REVIEW

OPEN

Ambulatory seizure detection

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Purpose of review
To review recent advances in the field of seizure detection in ambulatory patients with epilepsy.

Recent findings
Recent studies have shown that wrist or arm wearable sensors, using 3D-accelerometry, electrodermal activity or photoplethysmography, in isolation or in combination, can reliably detect focal-to-bilateral and generalized tonic-clonic seizures (GTCS), with a sensitivity over 90%, and false alarm rates varying from 0.1 to 1.2 per day. A headband EEG has also demonstrated a high sensitivity for detecting and help monitoring generalized absence seizures. In contrast, no appropriate solution is yet available to detect focal seizures, though some promising findings were reported using ECG-based heart rate variability biomarkers and subcutaneous EEG.

Summary
Several FDA and/or EU-certified solutions are available to detect GTCS and trigger an alarm with acceptable rates of false alarms. However, data are still missing regarding the impact of such intervention on patients' safety. Noninvasive solutions to reliably detect focal seizures in ambulatory patients, based on either EEG or non-EEG biosignals, remain to be developed. To this end, a number of challenges need to be addressed, including the performance, but also the transparency and interpretability of machine learning algorithms.

Keywords
device, machine learning, mobile health, seizure detection, wearable

INTRODUCTION

Reliable ambulatory seizure detection systems have become a major expectation for persons with epilepsy, their families and their physicians, with the double aim of triggering timely alarms to mitigate the potential harmful consequences of seizures and providing more precise information on seizure frequency to better guide therapy [1]. Indeed, this essential information currently relies on reports from patients or their caregivers, which often prove inaccurate or misleading [2–5]. Accordingly, surveys indicate that over 75% of individuals with epilepsy consider real-time seizure detection as highly important [6]. Yet, recent guidelines from the international league against epilepsy and world federation of clinical neurophysiology have concluded that current wearable devices can only reliably detect generalized tonic-clonic seizures (GTCS) and focal to bilateral tonic-clonic seizures, all of which will be referred as GTCS herein [7▪▪,8▪▪]. Furthermore, there is currently no evidence that using such device decreases the risk of sudden unexpected death in epilepsy (SUDEP) [7▪▪,8▪▪].

NON-EEG BASED SEIZURE DETECTION

Generalized tonic-clonic seizures

A plethora of technologies has been devised to detect seizures without the conventional use of EEG [9–14]. Commercially available devices mostly target the identification of motor seizures [15], and primarily GTCS. Yet, GTCS account for less than 15% of all seizures observed in individuals with uncontrolled epilepsy. This particular seizure type has undergone

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KEY POINTS

- Several medically certified wrist or arm wearables reliably detect generalized tonic-clonic seizures (GTCS) with acceptable rates of false alarms.
- The impact of GTCS detection on patients' safety has not yet been demonstrated.
- Until now, wearable EEG for long-time ambulatory seizure detection has only proved applicable to the monitoring of generalized absence seizures.
- There is no available solution to reliably detect focal seizures.
- Promising developments include ECG-based heart rate variability biomarkers and subcutaneous EEG.

comprehensive characterization, unveiling distinctive patterns that are readily discernible from nonepileptic physiological activity and psychogenic nonepileptic seizures through the utilization of upper limb 3D-accelerometry (3D-acc) [16–19], electromyography sensors (EMG) [20–23], electrodermal activity [24], and to some extent, electrocardiogram sensors (ECG) [25,26], with each biosignal employed either in isolation or in a multimodal manner.

Currently, only a limited number of devices implementing these biosignal modalities has undergone rigorous testing, clinical validation, and received approval from either the US Food and Drug Administration and/or the European Union, specifically for GTCS detection [15,27,28].

A wrist-worn 3D-acc based seizure detection device (Epi-Care mobile, Danish care technology, Sorø, Denmark) was recently tested in 71 participants (median age 27 years old, range 7–72 years old) in a phase 4 field study. The device achieved a median sensitivity of 90% for the detection of GTCS, with a median false alarm rate (FAR) of 0.1 per day [19], replicating the performance previously observed with the same device in epilepsy monitoring unit (EMU) studies.

Another wrist sensor combines 3D-acc and EDA (Embrace, Empatica Inc., Cambridge, USA) and was tested in a large EMU study involving 67 adults and 85 pediatric participants. The device demonstrated a sensitivity of 91% [95% confidence interval (CI): 84–99%] and a FAR of 0.27 per day (95% CI: 0.18, 0.36) [29▪▪], consistent with the outcomes of prior investigations [30,31].

