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FULL-LENGTH ORIGINAL RESEARCH

Real-world user experience with seizure detection wearable devices in the home environment

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Abstract

Objective: To evaluate direct user experience with wearable seizure detection devices in the home environment.

Methods: A structured online questionnaire was completed by 242 users (175 caregivers and 67 persons with epilepsy), most of the patients (87.19%) having tonic–clonic seizures.

Results: The vast majority of the users were overall satisfied with the wearable device, considered that using the device was easy, and agreed that the use of the device improved their quality of life (median = 6 on 7-point Likert scale). A high retention rate (84.58%) and a long median usage time (14 months) were reported. In the home environment, most users (75.85%) experienced seizure detection sensitivity similar (≥95%) to what was previously reported in validation studies in epilepsy monitoring units. The experienced false alarm rate was relatively low (0–0.43 per day). Due to the alarms, almost one third of persons with epilepsy (PWEs; 30.00%) experienced decrease in the number of seizure-related injuries, and almost two thirds of PWEs (65.41%) experienced improvement in the accuracy of seizure diaries. Nonvalidated devices had significantly lower retention rate, overall satisfaction, perceived sensitivity, and improvement in quality of life, as compared with validated devices.

Significance: Our results demonstrate the feasibility and usefulness of automated seizure detection in the home environment.

KEYWORDS

automated seizure detection, epilepsy, user experience, wearable devices

1 | INTRODUCTION

The International League Against Epilepsy and the International Federation of Clinical Neurophysiology have recently issued a joint clinical practice guideline (CPG) on using wearable devices for automated seizure detection.[1,2] The working group found high-level evidence for the accurate detection of generalized tonic–clonic seizures (including focal-to-bilateral tonic–clonic seizures) using wearable devices, and issued a conditional recommendation for using automated seizure detection for safety indications.[1,2] Most studies investigated these devices for only short periods (days) in the epilepsy monitoring units (in-hospital video-electroencephalographic

monitoring), and only few studies addressed the usability of these devices, and the outcome for the persons with epilepsy (PWEs) in their home environment.[1,2]

The CPG highlighted the need for in-field studies, to learn about the real-world experience of PWEs and their caregivers, concerning the use of the wearable devices in their home environment.[1,2] However, most survey studies of PWEs and their caregivers addressed the potential use of the devices (in future) in persons who had no direct experience with such devices.[3–7] The few previously published studies on direct experience with the wearable devices focused on usability in the epilepsy monitoring unit[8,9] or included a single type of device.[10]

We conducted a large, international survey study on the usability, clinical outcome, and patient and caregiver experience with using wearable devices for automated seizure detection in the home environment. We included aspects related to feasibility, perceived performance, retention rate, and clinical outcomes, such as decrease of seizure-related injuries, improved accuracy of seizure documentation, perceived improvement in quality of life, and overall satisfaction with the wearable devices. We compared the validated devices with the nonvalidated ones.

Key Points

- We evaluated direct experience with wearable seizure detection devices in the home environment of 242 patients and caregivers
- Most users (87%) had bilateral/generalized tonic–clonic seizures
- Users were overall satisfied with the wearable device, considered that it was easy to use, and experienced improved quality of life
- A high retention rate (85%) and a long median usage time (14 months) were reported
- Due to alarms, 30% experienced decrease in the number of seizure-related injuries and 65% experienced improvement in accuracy of seizure diaries

2 | MATERIALS AND METHODS

Persons with epilepsy and family members/caregivers who had direct experience with using wearable devices for automated seizure detection were invited to fill in an anonymous, online questionnaire. The survey aimed to strike a balance between the number of details acquired and the burden of filling in the online questionnaire. The survey consisted of 32 questions (Appendix S1), and it was available in four languages: English, German, Dutch, and Danish.

The structure of the questionnaire was adaptive; each choice determined the set of next questions asked. Estimated time of completion was 6 min. Both PWEs and caregivers could complete the survey. The inclusion criterion was specified at the beginning of the survey: direct experience with using an automated seizure detection device in the home environment. There were no exclusion criteria.

