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SPECIAL ISSUE ARTICLE

Automated detection of absence seizures using a wearable electroencephalographic device: a phase 3 validation study and feasibility of automated behavioral testing

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Summary

Objective: Our primary goal was to measure the accuracy of fully automated absence seizure detection, using a wearable electroencephalographic (EEG) device. As a secondary goal, we also tested the feasibility of automated behavioral testing triggered by the automated detection.

Methods: We conducted a phase 3 clinical trial (NCT04615442), with a prospective, multicenter, blinded study design. The input was the one-channel EEG recorded with dry electrodes embedded into a wearable headband device connected to a smartphone. The seizure detection algorithm was developed using artificial intelligence (convolutional neural networks). During the study, the predefined algorithm, with predefined cutoff value, analyzed the EEG in real time. The gold standard was derived from expert evaluation of simultaneously recorded full-array video-EEGs. In addition, we evaluated the patients' responsiveness to the automated alarms on the smartphone, and we compared it with the behavioral changes observed in the clinical video-EEGs.

Results: We recorded 102 consecutive patients (57 female, median age = 10 years) on suspicion of absence seizures. We recorded 364 absence seizures in 39 patients. Device deficiency was 4.67%, with a total recording time of 309 h. Average sensitivity per patient was 78.83% (95% confidence interval [CI] = 69.56%–88.11%), and median sensitivity was 92.90% (interquartile range [IQR] = 66.7%–100%). The average false detection rate was .53/h (95% CI = .32–.74). Most patients (n = 66, 64.71%) did not have any false alarms. The median F1 score per patient was .823 (IQR = .57–1). For the total recording duration, F1 score was .74. We assessed the feasibility of automated behavioral testing in 36 seizures; it correctly documented nonresponsiveness in 30 absence seizures, and responsiveness in six electrographic seizures.

Significance: Automated detection of absence seizures with a wearable device will improve seizure quantification and will promote assessment of patients in their home environment. Linking automated seizure detection to automated behavioral testing will provide valuable information from wearable devices.

KEYWORDS
absence seizure, artificial intelligence, automated detection, behavioral testing, epilepsy, wearable devices

1 | INTRODUCTION

Therapeutic decisions in epilepsy management are currently based on information from seizure diaries, derived from self-reported seizures. However, this is unreliable, as <50% of all epileptic seizures are reported by patients.[1] Absence seizures often lack a visible clinical correlate, which makes their identification by caregivers increasingly difficult.[2] Several papers demonstrated that self-reporting of absence seizures was unreliable; only 6%–14% of all electroencephalographically (EEG)-verified absences were reported by patients or caregivers.[2–4] Moreover, inaccurate reporting of absence seizures comprised both under- and overreporting; a recently published study found inaccurate self-reporting in more than two thirds of patients with absence seizures, 37.5% overreporting and 29.2% underreporting.[5]

There is need for an objective estimation of absence seizure frequency. However, the use of gold standard in-hospital video-EEG is resource demanding, and access to it is limited.[1] Other strategies, such as ambulatory home EEG recordings, are not yet broadly available, they generate huge datasets for visual review, and wearing full-array EEG caps is stigmatizing for the patients.[6] One could possibly circumvent this by using wearable devices and automated seizure detection.[7–9] Previously published, retrospective, single-center, phase 0–2 studies,[10] using either full EEG array or downsampled to 1–2 conventional EEG channels, showed promising results, with sensitivity between 93.94% and 99.1%, and false detection rates up to .9 per hour.[4,11–17]

Here we report the phase 3[10] clinical validation study of a fully automated, artificial-intelligence-based algorithm, using EEG signals from a wearable, one-channel headband EEG (Epihunter), for detection of absence seizures (NCT04615442). The study was prospective, multicenter, and blinded, with real-time detection, using a predefined algorithm and predefined cutoff values. To the best of our knowledge, this is the first report of a phase 3 trial of fully automated detection of absence seizures with a wearable device. The primary goal was to determine the accuracy of the seizure detection, measured by its sensitivity, false alarm rate, and F1 score. The secondary goal was testing the feasibility of an automated behavioral testing of patient responsiveness, triggered by the automated seizure detection.

