

# The impact of seizures and adverse effects on global health ratings

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## Abstract

This study was undertaken to explore the perceived impact of having a seizure (SZ) compared with having an adverse effect (AE). Patients ( $N = 201$ ) with partial-onset epilepsy taking two or more antiepileptic drugs (AEDs) rated their health state from 0 to 100 based on their health today, hypothetical health if experiencing a SZ today, and hypothetical health if experiencing an AE today. Overall health status ratings (HLTH) declined as SZ frequency increased ( $P = 0.01$ ). Perceived decrements in HLTH with SZs were greatest for patients with the least frequent SZs ( $P = 0.001$ ) and the most recent SZs ( $P = 0.004$ ). Perceived decrements in HLTH with SZs compared with AEs (SZ–AE) differed across SZ recency groups ( $P < 0.05$  except for muscle incoordination and weakness). Patients with the more remote SZs were most concerned with SZ control; patients with more recent SZs were more sensitive to AED side effects. These data provide insight into the risk–benefit concerns of patients at equipoise when addressing the efficacy and AEs of AEDs.

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## 1. Introduction

Little is known about the ways in which patients perceive the impact of their seizures relative to various adverse effects (AEs) attributable to antiepileptic drugs (AEDs). This is an important issue for patients whose partial-onset seizures are not fully controlled. If physicians consider changing or adding a medication, they face the risk–benefit balance between the potential for improved seizure control with increased AEs and the potential for improved seizure control without increased AEs. As with other disease conditions, physicians may have little information on how to advise patients about the likelihood of either outcome [1]. Physicians may advise about what to expect and offer to adjust the treatment if AEs occur, but the choice often is in the hands of patients who take the risks. Thus, patients

often are at equipoise with the possible choices: they may consider both continued seizures with no or fewer AEs and fewer or no seizures as reasonable options.

In some instances, physicians may be reluctant to initiate a recommendation for a medication change or use of more than one medication to treat epilepsy. This problem of “therapeutic inertia” is well characterized in other areas of medicine. For example, physicians often are reluctant to start insulin or raise the dose despite high glycosylated hemoglobin levels in patients receiving oral hypoglycemic agents or insulin [2]. Similarly, physicians often do not treat hypertension to target blood pressure [3,4]. On the other hand, patients often are reluctant to alter treatment because of potential risks. This may be a state of a complacent dissatisfaction wherein patients are either unaware that their condition (e.g., seizures or AEs) might be improved with a treatment change or are reluctant to ask for a treatment change because of concern about the risks of breakthrough seizures during a change, worse AEs, the

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cumbersome process of medication cross-titration, or lack of improved seizure control after a change. In a survey, Fisher et al. [5] found that patients were concerned about seizure control and AEs, but did not ask about the impact of each treatment component. The lack of information about patient-reported concerns leaves physicians with assumptions instead of evidence-based data on when and for whom to recommend treatment change.

We undertook a study of patient-reported concerns to learn how patients at equipoise perceived the balance between the impact of having another seizure and the burden of having an AE. The choices were based on AEs typically occurring with AED treatment.

## 2. Methods

### 2.1. Patients

A cross-sectional survey of adults with partial-onset epilepsy was undertaken among community-based neurology practices across the United States. Patients gave informed consent to participate in the survey. The study protocol was approved by an accredited central human investigational review board, and was compliant with Health Insurance Portability and Accountability Act (HIPPA) policies and procedures with all data de-identified. Patients were invited by their neurologists to participate if they were 18 or older, able to read and complete the questionnaire in English, had partial-onset seizures (with or without secondary generalization), and were currently (past 2 months) taking two or more AEDs. Patients also had to have experienced at least one partial-onset seizure (with or without secondary generalization) in the past 12 months, but none in the 2 days preceding completion of the questionnaire.

The physician recorded patient demographic and clinical characteristics, current medical therapy, and seizure history on a clinical case report form. On study enrollment, patients completed a survey in the physician's office. The patient survey and clinical case report form were completed once only by each patient and physician, respectively.

### 2.2. Data collection

Patients completed a questionnaire that included the Quality of Life in Epilepsy Inventory—10 (QOLIE-10) [6], the Hospital Anxiety and Depression Scale (HADS) [7], and the EuroQol EQ-5D [8]. In addition, patients were asked to rate their health state with a number from 0 (worst) to 100 (best) based on their health today. Patients also were asked whether they had a seizure “today” and, if not, what their hypothetical health rating would be if they were to experience a seizure “today.” In addition, patients were assessed with respect to whether they were experiencing any of 10 specified AEs (muscle incoordination, diplopia, dizziness, fatigue, weakness, headache, nausea, sleepiness, poor concentration, anomia) (AEs were described in lay language) and, if they were not, what their hypothetical health rating would be if they were to experience each AE “today.”

### 2.3. Analyses

Summary statistics were calculated including means and standard deviations (SD) for continuous variables and frequency distributions for categorical variables. Decrements in health rating with a seizure today or each type of AE “today” were calculated as change from health status “today.” Differences in decrements related to each AE (SZ–AE) were calculated to contrast the relative impact of having a seizure with that of having an AE. Higher positive SZ–AE values indicate a greater perceived decline in health status associated with experiencing a seizure; negative SZ–AE val-

ues indicate that the specific AE negatively impacts health status more than a seizure does. Health ratings and decrements in health ratings were compared across seizure frequency and recency categories using one-way analysis of variance (ANOVA). Statistical significance was evaluated at the 0.05 level, with no adjustments for multiple comparisons.

## 3. Results

Physicians enrolled 201 patients who met the eligibility criteria and completed the patient questionnaire. Table 1 describes the demographic and clinical characteristics of this community-based, outpatient sample. Two previous reports described self-reported quality of life and the prevalence of anxiety and depression in this group [9,10].

Patients reported a mean  $\pm$  SD overall health rating of  $71.6 \pm 19.8$  on the assessment day, and rated their overall

Table 1  
Demographic characteristics<sup>a</sup>

Number of subjects	201
Age, mean (SD) [range]	44 (12.5) [19–75]
Gender, <i>N</i> (%)	
Male	88 (44)
Female	113 (56)
Ethnicity, <i>N</i> (%)	
White, non-Hispanic	166 (86)
Black, non-Hispanic	10 (5)
Hispanic	13 (7)
Other	4 (2)
Education level, <i>N</i> (%)	
Grade school	8 (4)
Some high school	27 (14)
Completed high school	62 (32)
Some college	52 (27)
Completed college	23 (12)
Graduate work	21 (11)
Employment status, <i>N</i> (%)	
Employed, full-time	36 (19)
Employed, part-time	14 (7)
Unemployed	33 (17)
Disabled	79 (41)
Retired	14 (7)
Full-time homemaker	13 (7)
Student	3 (2)
Age at diagnosis of epilepsy, mean (SD)	21 (15)
Duration of epilepsy, mean years (SD)	25 (16)
Seizure type, <i>N</i> (%)	
Simple partial seizures only	12 (6)
Complex partial seizures with/without simple partial seizures but no generalized seizures	58 (29)
Secondarily generalized seizures with or without partial onset	129 (65)
Seizure frequency, <i>N</i> (%)	
Once in past year	
Once every 6 months	28 (14)
Once every 3 months	25 (13)
Once a month	63 (32)
Once a week	19 (10)
More than once a week, less than daily	30 (15)
Daily	6 (3)

<sup>a</sup> Missing data resulted in fewer than 201 responses for some items.

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