The study was approved by the regional human biomedical research ethics committee of the University of Szeged (approval number 141/2021-SZTE). Links to the online survey were distributed in the United Stated, the United Kingdom, Germany, Denmark, and the Netherlands through social media, patients' organizations, and user lists (Empatica and NightWatch). The study was conducted between September 10, 2021 and November 15, 2021.

We used chi-squared test to compare proportions, Mann–Whitney *U*-test to compare numerical scores (7-point Likert scale), and Kaplan–Meier survival analysis, with Mantel–Cox test for the retention rate.[11,12] First, we compared the validated devices with the nonvalidated ones. Then we compared the validated devices between each other, using Bonferroni correction for multiple measurements. Statistical analyses were conducted in R 4.1.2. We considered validated the devices that were tested in Phase 3 clinical studies (prospective, multicenter trials, using predefined algorithms and cutoff values for real-time detection with dedicated wearable devices).[1,2,13] All other devices were considered nonvalidated.

3 | RESULTS

Two hundred forty-two respondents returned the survey; 171 (70.66%) were family members caring for a PWE, 67 respondents (27.68%) had epilepsy themselves, and four respondents (1.65%) were health care professionals caring for a PWE, using the device. The median age of the 242 PWEs (48% female) when starting to use the device was 17 years (range = 1–82 years). The median age at seizure onset was 9 years (range = 0–70 years). Two hundred eleven PWEs (87.19%) had generalized tonic–clonic seizures (including focal-to-bilateral tonic–clonic seizures), and 83 of them had at least one seizure per month. Eighty-six PWEs who had generalized tonic–clonic seizures (35.55%) were living alone or not sharing a bedroom most of the time, hence having a high risk of sudden unexpected death in epilepsy (SUDEP).[1,2]

Thirty-three PWEs (13.63%) used nonvalidated devices. More than one third of them (12 PWEs, 36.36%)

TABLE 1 Comparison of validated and nonvalidated devices

	Empatica	Epi-Care	NightWatch	All validated	Nonvalidated
Overall satisfaction with the device, median (IQR) on 7-point Likert scale	6 (5–6)	5 (3.25–6)	6 (5–6.25)	5.5 (4–6)	5 (3–6)
Ease of using the device, median (IQR) on 7-point Likert scale	7 (5.5–7)	5 (4–6)	6 (6–7)	6 (5–7)	5 (5–7)
Median (IQR) perceived sensitivity	100% (95%–100%)	100% (95%–100%)	100% (100%–100%)	100% (95%–100%)	96.5% (0%–100%)
Percentage of PWEs with ≥95% of seizures detected	77.78%	75.55%	81.61%	78.92%	56.67%
Median (IQR) number of FA/day	.29 (0–.43)	0 (0–.29)	—[a]	0 (0–.43)	0 (0–0)
Median (IQR) number of FA/night	0 (0–0)	0 (0–.03)	.10 (.03–.43)	0 (0–.13)	0 (0–.13)
Improved quality of life, median (IQR) on 7-point Likert scale	6 (5–7)	5 (3.25–6)	6 (5–7)	6 (5–7)	4 (1–7)
Percentage of patients who experienced decrease in injuries due to the alarms	35.62%	31.11%	25.29%	30.24%	30.30%
Percentage of patients who experienced improvement in seizure documentation due to the alarms	69.86%	53.33%	72.41%	67.32%	69.70%

Abbreviations: FA, false alarms; IQR, interquartile range; PWE, person with epilepsy.

[a]NightWatch is used only at night, thus daytime false alarms are not applicable. All other devices were used both day and night.

reported the use of commercially available smart watches; most of them (nine PWEs) used Apple Watch with either SeizAlarm or PulseGuard applications (Appendix S2). Two hundred nine PWEs used devices that were validated in Phase 3 clinical studies[13]; 88 PWEs (36.36%) used NightWatch, a multimodal device based on accelerometry and heart rate, for detection of nocturnal seizures[14]; 73 PWEs (30.16%) used Empatica, a wristband with a multimodal seizure detection (accelerometry and electrodermal activity)[15]; and 46 PWEs (19.01%) used Epi-Care, a wristband with accelerometry-based seizure detection.[16] Two patients (.83%) used Seizurelink, a device based on surface electromyography.[17]