Key Points

- We conducted a phase 3 validation study of automated detection of absence seizures, using a wearable EEG device
- The gold standard was expert evaluation of simultaneously recorded video-EEGs, which identified 364 absence seizures
- The median sensitivity per patient was 92.0%, with a median F1 score per patient of .82 and device deficiency of 4.67%
- We did a feasibility assessment of automated behavioral testing triggered by automated seizure detection in 36 absence seizures
- The automated behavioral testing correctly documented nonresponsiveness versus responsiveness of the patients, as compared with the video-EEG

2 | MATERIALS AND METHODS

2.1 | Participants

We recruited consecutive patients referred to video-EEG on suspicion of absence seizures, between April 25, 2020 and June 28, 2021, at four centers: Danish Epilepsy Center (Dianalund, Denmark), Boston Children's Hospital (Boston, MA, USA), Leuven University Hospital (Leuven, Belgium), and Institute of Neurology and Neuropsychology (Tbilisi, Georgia). Regional ethics committees and institutional review boards of the participating centers approved the study, and patients/caregivers gave their informed consent in accordance with the Declaration of Helsinki. The prospective study was registered at clinicaltrials.gov (NCT04615442).

Inclusion criteria were as follows: patients aged 3 years or older, suspected of having absence seizures, referred to video-EEG monitoring, as part of their clinical assessment. Exclusion criteria were head circumference outsize the range of the wearable device (40–60 cm), inability to comply with the instructions, and behaviors that included removing the device before or during recording.

2.2 | EEG recordings

The wearable EEG was recorded using the Brainlink Lite device (Macrotellect), a consumer EEG headband (Figure 1), approved for use in the European Union (CE mark), which can be mounted by untrained personnel, and hence is also suitable for home recording. The headband uses a NeuroSky ThinkGear ASIC Module (NeuroSky). This chip connects to three dry EEG electrodes (active, reference, and ground), placed on the forehead by an elastic band (Figure 1), resulting in a bipolar EEG channel corresponding to F7-Fp1.[11] The device is connected via Bluetooth to a smartphone unit for further data processing. The 3.7-V 160-mAh lithium battery in the device enables 4–5 h of continuous EEG streaming. To monitor the quality of the recorded EEG signals, the device uses an algorithm that combines an assessment of the electrode contact to the skin (impedance) and the noise level from environmental or biological factors (electromyogram, electrocardiogram, electro-oculogram). Signal quality is measured once per second on a scale from 0 (very good) to 200 (very bad). If the average signal quality over the last 5 s is >40, then it is considered deficient.

FIGURE 1 The wearable electroencephalographic (EEG) device used in this study. The dry EEG electrodes in the elastic headband are placed close to the standard EEG locations F7 and Fp1 (bipolar channel). The third electrode is the ground (at Fpz location). The device is connected to a smartphone via Bluetooth

Simultaneously with the wearable EEG, clinical video-EEG was recorded using NicoletOne EEG system (Natus Neuro) in Denmark, Micromed BRAIN QUICK in Georgia, and Brainlab EEG system (OSG) in Belgium. The clinical EEG was recorded using the standardized electrode array of the International Federation of Clinical Neurophysiology,[18] and the recordings were done at the participating centers (in-hospital).

2.3 | The algorithm

For the fully automated detection of absence seizures, we used a predefined (previously developed) algorithm, with predefined cutoff values. The algorithm analyzed the EEG seizures in real time and logged the time points of the detected seizures. In the blinded clinical trial, the alarm function was disabled.

