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SEIZURE DETECTION DEVICES IN THE HOME ENVIRONMENT: A LONG SEARCH FOR LIFE-SAVING SOLUTIONS

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ABSTRACT

A reliable seizure detection device (SDD) in an ambulatory/home environment has been a much-needed solution. Benefits of developing such a device would include: improving Quality of Life (QoL) for patients and their caregivers; providing more information to physicians caring for these patients (which, in turn, could help adjust medication); and possibly reducing the risk of Sudden Unexpected Death from Epilepsy (SUDEP). However, searching for it has proven difficult. This short narrative review aims to: (1) introduce the reader to this particular field of study: its importance,scope, and problems; (2) show methods and technologies currently in use, recent developments in seizure detection devices - especially wearables, and new, less invasive solutions based on EEG; (3) discuss possible new approaches and emerging solutions.

KEYWORDS

Seizure Detection Devices (SDDs), Epilepsy, Home Environment, Wearable, Mobile Health

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1.Introduction

1.1 Importance of the studies

Wearable devices of all sorts became common not only in general use but also in the medical field. Ranging from smartwatches of well-known brands capable of detecting abnormal cardiac rhythms to Continuous Glucose Monitoring Sensors for patients with T1DM, they are becoming more common year by year. [1] The need for using wearables to detect seizures in patients with epilepsy has been expressed by patients and their physicians for years [2].

Caregivers' quality of life

For caregivers of patients with epilepsy, uncertainty is part of their day-to-day experience. The need to act to keep someone safe during a seizure influences almost every aspect of their life, affecting their QoL [3,4]. Being constantly on standby, not only during the day but also at night (sleeping with a child with epilepsy to keep them safe is commonly reported), takes a toll on their sleep [5] and possibly also their love life and the development of the child itself [6]

Although caregivers report that the burden of care remains unchanged, most indicate experiencing increased autonomy when using SDDs and perceive the care they provide as more timely and effective [7].

Autonomy and safety

Patients themselves have reasonable expectations of what such devices could and should provide. Recent analysis of patient experiences shows mixed results on the impact of these devices regarding safety, autonomy, quality of life, and anxiety [8]. However, some of these areas show improvement when SDDs are used. Regarding safety, SDDs have been reported to lead to quicker responses and reduced injuries [8]. Another notable finding was improvement in the “caregiving relationship” between adolescents with epilepsy and their parents because of increased autonomy given to patients by SDD, simultaneously with providing seizure safety and decreasing parental hypervigilance [9].

SUDEP

A commonly discussed topic in SDD research is its potential ability to prevent SUDEP. Defined as “Sudden, unexpected, witnessed or unwitnessed, nontraumatic and nondrowning death, occurring in benign circumstances, in an individual with epilepsy, with or without evidence for a seizure and excluding documented status epilepticus (seizure duration ≥30 min or seizures without recovery in between), in which postmortem examination does not reveal a cause of death”. [10] The lifetime risk of SUDEP in people with epilepsy is between 8% and 12%. [11]. As the definition states, the cause of death in those cases remains unknown, but what we know is that tonic-clonic seizures constitute the major risk factor for SUDEP. All SUDEP cases documented with video-EEG occurred after a tonic-clonic seizure [12]. Some suspect that alarm-triggering devices might prompt life-saving procedures and prevent such outcomes [13]; however, it is important to remember that no study has yet demonstrated that the use of mobile health solutions, including seizure detection devices coupled with alarms, has an impact on the risk of SUDEP. [13]

SDDs as a step towards more personalized healthcare

Seizure dairies have been shown to be an inaccurate, subjective method for counting seizures.[14]

Inaccurate documentation of seizure frequency affects therapeutic decisions in daily clinical practice [15]. SDDs could act as a more objective measure and provide physicians with more accurate information on seizure frequency. Based on this information, the physician receives better feedback, allowing him to adjust the medication to the patient's needs. That applies to clinical research as well and could be important in monitoring the effects of new drugs or other interventions.[6]

