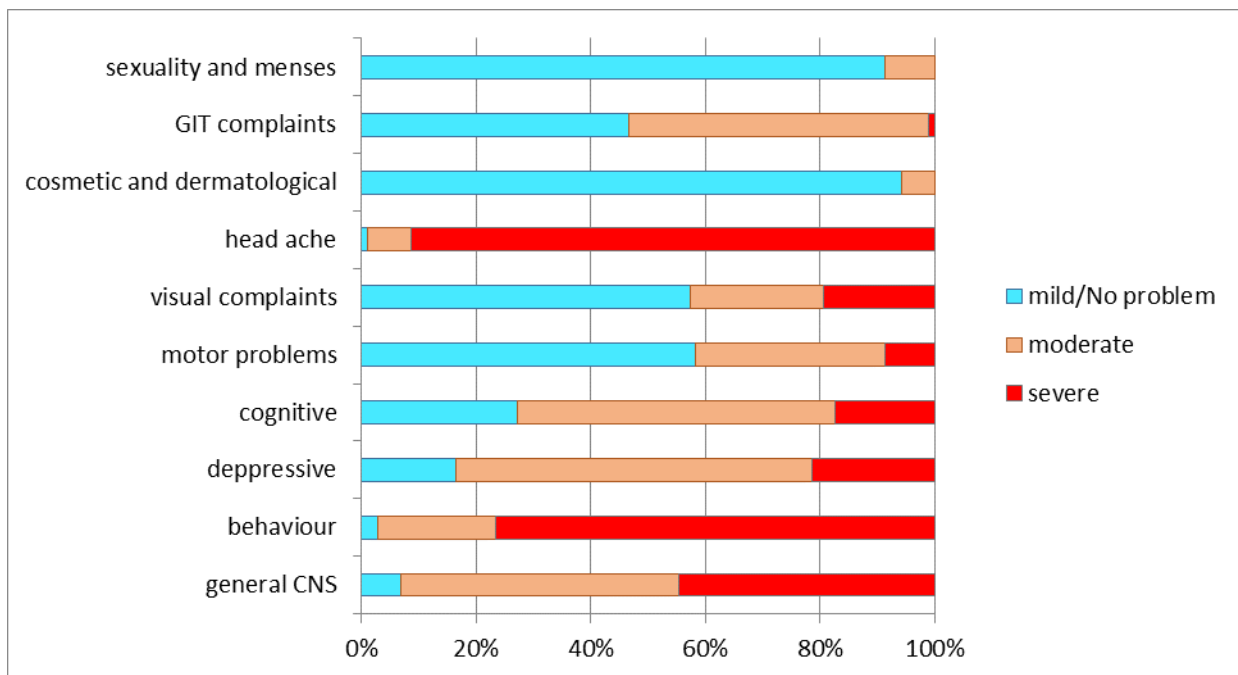


Figure.2 subjective complaints of patients

Patients who reported severe complaints in 4 or more categories were considered patients of severe subjective complaints 23% patients reported severe complaints and about 76% reported moderate complaints (figure 3).

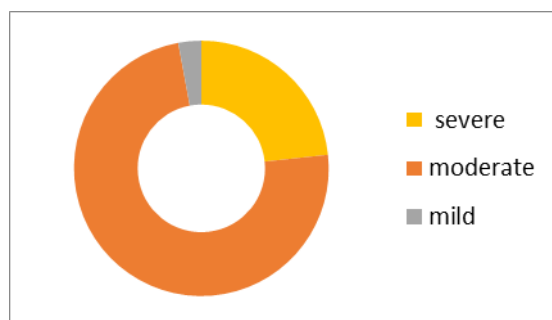


Figure 3

The SIDAED score showed a significant higher value, in female patients($p=.005$), in patients, with polytherapy ($p=.000$), in patients who were divorced compared to unmarried($p=.042$), in unemployed and housewives compared to student patients($p=.001$) (table 2).

Table 2: SIDAED SCORES

categories	Mean SIDAED score		T test	P value
sex	female	58.07	2.906	005
	male	50.45		
Type of therapy	monotherapy	47.17	-6.232	<0.001
	polytherapy	61.49		
Marital status	married	56.19	ANNOVA =0.042	
	unmarried	52.10		
	divorced	63.67		
occupation	Daily wages	53.32	ANNOVA F Sig. BetweenGroups5.461 .001	
	Govt. employee	52.33		
	Student	47.81		
	Housewife	57.95		
	unemployed	63.13		

The subjective complaints were positively correlated with age($r=.337$, $p=.000$), with duration of treatment ($r=.320$, $p=.001$) (table3).

