

Impact of a Brief Structured Psychoeducation Session on Antiepileptic Drug Adherence and Treatment Outcome in Persons with Epilepsy: A Prospective Cohort Study

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Abstract

Background: Poor adherence to antiepileptic drugs is one of the most important causes of treatment failure in persons with epilepsy (PWE). This study was aimed at assessing the impact of psychoeducation on drug adherence and treatment outcome in PWE. **Methods:** It was a prospective cohort study with a pre and posttest intervention design. A cohort of 100 epilepsy patients aged 18–65 years and on antiepileptic drugs for at least 6 months attending the outpatient department was enrolled in the study. Drug adherence was measured by Medication Adherence Rating Scale. A structured eight-domain epilepsy psychoeducation session with pictorial description was given to the study subjects in two parts (group and individually) lasting for a total of 30 min on the day of baseline assessment. Adherence and treatment outcome variables were assessed by an independent observer 4 months after the psychoeducation session. Chi-square test and paired t-test were used to analyze the data using SPSS version 20 with *P* value less than 0.05 considered as significant. **Results:** There was a statistically significant (*P* < 0.001) increase in the number of patients who were adherent to medications after psychoeducation session. There was a significant reduction in mean seizure frequency (0.68 ± 0.65) and seizure severity in terms of injuries sustained during seizure episodes post intervention. Regularities in the follow-up visits were also witnessed. A significant decrease in the number of hospital admissions (0.09 ± 0.32), mean inpatient treatment days (0.44 ± 2.19), and emergency room visits (0.19 ± 0.15) was noted 4 months after the psychoeducation session indicative of better treatment outcome. **Conclusion:** The present study proves the efficacy of a structured educational program in improving drug adherence and treatment outcome in a cohort of people with epilepsy.

Keywords: Adherence, education, epilepsy, seizure frequency, treatment outcome

INTRODUCTION

Epilepsy is one of the most common serious neurological disorders worldwide and in India. Over 70 million persons are affected with epilepsy globally. About 12 million persons with epilepsy (PWE) are from India, contributing to nearly one-sixth of the global burden.^[1] Antiepileptic drugs (AEDs) are effective in the treatment of epilepsy to the extent that about 60%–70% of people with epilepsy can be seizure-free with optimal AED treatment^[2] but poor adherence to medication is one of the most important causes of treatment failure and is associated with increased morbidity and mortality along with increased time of hospitalization, poor quality of life, and increased health care cost.^[3–6] As per the World Health Organization (WHO), medication adherence is defined as “the degree to which the person’s behavior corresponds with the agreed recommendations from a health care provider.”^[7] Research indicates that 30% to 50% of adults with epilepsy adhere poorly to their AED treatment schedules.^[8]

Various measures and interventions including counselling, psychoeducation, and behavioral interventions have been recommended in literature to improve adherence to AED. A randomized controlled trial in India conducted by Das *et al.* (2015) concluded an increase in adherence to antiepileptic

drugs after a structured educational program.^[9] Similarly, a higher level of medication adherence was reported by Dilorio *et al.* (2011) among participants completing an online epilepsy self-management program.^[10] Although a recent Cochrane review by Al-Aqeel *et al.* (2017) found a moderate effect on adherence, seizure frequency, and severity with behavioral or educational interventions, it recommended further well-designed research and inclusion of variables other than adherence to draw firm conclusions.^[11] In the background of scanty data, particularly in the Indian context, pertaining to the effect of educational interventions on AED adherence and

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more so on treatment outcome variables, the current study was undertaken with the aim to assess the impact of psychoeducation on AED adherence and treatment outcome in PWE seeking treatment from a tertiary care hospital in north India.

MATERIALS AND METHODS

Study design

It was a prospective cohort study with a pre and posttest intervention design conducted in tertiary care Hospital of Haryana from July 2019 to March 2020. Approval for the study was sought from the institutional ethics committee (KCGMCH/IEC/2019/52 dated 15.07.2019). Patients with an established diagnosis of epilepsy attending outpatient clinics of departments of General medicine and psychiatry in medical college and hospital were screened as per the inclusion and exclusion criteria. The diagnosis of epilepsy in the subjects was primarily based on detailed medical history and neurological evaluation by a qualified physician or neuropsychiatrist. Electroencephalography and neuroimaging techniques (i.e., computed tomography and magnetic resonance imaging) were considered as supportive evidence for the diagnosis but not mandatory. Adult patients of either gender aged 18–65 years with an established diagnosis of epilepsy and who had been on antiepileptic drugs (AEDs) for at least 6 months and provided written informed consent were included in the study. Exclusion criteria were PWE i) who were either pregnant or breastfeeding, ii) with comorbid mental retardation and serious mental illnesses, iii) who had serious neurological deficit, and iv) warranting hospitalization due to any comorbid serious physical illness. A hundred consecutive PWE who met the inclusion and exclusion criteria were finally included in the study. Taking prevalence of adherence to antiepileptic drug 64.5% (p_1)^[6] and prior assumption of finding difference of 24% adherence after 4 months of the postintervention session ($p_2 = 86.55$), the sample size was calculated. Assuming $\alpha = 0.05$, $\beta = 80\%$, $r = 1/1$ (ratio of cases to control), chance of nondetecting a difference 0.2, the final sample size came out to be 92.