1.2 Possible disadvantages and problems that researchers face

SDD ideally should have a high sensitivity and a low false alarm rate. On average, patients expected at least 90% sensitivity, with acceptable false alarm rates varying from 1 to 2 per week to 1 to 2 per month.[8] Unfortunately, achieving that is not easy for manufacturers and researchers. That brings another problematic aspect of automatic detection. The risk of “alarm fatigue”. Caregivers and patients may tend to stop paying attention to most alarms, treating them as mostly irrelevant, and, over time, stop responding altogether. A device that leads to such alarm fatigue defeats its purpose. [6]

There is also a challenge with validating studies. Thousands of studies on novel forms of SDDs are published each year, and with the rapid expansion of AI technologies and new algorithms, this number is likely to increase further. Consequently, potential biases and overly optimistic reporting may become even more pronounced [16]. To counter such problems, the Working Group of the International League Against Epilepsy (ILAE) and the International Federation of Clinical Neurophysiology (IFCN) developed clinical practice guidelines [17], [18]. Also, by adapting the key domains of the QUADAS-2 tool (quality assessment of diagnostic accuracy studies) to the specific application of seizure detection devices, prominent researchers in the field have proposed standards for clinical validation studies [19].

2. Currently used methods of detection

The most common way to classify SDDs is to divide them by EEG (Electroencephalography) use.

2.1 EEG-based methods

EEG-based systems' main problem for years has been usability. Full-array scalp EEG combined with video monitoring is the standard for non-invasive seizure monitoring in clinical settings, but long-term scalp EEG is considered too uncomfortable and obviously difficult to hide to be used in a home setting. That is not to say that less obtrusive solutions are not currently being developed. Small behind-the-ear EEG systems, such as Brain SD [20] and Epitel Epilog [21] (Figure 1D), are just a few examples of this technology. More invasive solutions, such as subscalp devices, have also been proposed and show promising results [22]. Clearly, EEG-based monitoring will remain one of the alternatives for patients, but in comparative studies, body-worn devices were found to be more convenient than EEG head sensors [8]. In this short review, we decided to focus on non-EEG solutions.

2.2 Non -EEG Sensors

The most reliably detected form of seizures are motor seizures, and more precisely, generalized tonic-clonic seizures (GTCS). Most available and validated solutions for detecting motor seizures are based (at least in part) on upper-limb 3D-accelerometry (3D-acc). The method utilizes a wearable sensor (e.g., positioned on the wrist or forearm) to capture movement patterns and compare them with characteristic features that can be distinguished from non-epileptic physiological activity. An example of that technology meeting the standards previously addressed in this review is Epi-Care mobile, developed by Danish care technology, Sorø, Denmark. In a phase-4 field study, the devices achieved a median sensitivity of 90% for detecting GTCS, with a median false alarm rate of 0.1 per day. [24] Which makes those results very close to those expected by the patients [8]

Other biosignal modalities used in seizure detection include surface electromyography (EMG), electrocardiography (ECG), photoplethysmography (PPG), and electrodermal activity (EDA).

An EMG sensor placed on the biceps of a patient has been shown to be a reliable seizure detection method on its own, detecting tonic-clonic seizures with 94% sensitivity and a FAR of 0.7/day (0.01/night). [25]

In recent years, however, the more common approach is to use a combination of those signals. A well-known and well-validated SDD based on that sort of approach is NightWatch, developed by LivAssured B.V., Leiden,The Netherlands. The device uses both photoplethysmography (PPG) to measure heart rate and accelerometry data (ACC). In a phase 4, multicenter, prospective, video-controlled, in-home implementation study, NightWatch showed promising results.[26] The median detection sensitivity per participant was 100%. Caregivers' stress decreased significantly with the use of the sensor (mean total CSI-Caregiver Strain Index score = 8.0 vs. 7.1, $p = .032$); unfortunately, caregivers' sleep and QoL did not change significantly during the trial. There is also a problem with FAR: the median individual false alarm rate was 0.04 per hour (range = 0–0.53). As noted by the authors, this may be partly attributed to the pediatric population on which the study was performed. Children, and especially those with developmental disorders, are more likely to exhibit challenging behaviors as well as repetitive, rhythmic movements during sleep.[27] They also have HR profiles that differ from those of adults, characterized by higher resting values and greater variability.[28] This illustrates one of the challenges faced by devices that rely on multiple signals to detect seizures: distinguishing normal physiological responses from pathological processes.