Another type of 3D-acc sensor is placed on the upper arm and includes photoplethysmography (PPG) [32,33] (NightWatch, LivAssured B.V., Leiden, The Netherlands). Using this device, a recent prospective multicentric phase 4 study, encompassing 2310 nights and totaling 28 174 h of recordings in 53 children, reported a median sensitivity for detecting nocturnal GTCS of 94%, ranging from 71% to 100% across patients, with a FAR of 1.2 per 24 h of recordings [34▪▪]. This device also detected other nocturnal major motor seizure types, though with a lower sensitivity of 86% [34▪▪].

Arm EMG sensors have also proved highly sensitive and specific for detecting GTCS [20–22,35]. In a prospective, multicenter, blinded study employing real-time seizure detection in a cohort of 71 patients (age range: 10–62), one such wearable EMG solution successfully identified 94% of GTCS with an FAR of 0.67 per day [23].

Wearable ECG patch, designed for monitoring heart rate variability (HRV), also demonstrated high sensitivity in the detection of GTCS. In a cohort of 100 patients, the device successfully detected 17 out of 18 GTCS, resulting in a sensitivity of 100% (95% CI: 79.4–100) with a FAR of 1/day [25]. Similar results were reported in another prospective phase 2 study in 47 patients, with a detection of 9 out 10 GTCS, and a FAR of 0.9/day (90%) [26]. In a more recent phase 2 multicenter trial aimed at detecting all seizure types, particularly nonconvulsive ones, 8 out of 10 GTCS were correctly identified (80%) [36▪▪].

Nonwearable sensors have also been developed to detect seizures, including under-mattress device incorporating a quasi-piezoelectric film integrated with pressure sensors [37]. Clinical studies have shown a sensitivity in detecting GTCS of 85% in children and 89% in adults, with rare false alarms occurring exclusively during daytime [38,39]. A recent retrospective study of 55 adult patients confirmed a lower sensitivity than that provided by wearables, at 78%. FAR was very low, at 0.007 per day [40▪].

Wearable devices detecting GTCS can potentially provide biomarkers of seizure severity, extracted from the different biosignals collected for detection, with the view that such biomarkers could help predicting the risk of sudden unexpected death in epilepsy (SUDEP) [41]. As a first step, two EMUs studies have explored the possibility to use surface EMG and HRV as surrogate indicators of seizure severity. Both biomarkers showed strong association with the presence and duration of a postictal EEG suppression (PGES), with the EMG-based algorithm predicting the presence of PGES longer than 20 s with an accuracy of 85% [42,43]. The presence of a progressive slowing of the clonic phase, which could be captures from 3D-acc, also correlated with the presence and duration of the PGES, as well as with the type of GTCS [44]. The above as well as other wearable sensors might also enable to infer from the duration of GTCS and

postictal immobility, as well as the severity of postictal autonomic changes [45].

Focal seizures

In contrast with GTCS, only a limited body of research has explored the utilization of extracerebral biosensors for the detection of focal seizures. As previously discussed, the NightWatch, which combines 3D-acc PPG has been tested for detecting major motor seizures other than GTCS, including 30 seizures with bilateral tonic seizures lasting >30 s, focal onset hyperkinetic seizures (HK), and other not otherwise categorized major motor seizures (OM). Sensitivity for detecting these three seizure types was 53%, 83% and 91% respectively [34▪▪]. Interestingly, the positive ($n = 492$) and false (n = 1642) alarms were mainly triggered by the 3D-acc (86% for positive alarms and 66% for negative alarms) followed by a rapid increase in heart rate (23% for positive alarms and 36% for negative alarms) and by tachycardia (18% for positive alarms and 6% for negative alarms). A minority of alarms, specifically 27% of true positive alarms and 8% of false positive alarms, were activated by multiple signals simultaneously [34▪▪].

The identification of focal seizures without conspicuous movement or muscle engagement obviously necessitates other biomarkers than those reliant on movement or muscle activity-based devices. Changes in hear rate and HRV have been proposed and recently tested as potential biomarkers for the detection of such seizures [25,26,36▪▪,46–50]. In a recent phase 2 clinical trial of 62 patients, an ECG patch associated with an HRV-based patient-adaptive logistic regression machine learning achieved a sensitivity of 77% for the detection of focal seizures with a FAR of 0.62% [36▪▪]. However, a major and expected difference was observed between patients with an ictal increased in heart rate > 50 bpm (sensitivity of 87%) and those without (sensitivity of 24%). The results confirmed those from a comparable previous study from the same group [26], though with improved FAR believed to reflect the implementation of the patient-adaptive algorithm.

EEG-BASED SEIZURE DETECTION

In recent years, notable advances in ambulatory scalp-EEG recordings have emerged, addressing the challenge of prolonged monitoring spanning weeks, months or even years. Novel systems employing subcutaneous or intra-auricular electrodes have been developed, indicating potential for reliable chronic EEG recordings in the future [9,51–53].

