



Counting seizures: The primary outcome measure in epileptology from the patients' perspective[☆]



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ABSTRACT

Purpose: Patient-reported seizure counts represent a key outcome measure for individual treatments and clinical studies in epileptology. Video-EEG based research, however, demonstrated lack of validity due to underreporting. Here we examined the practice of keeping seizure diaries and the patients' attitudes toward seizure counting.

Methods: Anticipating a low return rate, a comprehensive survey was mailed to 1100 adult outpatients. Besides methods and reasons to document or not to document seizures, the questionnaire addressed clinical, personality and sociodemographic characteristics as well as the subjective experience of seizures.

Results: Questionnaires from 170 patients (15%) could be included in our analysis. Patients estimated to be aware of 5.3 out of 10 daytime seizures (nocturnal seizures: 2.6) while they supposed that relatives/colleagues noticed 7.1 (nocturnal: 4.6). Almost two-thirds of the patients reported to keep a seizure diary with a self-estimated documentation rate of 8.7 out of 10 noticed daytime seizures (nocturnal: 7.7). Documenters and non-documenters showed only marginal group differences with regard to clinical, personality and sociodemographic characteristics. Importantly, patients were more committed to keep a seizure diary when they judged it to be relevant for clinical treatment decisions.

Conclusion: Patients appear to know that they underreport seizures. According to their view, seizure unawareness as induced by seizures themselves seems to be a more important factor than omitting documentation of noticed seizures. Thus, the potential to improve the validity of seizure diaries of electronic devices which facilitate documenting noticed seizures appears limited.

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1. Introduction

Seizures represent the key symptom of epilepsy and the primary target of epilepsy treatment. To date, there is no feasible and sufficiently sensitive technique for long-term outpatient registration of epileptic events, especially complex partial seizures. Like in many other chronic conditions, epilepsy patients are therefore asked to keep a seizure diary [1,2]. The relative reduction of the monthly seizure frequency from baseline to follow-up calculated from

patient seizure counts is accepted as a primary outcome in epilepsy research; actually, some reports do not even mention that the primary outcome relied on patient reports (e.g. [3–5]).

Several publications from the last 15 years, however, provided unambiguous evidence that patient-reported seizure counts lack validity due to underreporting [6–15,17,23–25,31]; for review see: [1,11,16]. For instance, in one recent study using implanted electrodes, patient-reported seizure documentation appeared more or less unrelated to objective seizure records [7]. In a former study of our own group, documentation accuracy was shown to be specifically reduced for seizures which impair consciousness (i.e. complex-partial seizures) or which occur during sleep [17]. In the same study, daily reminders of keeping their seizure diaries had no effect on the patients' documentation accuracy indicating little impact of motivation or carefulness. Incomplete seizure documentation rather resulted from *seizure unawareness as induced by the seizure itself*. Accordingly, Poochikian-Sarkissian et al. [14]

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recently showed that patients often failed to note that they suffered from a seizure. One study which applied objective recording (i.e. 24-h ambulatory EEG) even showed that patients who claimed to be seizure free (and held a driving license) actually were not [10]. Lack of validity of patient-provided seizure data challenges established seizure freedom rates of epilepsy treatments including epilepsy surgery as most outcome studies relied on this measure (e.g. [18]).

Based on our clinical experience, we hypothesized that patients might be aware of the fact that they are unaware of some of their seizures. In the present questionnaire study we asked patients how exactly they keep their seizure diaries; which attitudes toward seizure documentation (or non-documentation) and which reasons to (not-) document their seizures they have; how they evaluate their own awareness of seizures and the rate of documenting those noticed seizures; how they experience the therapeutic relevance of their records; and whether they would appreciate novel technical tools for easier documentation. In addition, we explored effects of sociodemographic, personality and clinical characteristics on the patients' practice of and attitudes toward seizure self-monitoring.

2. Material and methods

This non-interventional single-arm postal survey study was carried out in accordance with *The Code of Ethics of the World Medical Association* (2008) and approved by the Ethical Review Board of the Medical Faculty at the University of Bonn (No. 067/14).

