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SUPPLEMENT ARTICLE

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User-based evaluation of applicability and usability of a wearable accelerometer device for detecting bilateral tonic–clonic seizures: A field study

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Summary

Clinical validation studies of seizure detection devices conducted in epilepsy monitoring units (EMUs) can be biased by the artificial environment. We report a field (phase 4) study of a wearable accelerometer device (Epi-Care) that has previously been validated in EMUs for detecting bilateral tonic–clonic seizures (BTCS). Seventy-one patients using the device (or their caregivers) completed the modified Post-Study System Usability Questionnaire. Median time patients had been using the device was 15 months (range = 24 days-6 years). In 10% of cases, patients stopped using the device due to reasons related to the device. The median sensitivity (90%) and false alarm rate (0.1/d) were similar to what had been determined in EMUs. Patients and caregivers were overall satisfied with the device (median = 5.5 on the 7-point Likert scale), considered the technical aspects satisfactory, and considered the device comfortable and efficient. Adverse effects occurred in 11%, but were only mild: skin irritation at the wrist and interference with home electronic appliances. In 55% the device influenced the number of seizures logged into the seizure diary, and in 40% it contributed to fewer seizure-related injuries. This field study demonstrates the applicability and usability of the wearable accelerometer device for detecting BTCS.

KEYWORDS

field study, phase 4, seizure detection, wearable accelerometer device

1 | INTRODUCTION

Wearable health technology is advancing quickly, and the market has grown into a billion-dollar industry.[1] Hundreds of devices are available that measure vital signs and parameters for health and disease, with a promise to improve the quality of life of consumers.

Reliable seizure detection devices might help patients with epilepsy in various ways, including by reducing premature mortality. Seizure-related accidents contribute to 30% of seizure-linked deaths, and sudden unexpected death in epilepsy (SUDEP) accounts for up to 38%.[2,3] It might provide better, objective data on seizure frequency, because patients' seizure logs underestimate seizure frequency, due to seizure-related unawareness and memory impairment.[4,5] The unpredictability of seizures influences the quality of life of patients with epilepsy as well as their caregivers[6,7]; hence, detecting seizures could potentially improve their quality of life. Knowing when a seizure occurs might aid caregivers in preventing injuries and SUDEP.

There is a well-documented need for wearable seizure detection devices[8] and a marked increase in the number of papers reporting such attempts.[9] However, more validation studies are needed to provide proof of utility and accuracy of these tools.[10] Only very few multicenter, prospective, blinded phase 3 studies[10] have provided compelling

evidence of effective real-time seizure detection.[9] These studies are typically conducted in epilepsy monitoring units (EMUs), which differ from the natural home environment, in particular regarding patients' mobility.[11] Thus, it has been proposed that phase 3 validation studies are followed by field studies (phase 4) in the patients′ home environment, addressing issues of applicability and usability from patients' and caregivers' perspective.[10]

Here, we present a field study of a wrist-worn accelerometer-based seizure detection device (Epi-Care; Danish Care Technology, Sorø, Denmark). The device has previously been validated in a phase 3, multicenter, prospective, blinded study using real-time detection in EMUs, showing that the device has had a sensitivity of 90% (range = 85%-100%) and a false alarm rate (FAR) of 0.2/d for detecting bilateral tonic–clonic seizures (BTCS).[12] Because the study was blinded, the seizure-alerting functionality was not tested in the previous study.[12] Our aim was to assess the performance, applicability, and usability of the device in the home environment of patients, using a modified form of the standardized questionnaire developed by IBM to evaluate user satisfaction and applicability of technical/computer-based devices: the Post-Study System Usability Questionnaire (PSSUQ).[13] To the best of our knowledge, this is the first study systematically addressing these issues for seizure detection devices.

Key Points

- Seventy-one patients used a wearable accelerometer-based seizure detection device in their home environment
- Median time patients had been using the device was 15 months (range = 24 days-6 years)
- In 10% of cases, patients stopped using the device due to reasons related to the device
- Patients and caregivers were overall satisfied with the performance of the device
- In 55% it influenced the number of seizures logged into the seizure diary, and in 40% it contributed to fewer seizure-related injuries

2 | MATERIALS AND METHODS

From the list of registered Epi-Care device users, provided by Danish Care Technology, 112 persons agreed to be contacted and to receive information about the study. The regional ethics committee reviewed the study protocol (Zealand Region, no. 52528). The questionnaire and the consent form were sent by mail to the users. We informed the participants that the questionnaire would be answered during a telephone interview and that it was previously sent by mail for preparation and better overview. After we received the consent forms, we made a second call to the participants who then answered the questionnaires during a telephone interview.