Table 3: CORRELATION DATA OF SIDAED SCORES

Category	Pearson Correlation Coefficient	P Value
Age	.377	<0.001
Duration Of Treatment	.320	0.001
Seizure Worry	-.230	0.020

QOL SCORES

QOL scores ranged between 2.1-58.5. The mean QOL scores were 23.706.

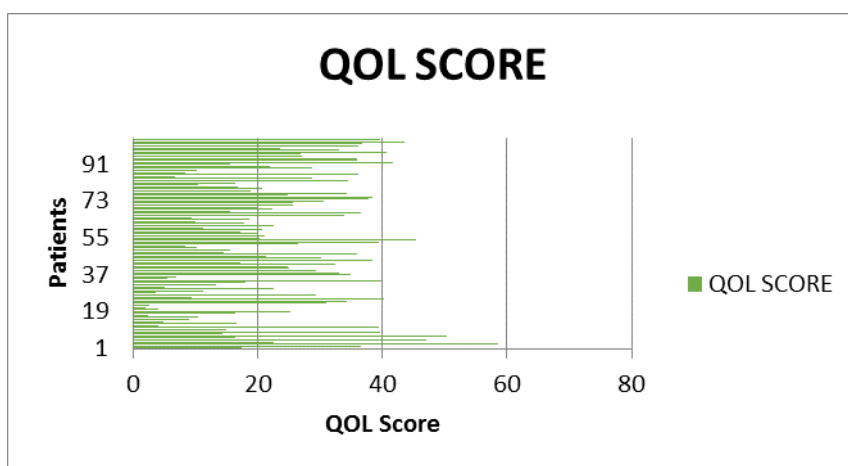


Figure 4 QOL score of each patient

Age and QOL showed a negative correlation ($r = -.285, p = .004$). As the duration of treatment increased QOL decreased ($r = -.283, p = .004$). again a negative predictor of QOL was the seizure worry. Those who were highly worried of frequent seizures marked a much lesser QOL score ($r = -.486, p = .000$) QOL was low in patients with higher SIDAED score ($r = -.755, p = .000$). QOL showed significant lower values, in patients on polytherapy ($p = .000$), in patients who are divorced compared to unmarried ($p = .038$) (table 4).

Table 4 QOL SCORES

categories	Mean QOL score		T test	P value
Type of therapy	monotherapy	30.437	5.865	<0.001
	polytherapy	17.831		
Marital status	married	22.530	ANNOVA =0.038	
	unmarried	26.190		
	divorced	15.247		

DISCUSSION AND CONCLUSION

The study shows that majority of patients who were considered well controlled reported subjective complaints. General CNS, Depressive, Head ache, and Cognitive complaints were more frequently mentioned. This was an observational study, so no experimental intervention was performed on the patients groups and physicians followed their usual clinical practice. The characteristics of our study population was in agreement with the study criteria more number of patients was maintained on polytherapy.

The total SIDAED score ranged from 6 -87 comparable to as in study by S.G Uijl et.al⁹ Patients who reported severe complaints in 4 or more categories were considered patients of severe subjective complaints. Accordingly 23% patients reported severe complaints and about 76% reported moderate complaints these observed results were greater than observed in studies by S.G Uijl.et.al⁹ and J.A Carpay.et.al.⁴

The factors which related well with the increased complaints were Gender, Type of therapy (whether the patient is on monotherapy or polytherapy), occupation and marital status. Even though total subjective complaints score correlated well with increasing age, there was no association between reported severe complaints and age.

Majority of the patients mentioned poor quality of life. We were able to find several indicators that have influence on the quality of life of patients with epilepsy. We found that more number of AED (polytherapy), increased age and higher subjective complaints as predictors of poor QOL. Divorced patients reported very poor QOL these results concur with previous studies.^{16,17,,25,27}

Regular monitoring for adverse effect play a crucial role in achieving seizure freedom and optimal QOL in patients with epilepsy. The findings suggest a need to improve the monitoring of complaints of side effects of AEDs and to explore the feasibility of interventions aimed at reduction of such complaints in everyday clinical practice. In day to day practice we use only a generalized question to evaluate the complaints and quality of life. This study reveals that systemic questionnaires may be used at specified intervals to assess them. The presence of subjective complaints and QOL are key indicators towards the patients' benefit and satisfaction from the treatment.

A control group was not included in the study since other patients may also report the listed complaints in the SIDAED questionnaire. Our study was focused on complaints in AED users so it was irrelevant to include them.

A short study period and limited number of patients enrolled may be a limitation of my study. If the study was conducted with a larger sample size for a longer duration more significant results in all outcomes may have been obtained.

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