2.1. Subjects

At study onset (February 2014), we identified $N = 1100$ outpatients from our clinic who recently visited our department (age: 20–70 years; for further details see Supplementary Methods). Patients were asked only to enroll if they had experienced seizures during the last year. No reimbursement was offered for study participation. The large initial sample size was chosen because we anticipated an overall low return rate due to presumably low interest in this issue and an unknown percentage of currently

seizure-free patients. The questionnaire was piloted in ten inpatients; as no substantial changes were necessary after piloting, data from these patients were also included.

2.2. Measures

The newly developed instrument (see Supplementary Material, Attachments A/German and B/English) comprises sections addressing socio-demographic and clinical data, personality, seizures (daytime/nocturnal), and either seizure documentation or non-documentation. Open-ended and closed-ended questions were used. For measuring attitudes, 6-stepped Likert-scales (from 1 = *rejection* to 6 = *full approval*) or German school grades (from 1 = *very good* to 6 = *very bad*) were applied. Several items were derived from questionnaires previously published by our group [19–21]. In particular, the single most selective item from each of the 18 scales of a comprehensive questionnaire on personality was extracted [19].

2.3. Statistics

If appropriate, descriptive statistics were reported together with 95% confidence intervals (95% C.I.); 95% C.I. for relative frequencies were estimated by bootstrapping ($N = 1000$ samples). Group differences and correlations were assessed using parametric (e.g. T -tests for dependent and independent samples, Pearson's r) and non-parametric tests (e.g. χ^2 -test, Wilcoxon U -test, Mann-Whitney U -test, Kendall's τ) according to the level and distribution properties of the respective data. The significance level was set to $\alpha = 0.05$ (two-sided). All statistical analyses were performed with IBM® SPSS® Statistics (German release, version 22.0.0.0).

3. Results

We received surveys from 174 patients (return rate: 15.7%) but four surveys filled-in inappropriately had to be excluded from analysis. The sociodemographic, clinical and seizure characteristics of the included patients are shown in Table 1. The sample

Table 1
Sociodemographic, clinical and seizure characteristics.

	Mean (standard deviation) [range]/frequencies
Sample size	170
Age at survey (years)	42.7 (13.7) [16–71]
Sex: male/female	74 (43.5%)/96 (56.5%)
Academic achievement: high/medium/low	57 (33.6%)/42 (24.7%)/71 (41.8%)
Living alone/with parents/with own family/assisted/other	41 (24.6%)/23 (13.8%)/95 (56.9%)/5 (3.0%)/3 (1.8%)
Employment: employed/housewife (husband)/incapacitated for work/age retirement/unemployed	77 (48.1%)/11 (6.9%)/44 (27.5%)/11 (6.9%)/17 (10.6%)
Age at seizure onset	18.1 (14.6) [0–69]
Monthly frequency of "little" daytime seizures ^b	11.0 (32.3) [0–300]
Monthly frequency of "big" daytime seizures ^b	2.7 (13.4) [0–150]
Monthly frequency of "little" nocturnal seizures ^b	3.7 (19.2) [0–200]
Monthly frequency of "big" nocturnal seizures ^b	0.5 (1.4) [0–10]
Seizures ^{b,c} : auras only/simple partial/complex-partial/grand mal/drop attacks/absence seizure/other	52 (30.6%)/46 (27.1%)/48 (28.2%)/47 (27.6%)/21 (13.4%)/51 (30.0%)/34 (20.0%)
Psychogenic seizures only ^b	18 (10.6%)
Number of antiepileptic drugs	2.5 (1.1) [0–5], Median: 2.0
Number of antiepileptic drugs: 0/1/2/3/4/5	4 (2.5%)/26 (16.1%)/59 (36.6%)/45 (28.0%)/19 (11.8%)/8 (5.0%)
Epilepsy surgery	28 (16.5%)
Vagus nerve stimulation	20 (11.8%)
Annual frequency of doctor visits for epilepsy	3.7 (3.0) [0–18]
Annual number of days in hospital for epilepsy	4.4 (8.8) [0–53]
Annual number of emergencies due to epilepsy	1.0 (2.0) [0–18]
Evaluation ^a of treatment by local neurologist	2.9 (1.6) [1–6]
Evaluation ^a of treatment by epilepsy center	1.8 (0.8) [1–5]

^a German grades: 1 = very good, 6 = insufficient ("ungenügend").

^b Patient-reported data.

^c Multiple responses possible.

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