All participants used the wrist-worn, accelerometer-based seizure detection device, Epi-Care.[12] The device has CE certification and is commercially available. Two models had been in use: Epi-Care Free and Epi-Care Mobile. When a seizure was detected, the device sent an alarm to a portable control unit accessible to parents/caregivers (Epi-Care Free) or to a connected mobile phone, which then sent the message further to a particular family member/caregiver, specified in the individual setting of the device (Epi-Care Mobile).

The questionnaire consisted of 10 background questions about the patients and their seizures and a 15-item questionnaire on the applicability and usability of the device, modified after the PSSUQ.[13] Appendix S1 shows all items of the questionnaire.

The introductory questions about the patients and their seizures recorded demographic data, their living conditions (at home/institution), device model (Epi-Care Free or Mobile), epilepsy and seizure classification, nighttime and/or daytime usage, duration of using the device, and reasons for discontinuing the device (when applicable).

The PSSUQ questionnaire items were presented as statements (13 items) or open-ended questions (2 items) addressing usability and user satisfaction with the wearable device. The items were grouped as follows: device usefulness (items 1-8), quality of the provided information (items 9-12), and device quality (items 13-15; Appendix S1). The participants were asked to grade how much they agreed or disagreed with the statements on a graphic Likert scale, grading from 1 ("I strongly disagree") to 7 ("I strongly agree"). The 2 open-ended questions addressed the percentage of BTCS registered by the device, as well as the FAR.

3 | RESULTS

Seventy-one (63%) patients or their caregivers completed the structured interview and questionnaire. The caregivers were staff in residential care institutions (for 36 patients) and family members (for 25 patients). Of the 41 patients who initially agreed to be contacted but did not complete the questionnaire, 13 (32%) withdrew their consent after observing they were not able to answer the questions; 24 (58%) were not reachable despite several attempts to contact them; and 4 were no longer living in the same institution by the time of the second call.

The median age of the patients who completed the study was 27 years (range = 7-72 years); 39 were males and 32 were females. 46% (n = 33) of the patients were living at home, 44% (n = 31) in an institution, and 10% (n = 7) partly in both places. The questionnaire was answered by personnel in residential institutions in 45% of cases (n = 32), by a family member in 31%, and by the patients themselves in 17%. In 7%, it was a combination of patient, personnel, and family member (n = 3) or personnel and family member (n = 2). This reflects the profile of the patients using the device: patients with severe epilepsy and BTCS.

In 41% (n = 29), the patients had BTCS only; in the majority (59%) of cases, the patients had both BTCS and other seizure types: absence, myoclonic, tonic, clonic, and focal seizures (with and without impaired consciousness). There was no documentation of BTCS in 3 patients, 2 of whom suffered clonic seizures (with a 100% detection rate by the device in both cases), whereas the third had a history of tonic and focal seizures but was seizure-free during the period when the device was in use. The most common type of epilepsy, according to the new International League Against Epilepsy classification, was focal epilepsy of unknown etiology (34%), followed by unknown epilepsy type of unknown etiology (28%) and focal epilepsy with structural etiology (15%).[14]

The model of device used was Epi-Care Free in 75% (n = 53) and Epi-Care Mobile in 24% (n = 17); 1 patient used both types of devices. The device was used during both daytime and nighttime in 56% (n = 40) of patients, during nighttime only in 27% (n = 19), and during daytime only in 17% (n = 12).

The median time for usage of the device was 15 months (range = 24 days-6 years). In 6 cases, the use of the device was discontinued due to reasons not related to the device: patient transferred to another institution (n = 4), patient achieved seizure freedom (n = 1), and device was used only during hospital stay (24 days; n = 1). In 7 cases (10%), the use of the device was discontinued due to reasons related to the device: unacceptably high FAR (n = 4), patient not being able to use it (n = 2), and damaged device during a seizure not being replaced afterward (n = 1; Figure 1).

Table 1 summarizes the results of the modified PSSUQ, with the details for all responses provided in Appendix S2. Regarding satisfaction with using the system: 18% (n = 13) of the responders strongly agreed, 32% (n = 13) agreed, and 21% (n = 15) predominantly agreed (Likert scale median = 5.5). The reasons given for being dissatisfied were: high FAR, irritation or discomfort from wearing the wristwatch, unstable connection between the sensor and the control unit, low effectiveness for detecting seizures, short battery time, and the device not being water-resistant.