Study tools

Antiepileptic medication adherence was measured by using Medication Adherence Rating Scale (MARS) by Thompson *et al.* 2000.^[12] This scale has features of both Morisky *et al.* 1986^[13] and Drug Adherence Inventory (DAI) scales. The MARS is a self-administered test consisting of ten items that require yes/no response. However, if any subject could not read, assisted application was used, in which the researcher read the questions and marked the correct responses given by the respondents. The scores 0–3, 4–6, and 7–10 indicate nonadherence, partial adherence, and adherence, respectively.

Method

Detailed information pertaining to sociodemographic variables, epilepsy, and treatment-related variables was taken from all the study subjects. Subsequent to this, they were assessed for the level of adherence to antiepileptic medication

using MARS which enquired about their behavior and attitude toward medication during the past week. Treatment outcome details, viz., seizure frequency, numbers of hospital admissions, inpatient treatment days, emergency room visits, regularities in the follow-up visits, injuries sustained during seizures, etc., were also noted down for all the study subjects during a period of 2 months preceding the baseline assessment. The subjects were then given the psychoeducation session by author CS in the teaching room of Psychiatry outpatient department in two parts on the same day. The first part of the psychoeducation program was a group session of 5–10 patients and their caregivers (if available) lasting about 20 min. The details of this psychoeducation session are as follows: It was a pilot-tested, structured epilepsy psychoeducation health program developed by a group of psychiatrist (CS), general physician (GN), and community medicine specialist (NA). The session had the following domains: 1) what is epilepsy, 2) clinical features of epilepsy (in brief), 3) nature and duration of treatment, 4) harms of nonadherence to treatment, 5) what patient can do to overcome problem of nonadherence, 6) when and how to stop treatment, 7) precautions to be taken while on treatment, and 8) precautions to be taken during seizure episode. Pictorial representation covering different aspects of epilepsy was also shown on the laptop for a better understanding of the patients. This was followed by part two of the session where study subjects were attended individually for 5–10 min. During this individual session, they were given clarifications for queries, if they had any. They were also explained when and how to take their AEDs based on their individual prescriptions and the same was marked on their pill strips in local language using a permanent marker. They were immediately asked to repeat what they had understood regarding AED regimen they were supposed to follow. They were also told the date of next follow-up and the same was mentioned on their OPD cards. They were also told that they were free to seek consultation before the scheduled visit if the need for the same arose.

These subjects were reassessed by an independent observer 4 months after the baseline assessment for adherence as well as treatment outcome parameters in last 2 months of treatment (to minimize recall bias) using the same questionnaires.

Statistical analysis

Data was entered in Microsoft excel and examined with SPSS version 20 (IBM Corp., Armonk, NY, USA). Mean, percentage, and standard deviation (SD) were calculated. Comparison between preintervention and postintervention scores was done using a paired t-test and for categorical data, Chi-square test was applied; P value less than 0.05 was considered significant.

RESULTS

Sociodemographic and epilepsy-related characteristics

The majority of the subjects were males (around 60%) and the female patients (32.23 ± 10.6) were significantly younger than their male counterparts (34.26 ± 14.1) at the time of presentation in OPD. Majority of the participants

were matriculates (37%) followed by those with primary education (28%). Approximately one-third (39%) of the study subjects were employed [Table 1].

Majority of the study subjects had generalized tonic-clonic seizures (72%) followed by focal seizures (22%). 36% of the patients had undergone EEG and 88% had undergone radiological investigations (CT or MRI). Most common antiepileptic drug prescribed was sodium valproate (72%) and topiramate being the least common (5%) [Table 2].

Reasons for poor adherence

Forgetfulness was cited as the most common reason for poor adherence to AED by 26 (40%) of the subjects. Self-perceived cure from epilepsy following seizure control was the next most important reason behind poor adherence as reported by 17 (26.2%) participants followed by discontinuation of AEDs due to development of any minor medical ailment during the course of treatment (20%) [Table 3].