The algorithm was previously developed using artificial intelligence (deep learning). We used TensorFlow (https://www.tensorflow.org/), an open source software library for high-performance numerical computation (Figure 2). Its flexible architecture allows easy deployment of computation across a variety of platforms, and from desktops to clusters of servers to mobile and edge devices. Deep learning is a promising approach from artificial intelligence. It has been applied before to EEG seizure detection with promising results.[19–21] The neural network consists of four convolutional layers, followed by two dense layers and a final logits layer (Figure 2). We used a combination of batch normalization and dropout layers to avoid overfitting. The algorithm analyzed the EEG signals in windows of 2 s, with 1-s overlap. Automatically detected absence seizures were defined as three consecutive seizure windows. The training of the algorithm was previously performed on 141 h of clinical EEG data from people with absence epilepsy, including 271 absence seizures. For the training, only the frontal Fp1-F7 leads were retained, as they are the closest to the wearable electrode locations. None of the patients from the training phase was recruited to this validation study.

2.4 | Primary outcome measures

In the validation study, absence seizures were defined electrographically as bilateral–synchronous spike–wave discharges, at a frequency of 2.5–3.5 Hz, and duration of at least 5 s.[22,23] The gold standard for the seizure time

points was based on the assessment of the clinical video-EEG recordings, by trained experts. At each center, two experts, blinded to the automated detections, evaluated each EEG. Discordant assessments were resolved by consensus discussions.

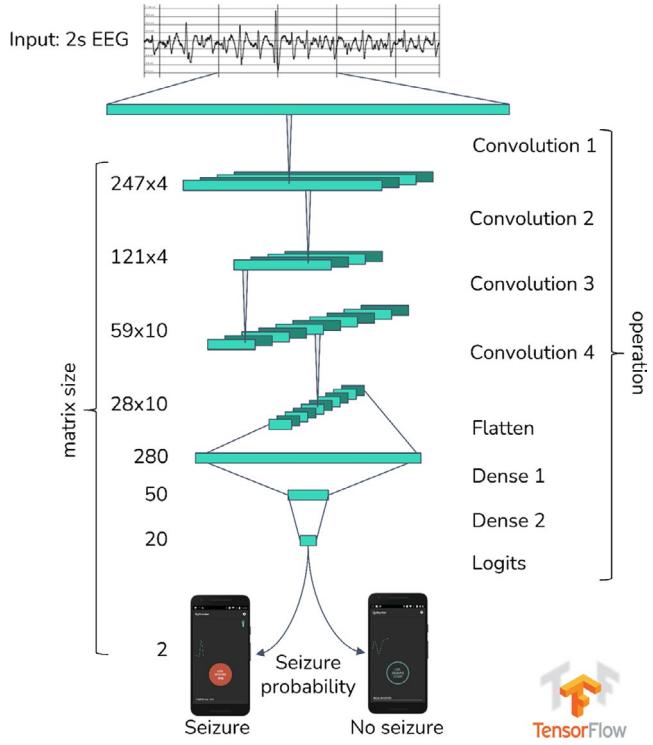

FIGURE 2 Deep learning algorithm running in TensorFlow. EEG, electroencephalogram

We compared the time points of automated seizure detection with the seizure time points from the gold standard. When these overlapped, the detection was considered true positive (TP). Seizures listed in the gold standard, which were not detected by the algorithm, were considered false negatives (FNs). We considered false positives (FPs) the automated detections without corresponding spike–waves identified in the gold standard, or corresponding to spike–waves shorter than 4 s, without clinical correlate.

We measured and reported device deficiency periods, when the device was not recording or the signal quality monitored by the device was poor. Seizures occurring during device deficiency periods were not listed in the gold standard.

We calculated the percentage of device deficiency periods for the entire recording duration, sensitivity, false detection rate, and F1 score. Sensitivity (the proportion of detected seizures) was calculated as TP / (TP + FN). F1 score (the harmonic mean of precision and sensitivity) is a measure of the detection accuracy, with values between 0 (poor) and 1 (excellent). F1 score was calculated as 2 × (precision × sensitivity) / (precision + sensitivity), where precision was calculated as TP / (TP + FP).