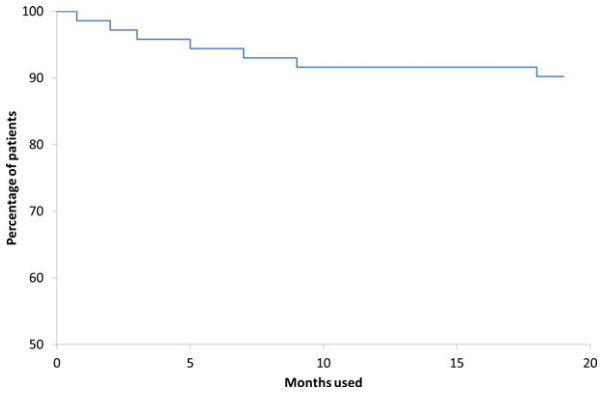

FIGURE 1 Kaplan-Meier curve showing the decrease in the number of users due to reasons related to the device

TABLE 1 Results of the modified Post-Study System Usability Questionnaire

Evaluated items	Median (interquartile range) on the 7-point Likert scale
Overall, I am satisfied with using this device.	5.5 (4-6)
It was easy to learn to use this device.	7 (6-7)
It is simple to use this device.	7 (6-7)
The device can effectively detect BTCS.	6 (5-7)
The rate of false alarms is acceptable.	6 (4-7)
The use of the device has resulted in fewer injuries to the patient.	4 (1-6)
The device gives clear alarm signals.	7 (6-7)
The alarm time points from the device are clearly readable.	7 (6-7)
The device has an influence on how many seizures are logged into the seizure diary.	5 (1-6)
The device gives error messages when technical problems occur.	7 (6-7)
The sensor (wristwatch) is comfortable to wear.	5 (4-6)
The connection between sensor and display is functioning well.	6 (5-7)
There have not been any side effects related to using the system.	7 (6-7)

BTCS, bilateral tonic–clonic seizures.

In 18 of the 45 patients (40%) who previously had had seizure-related injuries and who experienced seizures during the period of the study, the patients and the caregivers agreed that the use of the device had resulted in fewer injuries to the patient.

In 48 patients, BTCS occurred while the device was in use. The median reported sensitivity for detecting BTCS was

90% (mean = 85%, range = 0%-100%). In 86% of patients with BTCS, the sensitivity of the device exceeded 90%, whereas in 2 patients, none of the seizures were detected.

The median reported FAR was 0.1/d (mean = 1.4/d, range = 0-12/d). Fifty-one patients (72%) had <1 false alarm/d, and 69% of the users considered the FAR to be acceptable.

Eighty-nine percent (63/71) agreed that they did not experience any adverse effects related to using the device (median = 7, interquartile range = 6-7). Four patients developed a rash or skin irritation from the wristwatch, and 2 users found that the device disturbed the function of other home appliances.

4 | DISCUSSION

Due to the need for an unequivocal reference standard, phase 3 clinical validation studies of seizure detection wearable devices are conducted in EMUs.[10] However, artificial environment and restricted mobility of patients could bias the results of such studies. In this field study (phase 4), the reported sensitivity and FAR were similar to a previously published phase 3 study,[12] with the caveat that seizures account was provided by patients and caregivers rather than by the gold standard method of video-electroencephalography.

An advantage of phase 4 studies is the possibility of long-term follow-up, yielding important information on adverse effects, applicability, and usability. In this study, the vast majority of users were overall satisfied with the device; they considered that the device effectively detected BTCS, that it was comfortable to wear, and that the FAR was acceptable. Most of the false alarms occurred in a small subgroup of patients (n = 11) with >5 seizures per day. Free text responses suggest that this mainly depended on the activity pattern of the patients (eg, hand shaking, dancing, playing, patient triggering alarm on purpose for seeking attention, tooth brushing, caregivers handling the device, clapping). Users were also satisfied with the technical aspects and functioning of the device. Adverse effects occurred in 11%, but they were only mild: skin irritation at the wrist and interference with other home electronic appliances.

The device influenced the number of seizures logged into the seizure diary in 55% of the patients. This relatively low number is probably explained by most patients living in residential institutions or with their parents, who would eventually have noticed that BTCS occurred, even without the device. However, users considered that the device had resulted in fewer injuries in 40% of the patients, because the timely alert helped in repositioning the patients or removing objects adjacent to the patients, which could have caused injuries. This is potentially an important effect, considering that seizure-related accidents contribute to 30% of deaths in epilepsy patients.[2] Users reported beneficial effect of the device even when seizures did not occur during its use; patients with low seizure frequency stated that although they could not assess the efficiency of the device, it gave them a feeling of security and decreased the psychological burden for both patients and caregivers.

The large proportion of patients who kept using the device further demonstrated its usability. Patients stopped using the device for reasons related to it in only 10% of cases.

A possible source of bias is that questions were asked in a favorable (positive) way (Table 1). However, these questions were those of the standardized PSSUQ survey, which is broadly used for assessment of user satisfaction and applicability of technical/computer-based devices. Another limitation of this study is that caregivers and patients were not surveyed on the timing and benefit of seizure alerting and interventions, to prevent SUDEP.

In conclusion, this field study confirmed the performance of the device previously determined in EMUs and showed that it was usable in the home environment.

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DISCLOSURE

None of the 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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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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