The vast majority of the respondents were overall satisfied (median = 6 on 7-point Likert scale) with the device used (Table 1). However, the score was significantly higher with validated devices compared to the nonvalidated ones ($p = .011$). Reported satisfaction did not differ significantly between validated devices. Two hundred four PWEs (84.30%) were still using the device, with a median usage time of 14 months (range = 1–90 months). Thirty-eight PWEs (15.70%) stopped using the device, after a median usage time of 6 months (range = 0–24 months). Figure 1 shows the Kaplan–Meier analysis of device retention for the validated versus nonvalidated devices, after excluding eight PWEs who stopped using the device for a reason unrelated to the device itself; they became seizure-free ($n = 4$) or were using the device only during a study, and had to hand the device back after it was finished ($n = 4$). The retention rate was significantly lower for the nonvalidated devices ($p = .038$). There was no statistically significant difference between the validated devices. The most frequent reasons for stopping using the devices were: too many false alarms ($n = 18$ PWEs, 52.94%) and missed seizures ($n = 10$ PWEs, 29.41%). Other reasons were related to the difficulty of using the device ($n = 3$ PWEs, 8.82%) and to the design (look) of the device considered to be stigmatizing ($n = 2$ PWEs, 5.88%).

Most users considered that it was easy to use the devices (median = 6 on 7-point Likert scale). However, the score was lower for the nonvalidated devices compared to the validated ones ($p = .029$), and lower for Epi-Care, compared with the other validated devices ($p = .003$; Table 1). Fifty-four PWEs (22.50%) reported some type of mild adverse effect (Appendix S3). There was no statistically significant difference between the devices concerning the adverse effects. The most common adverse effect was skin irritation ($n = 34$).

The median perceived sensitivity was significantly higher for validated devices ($p = .003$), and they more often reached (75.55%–81.61% of PWEs) the sensitivity target of ≥95%, as compared with the nonvalidated devices (56.67%, $p < .001$; Table 1). There was no difference

in sensitivity between the validated devices. Most users reported a low false alarm frequency both at daytime and at night (Table 1). There was no significant difference between the devices in daytime false alarm frequency. Nocturnal false alarm frequency was significantly lower for Empatica and Epi-Care users than for NightWatch users ($p < .001$ and $p = .006$, respectively).

Most respondents agreed that the use of the wearable devices led to increased quality of life (Table 1). However, this was significantly lower for the nonvalidated devices, compared with the validated ones ($p = .009$). There was no statistically significant difference between the validated devices. Almost one third of PWEs (30.00%) experienced decrease in the number of seizure-related injuries due to the alarms, and almost two thirds of PWEs (65.41%) experienced improvement in the accuracy of seizure diaries due to the alarms (Table 1). There was no statistically significant difference between the devices concerning the decrease in injuries and the improvement in seizure quantification.

4 | DISCUSSION

Most previously published studies on wearable seizure detection devices were based on relatively short periods of in-hospital usage (up to 1 week in the epilepsy monitoring units), where devices were managed by health care personnel.[1,2] However, these results may not extrapolate to the intended use, for ultralong periods (several months) in the home environment, where the PWEs or their caregivers need to handle the wearable device. The recently published CPG highlighted the scarcity of data about the home use of these devices.

Here, we evaluated the direct experience of 242 users, with wearable seizure detection devices in their home environment. The vast majority of the users were satisfied overall with the wearable device, considered it was easy to use the device, and agreed that the use of the device improved their quality of life. The overall positive user evaluation was further supported by the high retention rate (84.58%) and the long median usage time (14 months).

Most users (75.85%) experienced a seizure detection sensitivity in the home environment similar (≥95%) to what was previously reported in Phase 3 clinical validation studies in epilepsy monitoring units, which is reassuring concerning the clinical relevance of the trials. The experienced false alarm rate was relatively low (0–.43 per day). Although an absolute reference (gold standard) is not available for seizures occurring in the home environment, these estimates were probably realistic, as they were experienced by the caregivers of the PWEs (72.31%), and most patients (87.19%) had generalized tonic–clonic seizures.

