Epilepsy & Behavior 52 (2015) 1–7

Contents lists available at ScienceDirect

Epilepsy & Behavior

journal homepage: www.elsevier.com/locate/yebeh

Novel techniques for automated seizure registration: Patients' wants and needs

Christian Hoppe *,[1], Mieke Feldmann [1], Barbara Blachut, Rainer Surges, Christian E. Elger, Christoph Helmstaedter

Department of Epileptology, University of Bonn Medical Centre, Sigmund-Freud-Strasse 25, FRG-53127 Bonn, Germany

ARTICLE INFO

Article history:
Received 24 July 2015
Accepted 5 August 2015
Available online 11 September 2015

Keywords:
Seizure registration
Seizure detection
Patient survey
Seizure diary
Seizure frequency

ABSTRACT

Objectives: Patient-reported seizure frequency is essential for therapy management and clinical research but lacks validity mainly due to seizure-induced seizure unawareness. Automated seizure detection by mobile monitoring devices promises to settle this serious methodological issue. Here, we explored attitudes and preferences towards future devices for seizure detection in adult patients with therapy-refractory epilepsies.
Methods: A total of 102 inpatients enrolled and underwent a newly constructed semistructured 30-minute interview on automated seizure registration.
Results: Most patients would generally apply and permanently use seizure registration devices. Removable devices were preferred (e.g., wristband sensors), but also patch electrodes at invisible body sites appeared acceptable. Only a minority of patients would accept implantations for seizure registration (especially of depth electrodes). Also, permanent optical or acoustical surveillance were accepted by a few patients only. Most patients were ready to care for the device (e.g., charging battery), to have doctor's appointments for device control, and even to pay for the device. Seizure prediction was evaluated as an essential additional function. Only half of the patients wanted emergency calls in case of a seizure.
Significance: Patients would accept automated seizure registration if the device had as little as possible negative effect on daily living. High acceptance might, therefore, be expected for hardware equipment as it is nowadays used by many healthy subjects for physiological self-monitoring and life-logging. The proper medical engineering task of the future, therefore, is to optimize sensors in those highly feasible devices and to establish reliable biomarkers and outcome measures for a diversity of diseases (including epilepsy) from data obtained by this generic hardware.

1. Introduction

The importance of seizure frequency as a key outcome measure for both individual therapy management and scientific treatment evaluation is undoubted [1]. As seizures usually are infrequent and, therefore, cannot be observed objectively, seizure frequency is commonly self-reported by the patients in paper diaries. However, there is a solid body of evidence that patient seizure counts lack clinical validity due to underreporting [2–6]. Several video-EEG studies found that no more than 50% of all seizures are reported by the patients. Interestingly, many patients do well know that they are unconscious for a part of their seizures [7]. Unfortunately, *seizure-induced seizure unawareness*, i.e., not noticing that a seizure took place in consequence of the seizure's impact on consciousness, is likely to play the major role whereas missing to document *noticed* seizures seems to be less important [7,8]. Thus, improving patient education on keeping seizure diaries or providing electronic tools for more feasible documentation (e.g., the *My Epilepsy Diary* app, [9]) will probably not solve the serious issue of the lack of validity of a key outcome measure in epileptology.

Automated registration of seizures by mobile monitoring devices appears to be more promising, and several groups worldwide (including our own) are exploring novel technologies (for a recent comprehensive review, see [10]). In combination with additional features, e.g., automated emergency calls in case of a seizure, such devices might be of great benefit for patients beyond improved documentation. Of course, automated registration of important disease biomarkers as well as the detection of possibly life-threatening events is desirable not only for epilepsy, but also for many other chronic somatic and psychiatric conditions [11]. In all likelihood, physiological measures from which disease-specific biomarkers can be calculated will overlap to some extent suggesting generic technologies for different diseases.

* Corresponding author. Fax: +49 228 287 90 16172.
E-mail address: christian.hoppe@ukb.uni-bonn.de (C. Hoppe).
[1] First authorship is shared.

http://dx.doi.org/10.1016/j.yebeh.2015.08.006
1525-5050/

With regard to the detection of epileptic seizures, a wide range of possible physiological approaches is currently under evaluation [10]: mobile long-term EEG with surface or implanted depth electrodes; registration of limb and body movements by wristband accelerometers or sensors fixed under the mattress (for nocturnal monitoring); recordings of more specific muscular activity by transcutaneous electromyography with electrodes patched to specific muscle groups; wristband biosensors registering autonomous parameters such as heart rate, heart rate variability, body temperature, or electrodermal activity; and, finally, microphones for acoustic and miniature cameras for optical self-surveillance. Of note, wristband biosensors or all-in-one wristband smart watches for physiological self-monitoring and cameras for life-logging are nowadays used by many healthy subjects on a regular basis.