In parallel, numerous EEG-based seizure detection algorithms have been developed [54]. These algorithms, which are usually trained and tested on EEG datasets recorded in EMU rather than in ambulatory patients, exhibit sensitivities ranging from 75% to 90%, with false detection rates between 0.1 and 5 per hour [54]. Transitioning these algorithms to ambulatory settings raises critical considerations. On the one hand, long-term ambulatory EEG recordings with noninvasive wearable devices are likely to suffer from much more artefacts than in the EMU, leading to reduced sensitivity and specificity, whereas on the other hand, acceptable rates of false alarms shall be much lower in ambulatory settings than in-hospital where such alarms are primarily managed by the EMU staff.

Yet, some recent data suggest that headband EEG can achieve clinically relevant detection for some seizure type [55,56,57▪,58]. Indeed, a recent multicenter prospective phase 3 clinical trial using a headband embedded with dry electrodes to detect generalized absence seizures in 39 patients achieved a median sensitivity per patient of 93% [interquartile range (IQR) = 66.7–100%] [56]. In contrast, another study focusing on tonic seizures only reached a 41% sensitivity (41%) with a high FAR of 0.75 per hour [58]. Poor findings were also reported for focal impaired awareness (FIA) seizures in both inpatient and outpatients, with 52% and 23% sensitivity, respectively, and FAR up to 7.13 per hour [57▪].

To mitigate these issues, multibiosignal correlations might prove pivotal [59], with a synergistic combination of EEG and non-EEG technologies utilizing wireless-coupled biosensors positioned on the head (e.g., behind or around the ear) and peripheral regions (e.g., the wrist) [60]. Minimally invasive subcutaneous EEG electrodes, which are less susceptible to artifacts than those on the scalp, offer an alternative approach to clinically-relevant EEG-based seizure detection in ambulatory patients [61].

MACHINE LEARNING FOR SEIZURE DETECTION

Machine learning algorithms have become an integral part of seizure detection and prediction systems, with particular emphasis on Deep Learning frameworks [62–68]. They can be developed to operate in real-time when embedded in seizure detection devices or offline for analysis after the recording. Yet, algorithms embedded in seizure detection devices must meet low computing, memory and power requirements that are constrained by the wearable devices [69]. The 2023 ICASSP Seizure Detection Challenge was specifically organized to evaluate

algorithms designed for wearable EEG devices. The challenge provided participants with the SeizeIT1 dataset that contains 42 subjects with one week of continuous EEG recorded in the EMU, with four additional electrodes placed behind the ear (Byteflies Sensor Dot) representing potential ambulatory wearable EEG data [70]. While the challenge highlighted some of the state-of-the-art methods for EEG-based wearable seizure detection methods, it also highlighted the continued need for algorithm improvements as the best-performing algorithm obtained a sensitivity of 63% with 15 false-alarms per hour which is not acceptable by patients for real-time seizure alarming devices [71]. At the same time, algorithms designed for use in an EMU setting perform considerably better. A recent assessment of commercially available algorithms for EEG-based EMU seizure detection showed that these algorithms have a sensitivity close to 90% for a false alarm rate of 1.7–5.5 per day [72▪▪].

The development of seizure detection algorithms raises a number of issue, including comparison of performance across studies, transparency and interpretability [73]. Comparison across studies can be promoted by using similar public datasets, as illustrated by the 2023 ICASSP Seizure Detection Challenge. Other publicly available datasets for EEG-based seizure detection are available [74], but remain scarce overall. Recent research has also highlighted the importance of proper cross-validation methodology and the choice of proper performance metrics for the evaluation of algorithms [75,76]. Addressing this issue requires a collective effort from the research community. Collaborative initiatives, akin to those proposed by prominent scholars [73,77▪], are vital in establishing standardized datasets that encompass diverse seizure types, durations, and clinical contexts. These standardized datasets would serve as a common ground for algorithm evaluation, enabling fair and accurate comparisons between different methodologies. Furthermore, a consensus on evaluation metrics, incorporating measures such as sensitivity, specificity, positive predictive value, and false alarm rate [2,3], is imperative. Establishing a set of universally agreed-upon metrics will facilitate the comprehensive assessment of algorithms and enhance the reproducibility of results.

CONCLUSION

Several commercial wrist or arm wearable sensors, using 3D-acc alone or combined with EDA or PPG, enable a reliable detection of GTCS with acceptable level of false-alarm rates. No such wearable currently offer clinically-relevant solution to detect focal seizures. This conclusion also applies to wearable EEG which utility remains restricted to the detection of generalized absence seizures. Promising developments in the field include the utilization of ECG-based HRV biomarkers and subcutaneous EEG. Improvements are needed in the standardization of datasets and metrics used to trained and tested seizure detection algorithms, as well as in the transparency and interpretability of the underlying machine learning tools.

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Conflicts of interest

There are no conflicts of interest.

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- ▪▪ of outstanding interest

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