Another device that combines outputs from several sensors into a single algorithm is the Embrace wristband, developed by Empatica Inc., Cambridge, USA. The device uses a three-axis ACM sensor, a three-axis gyroscope sensor, and an EDA sensor. Electrodermal activity (EDA) is an autonomic marker for sympathetic skin activity; it reflects changes in the sympathetic nervous system via sweat gland activity and is associated with arousal and other physiological stimuli. In the context of epilepsy, EDA demonstrates characteristic alterations, supporting its value in seizure monitoring, detection, and prediction. A surge in EDA is observed at the onset of GTCS. Additionally, disruptions in this autonomic signal can be detected even before a seizure occurs, during the pre-ictal phase.[29] Tested in a large EMU (Epilepsy Monitoring Unit) study involving 67 adults and 85 pediatric participants. Embrace sensitivity was 0.92 for the pediatric population and 0.94 for adults. It also demonstrated an acceptable FAR in the adult group, 0.57/day. However, in the children group, FAR was much higher (1.26/day). The result was likely due to higher pediatric activity. This problem, however, disappears when patients are at rest. Using the less sensitive mode, researchers achieved no false alarms. Demonstrated high Sensitivity and precision might prove useful in monitoring patients during sleep [30]. Please view Figures 1A-D for an illustration of different forms of SSDs mentioned in this short review.

Fig. 1. *A) Epi-Care mobile, sensing device based on 3D-acc B) NightWatch device based on both photoplethysmography (PPG) to measure heart rate and accelerometry data (ACC) C) Embrace Wristband, this device uses three-axis ACM sensor, a three-axis gyroscope sensor, and an EDA sensor D) EpitelEpilog - a wearable, wireless behind the ear, electroencephalography (EEG) sensor system*

3. Possible new approaches and emerging solutions

Other types of seizure detection and tailoring

An apparent problem in seizure detection is detecting non-convulsive seizures. Noninvasive solutions to reliably detect focal seizures in ambulatory patients, based on either EEG or non-EEG biosignals, remain to be developed. [31] Wearable EEG devices mentioned earlier could be an answer to that problem in the future; more research is needed. This also emphasizes the challenge of selecting an appropriate device for an individual patient, as device requirements may vary depending on the patient's specific seizure types and their clinical characteristics. Such selection and fine-tuning of the seizure detection device for the individual patient might be performed during video-EEG monitoring in an EMU to minimize risk and provide patients with even more suitable and safer solutions. [16]

Seizure forecasting

An interesting area of research is also seizure forecasting. It has been observed that, in some patients, epileptic activity follows circadian, ultradian, and infradian (multidian) rhythms and shows strong correlation with self-forecasting approaches.[32] An effective forecasting model would provide patients with a probabilistic estimate of seizure or seizure cluster occurrence within a defined time window, based on the intra-individual cyclic patterns of seizure distribution [33]. SDDs could be crucial in developing such models; however, more research is needed.

Conclusions

Research in wearable seizure detection devices (SDDs) has advanced substantially in recent years, with several solutions now commercially available and supported by solid validation among the scientific community. However, there are still many problems to solve, such as providing patients with acceptable rates of false alarms during daytime activities, constant need for improvement in usability of already developed devices, providing real substantial change in caregivers' QoL, and validating new devices with new solutions, especially those focused on non- convulsive seizure types. The importance of this area of research is undeniable, and hopefully, with new developments in artificial intelligence and algorithmic methods, new breakthroughs and life-saving devices are on the way.

Conflicts of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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