An important finding of this study is the perceived usefulness for the PWEs. Almost one third of the users reported that alarms helped prevent injuries, and almost two thirds reported an improvement in the accuracy of seizure diaries, due to the automated detections and alarms from the wearable devices. Although it was beyond the limitations of this study to assess whether the use of the wearable devices could have prevented SUDEP, it is relevant in

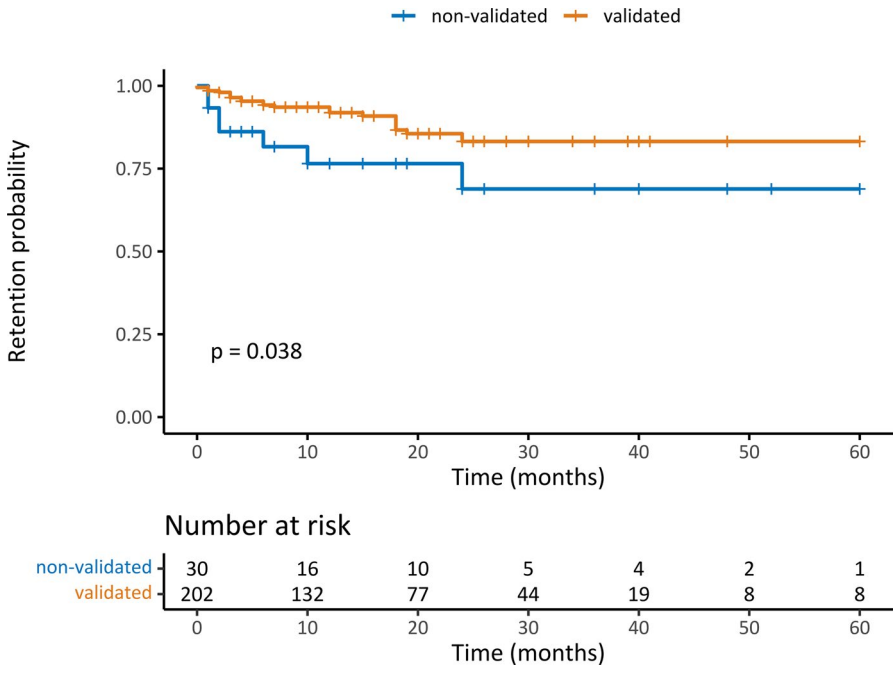

FIGURE 1 Retention probability for seizure detection devices

this context that 86 PWEs (35.55%) using the devices had generalized tonic–clonic seizures and were living alone or not sharing a bedroom most of the time, hence had a high risk of SUDEP.

Although the survey studies on possible (hypothetical) use of seizure detection wearable devices emphasized the importance of the design (look) of the device, only few PWEs (5.88%) stopped using the device for this reason. The most frequent reasons for stopping use of the devices were related to the poor perceived performance of the device: too many false alarms or missed seizures (52.94% and 29.41%, respectively, of PWEs who stopped using the device). Another important finding of this study on direct user experience was that the perceived in-field performance of nonvalidated devices was significantly lower for numerous aspects: retention rate, overall satisfaction, detection sensitivity, and improvement in quality of life.

The major limitation of this study is that there is no available registry with the users of seizure detection devices; hence, despite the large number of users evaluated in this study, it is not possible to determine whether the respondents are representative of all users of such devices. A potential responder bias toward users experiencing good performance may imply an overly optimistic overall assessment of the devices, with detection sensitivity and false alarm rate estimates similar to what have been previously reported in studies performed in epilepsy monitoring units. Besides the generic channels (social media, patients' organizations/societies) the survey was distributed via user lists of Empatica and NightWatch. Although the companies were not involved in collecting and evaluating the responses, the user lists may have induced an inclusion bias in favor of these devices. Bearing these limitations in mind, our results support that validated seizure detection wearable devices are feasible and useful in the home environment, and can be recommended for clinical application.[1,2]

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CONFLICT OF INTEREST

S.B. has served as scientific consultant for Epihunter. None of the other authors has any conflict of interest to disclose. We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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