Given that less than half of the patients with epilepsy are committed to documenting their seizures [7], we wanted to explore their preferences and attitudes towards devices for automated seizure registration: do they want their seizures to be objectively registered at all? Which modes and sites of body measurements for seizure detection do they prefer? Will patients apply automated seizure registration permanently or only during limited periods of time (e.g., participation in a clinical study)? In terms of additional functional features, what are the essential must-haves or desirable nice-to-haves from the patients' view? By this study, we wanted to contribute to timely implementation of patients' needs and wants into the engineering process. At the same time, our data may allow a first estimate of the future marketing potential of seizure registration devices.

2. Material and methods

This prospective, open and non-interventional study at a level 4 epilepsy center was based on a newly developed semistructured patient interview and approved by the local Ethics Committee (proposal no. 361/14).

2.1. Subjects

Adult inpatients with a diagnosis of medically refractory epilepsy (i.e., failure of >2 adequately performed antiepileptic drug regimens) referred to our center for optimization of medical treatment, presurgical workup, or less frequently, etiology/syndrome diagnosis (including the exclusion of psychogenic nonepileptic seizures) were included in this study. Patients had to be able to participate in the interview without the need of further assistance.

2.2. Interview: guideline and measures

An English translation of the German interview guideline is given in Appendix A. To exclude (as far as possible) several obvious concerns, patients were instructed to imagine a "perfect device" which is capable of registering *all* seizures with *no side effects*; also, *safety of patient data* was supposed to be guaranteed. Besides basic clinical and sociodemographic patient data, the interview guideline covered the general readiness to use such a "perfect device", essential needs and desirable wants with regard to further device features, the acceptable duration of using such a device (permanently versus limited time periods), and the acceptable mode and sites of sensors (e.g., microphone/acoustic surveillance, camera/optical surveillance, patch electrodes at different body sites, or sensors implanted into the body or the brain). In addition, the interview guideline included several questions on seizures, seizure awareness, and current seizure documentation practice which aimed at a replication of a recent study from our group [7]. Most questions were yes/no items, but for a couple of items, a scale was used (e.g., from 1 = *completely unimportant* to 6 = *very important*). The interview guideline was meant to be semistructured; therefore, space for additional relevant remarks of the interviewees was provided. All interviews were performed by one of the two first authors of this study (M.F.), usually at the beginning of the inpatient's stay at our unit. On average, study enrollment and taking the interview took about 35 min.

2.3. Statistics

This study aimed at an overall impression of the patients' wishes and needs as regards objective seizure registration by mobile monitoring devices. Therefore, we focused on descriptive statistics and made only sparse use of statistical hypothesis testing. As the total sample size was close to 100, we refrained from reporting percentages for better readability. If required, nonparametric statistical tests of group effects or correlations were applied; 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

A total of 102 patients were enrolled in this study. Patient characteristics are shown in Table 1. Sample composition appeared characteristic for a population of inpatients as typically treated in level 4 epilepsy centers. Those six patients without current antiepileptic medication were reevaluated for a diagnosis of epilepsy versus psychogenic nonepileptic seizures (PNES). As a diagnosis of PNES would not necessarily rule out the use of seizure detection devices, we decided not to exclude these patients from the study. The major findings are shown in Table 2.

3.1. General acceptance

Nearly all patients (96 out of 102) would agree to use the "perfect" seizure registration device, and more than half of these patients (57/96) even stated they were willing to contribute to the financing of their "perfect device". The patients who were not interested in wearing such a device tended to have longer epilepsy duration (4/6 with duration of epilepsy of >14 years), lower academic achievement (6/6), and older age (3/6 older than 60 years). In the following, frequencies refer to the subsample of those 96 patients who were ready to use a seizure registration device.

Most patients (62/96) wanted to use the "perfect device" permanently, but one-quarter of the patients (28/96) preferred using the

Table 1
Patient characteristics.

Variable	Frequency
Sample size	102
Gender male/female	57/45
Age groups: < 20/20–29/30–39/40–49/50–59/60+ years	7/26/22/16/13/18
Academic achievement: none/middle school/A level/university education	8/59/26/9
Occupational status: apprenticeship or study/occupied/disability pension/pension annuity/unemployed	16/47/15/10/14
Duration of epilepsy: 0–5/6–10/11–15/15+ years	31/19/10/42
Number of antiepileptic drugs*: 0/1/2/3/4/5/6	6/28/36/15/13/2/1/1
Previous surgical epilepsy treatments: resective surgery/vagus nerve stimulation/deep brain stimulation	6/2/1

* Number of drugs taken at the time of the interview.