Table 1: Sociodemographic characteristics of persons with epilepsy (n=100)

Variables	Total (%)
Gender	
Male	61 (61)
Female	39 (39)
Age (Mean±SD)	
Male	34.26±14.1
Female	32.23±10.6
Education	
Illiterate	20 (20)
Primary	28 (28)
Matriculation	37 (37)
Above Matriculation	15 (15)
Occupation	
Unemployed	11 (11)
Employed	39 (39)
Student	19 (19)
Homemaker	31 (31)
Marital Status	
Married	57 (57)
Single	43 (43)
Background	
Rural	70 (70)
Urban	30 (30)
Type of family	
Nuclear	48 (48)
Joint	52 (52)
Monthly family Income (in INR)	
≤25,000	58 (58)
>25,000	42 (42)
Substance Use	
Yes	29 (29)
No	71 (71)
Physical Comorbidities	
Present	22 (22)
Absent	78 (78)

Impact of psychoeducation on treatment adherence

The difference in treatment outcome was more evident among PWE who were on polytherapy ($P < 0.001$) compared to their counterparts receiving monotherapy ($P = 0.035$) though both were statistically significant [Table 4]. In preintervention arm out of 65% nonadherent PWE, 41% had uncontrolled seizure. In postintervention arm 32% nonadherent PWE, 16% had uncontrolled seizure. There was a statistically significant increase in the number of patients who showed adherence to medication and decline in the number of subjects reporting nonadherence after psychoeducation session ($P < 0.001$) [Table 5].

Impact of psychoeducation on epilepsy treatment outcome

To determine the changes in epilepsy treatment outcome parameters, post psychoeducation session paired t-test was applied. Complete seizure control in preceding 2 months was witnessed in 90% of the subjects post intervention compared to 51% at baseline [Table 4]. Significantly fewer injuries were sustained during seizure episodes after psychoeducation session ($P < 0.01$). Regularities in the follow-up visits were also seen post intervention [Table 5]. A significant difference was seen in the mean seizure frequency, number of hospital admission, inpatient treatment days, and emergency room visits before and 4 months after psychoeducation session. No death was reported during the study period [Table 6].

Table 2: Epilepsy-related characteristics of persons with epilepsy (n=100)

Parameters	Total (%)
Duration of Epilepsy	
<5 years	20 (20)
5-10 years	27 (27)
10-20 years	32 (32)
≥20 years	21 (21)
Type of Seizures	
Generalized Tonic Clonic Seizures	72 (72)
Focal Seizures	22 (22)
Absence Seizure	03 (3)
Myoclonic Seizure	03 (3)
Duration of treatment (in years)	
<1 year	16 (16)
1-5 years	73 (73)
>5 years	11 (11)
Type of Therapy	
Monotherapy	38 (38%)
Polytherapy	62 (62%)
Type of AED	
Phenytoin	44 (44)
Sodium Valproate	72 (72)
Carbamazepine	12 (12)
Phenobarbitone	07 (7)
Levetiracetam	12 (12)
Clobazam	27 (27)
Topiramate	05 (5)

DISCUSSION

Nonadherence is a very common phenomenon in all patients with drug-taking behavior. Previous studies on this subject have demonstrated a positive impact of educational interventions on medication adherence in PWE. Dash *et al.* in a randomized control trial on PWE found a statistically significant increase in the self-reported antiepileptic drug adherence following a structured six-domain epilepsy educational program given over four sessions by a trained staff member.^[9] May and Pfaffian evaluated an educational program Modular Service Package Epilepsy (MSPE) covering nine domains of epilepsy and found improved seizure outcomes and adherence of antiepileptic drugs after education program.^[12] A review article by Mittan

also concluded that educational interventions were associated with an increase in the knowledge of epilepsy and a decrease in the seizure frequency which resonates with the findings of our study.^[13]

A Cochrane review by Al-Aqeel *et al.* including 12 studies and 1642 participants concluded that educational interventions and mixed interventions (i.e., using both behavioral and education interventions) resulted in a moderately positive effect on adherence in the intervention groups as compared to the control groups. Four trials included in the Cochrane review showed that seizure frequency or seizure severity was decreased in the intervention groups post intervention.^[11]

Ibinda *et al.* in a randomized control trial on 738 patient of epilepsy found no significant difference in adherence to antiepileptic medication (measured by drug level or self-reports) as well as seizure frequency after 1 year of an educational program.^[14] This difference in results could be attributable to the relatively longer duration of follow-up (1 year) in contrast to a short duration of follow-up (4 months) in the present study.

Although measures of other outcomes like beliefs and attitudes, knowledge of AEDs, and self-efficacy were found significantly changed and improved after education in previous international literature,^[11-17] treatment outcome variables other than seizure frequency and severity have not yet been well studied. An important strength of this study was that multiple additional details about treatment outcome were also duly investigated apart from seizure frequency which included the number of patients requiring inpatient admission or emergency room visits, mean inpatient days, number of patients achieving full seizure control, number of patients sustaining injuries during the seizure episodes, or deaths as corroborative evidence to measure adherence. Complete (100%) follow-up was another noticeable finding of the index study. Factors possibly explaining the success of follow-up in our study could be that antiepileptic medications were made available to patients free of cost or at a minimal cost and ours was the single government run tertiary care health facility in the easy access of study participants where radiological investigations (both

Table 3: Reasons for poor adherence to AED in persons with epilepsy (n=65)*

Reasons	Frequency (%)
Forgetfulness	26 (40)
Switching treatment temporarily to alternative systems of medicine (Ayurveda, Homeopathy, etc.)	7 (10.8)
Withholding antiepileptic treatment during the development of any minor medical ailments (flu, diarrhea, fever, etc.)	13 (20)
Bored with taking medication	12 (18.5)
Felt medication to be ineffective in controlling seizures	4 (6.2)
Skipping treatment due to observance of religious fasting	3 (4.6)
Stopping treatment due to stigma and fear of disclosure of illness to spouse or in-laws	7 (10.8)
Lack of knowledge about duration of treatment course	6 (9.2)
Stopping medicines due to perceived cure from illness following seizure control	17 (26.2)
Experiencing side effects	4 (6.2)
Financial burden	5 (7.7)
Complexity of drug regimen (Multiple medications, high doses, frequent dosing)	9 (13.8)
Temporary nonavailability of medication in hospital pharmacy	6 (9.2)
Others**	6 (9.2)

*multiple responses. *n=subjects with partial or nonadherence. **Others included long waiting period in hospital, failure to get prescription renewal, busy work schedule, being away from home

Table 4: Effect of monotherapy versus polytherapy on treatment adherence post psychoeducation session in PWE (n=100)

Variables	Preintervention n (%)	Postintervention n (%)	P
Monotherapy (n=38)			
Adherent	23 (60.5)	31 (81.6)	0.035
Partially adherent	07 (18.4)	06 (15.8)	
Nonadherent	08 (21.1)	01 (2.6)	
Polytherapy (n=62)			
Adherent	12 (19.4)	37 (59.7)	<0.001
Partially adherent	18 (29.0)	13 (21.0)	
Nonadherent	32 (51.6)	12 (19.4)	
Seizure control			
No seizure (zero) during last 2 months	51	90	<0.001
≥1 seizure	49	10	

Table 5: Change in adherence pattern and treatment outcome post psychoeducation session (n=100)

Variables	Preintervention n (%)	Postintervention n (%)	P *
Level of adherence			
Adherent	35 (35)	68 (68)	<0.001
Partially adherent	25 (25)	19 (19)	
Nonadherent	40 (40)	13 (13)	
Regularity of follow-up visits			
On Scheduled visit	11 (11)	27 (27)	<0.001
Before Scheduled visit	28 (28)	57 (57)	
After Scheduled visit (delay)	61 (61)	16 (16)	
Number of patients sustaining injuries during seizures			
Yes	29 (29)	02 (2)	<0.001
No	71 (71)	98 (98)	

*Chi-square test

Table 6: Changes in treatment outcome parameters post psychoeducation session (n=100)*

Epilepsy Outcome parameters	Preintervention Mean (SD)	Postintervention Mean (SD)	Std. error of the mean	95% CI for the difference	t	P
Seizure frequency (Seizures in preceding 2 months)	0.79 (0.99)	0.11 (0.35)	0.092	0.495-0.859	7.377	<0.001
Number of patients requiring hospital admissions	0.09 (0.32)	0.0 (0.0)	0.032	0.026-0.154	2.805	0.006
Number of inpatient treatment days	0.44 (2.19)	0.0 (0.0)	0.219	0.006-0.874	2.010	0.047
Number of emergency room visits	0.25 (0.44)	0.06 (0.28)	0.049	0.094-0.286	3.909	<0.001
Deaths	0.0	0.0				

*paired t-test

CT and MRI) were available. Further, involvement of family members, routine use of Health Management Information System (HMIS) in hospital, and a relatively short follow-up period could have positively affected the follow-up success.

The study was, however, limited by the lack of a control group that did not receive psychoeducation session and definitive measures of adherence like blood levels of antiepileptic drugs. Further, the treatment outcomes were not monitored over a longer period of time. Another limitation of the study was noninclusion of subjects with uncertain, unclassified, or intractable epilepsy as they were usually referred to higher centers having superspecialty services in neurology. This study warrants further research including larger community-based trials and involving multiple comparison groups like those receiving multiple versus single versus no psychoeducation sessions at all or those receiving educational versus behavioral versus mixed interventions, with longer follow-up and more definitive measures of medication adherence. In future, we also plan to build upon the information from this study by inclusion of these educational interventions in routine practice which will result in comprehensive management and ultimately improved outcome in PWE. The authors further suggest that in a developing country like India where doctor population ratio is low, medical social workers or nursing staff may be trained to deliver psychoeducation sessions to patients.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be

reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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