2.5 | Automated behavioral testing

We assessed the feasibility of automated testing of patients' responsiveness, triggered by automated seizure detection. For this part of the study, the seizure alarm

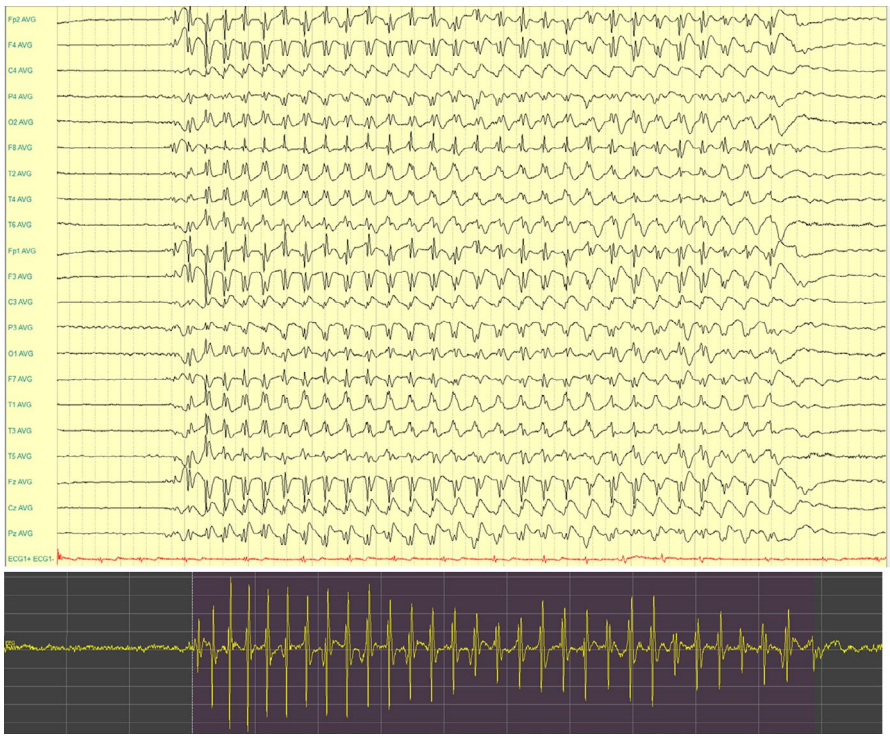

FIGURE 3 Absence seizure recorded with the full-array clinical electroencephalogram (EEG; top) and the one-channel, wearable EEG (bottom trace)

function was turned on (vibration of the smartphone and acoustic alarm). Patients were instructed to use the smartphone and turn the alarm off as soon as they hear the seizure alarm. When patients turned off the alarm during a detected absence seizure, they were considered responsive. When patients failed to turn off the alarm during a detected absence seizure, they were considered nonresponsive. The behavioral response to the smartphone alarm, triggered by the automated seizure detection, was compared with the evaluation of the clinical video-EEG recordings.

We conducted the study according to the ISO 14155 requirements, and we report the study according to the STARD guideline.[24]

3 | RESULTS

We recruited 102 consecutive patients (57 female). The median age was 10 years (range = 4–28 years). Patients were diagnosed with childhood absence epilepsy ($n = 33$), juvenile absence epilepsy ($n = 24$), idiopathic generalized epilepsy–not classified further ($n = 14$), epilepsy with myoclonic absences ($n = 2$), and genetic generalized epilepsy ($n = 1$). Twenty-eight patients were referred to the video-EEG on suspicion of absence seizures, but the recording did not show abnormal findings (neither ictal nor interictal). Thirty-nine patients had 364 absence seizures in total. Figure 3 shows an absence seizure recorded with the full array clinical EEG and the one-channel wearable EEG device.

Device deficiency was 4.67% of the total recording time, yielding 309.4 h of recording with good signal quality. The fully automated seizure detection had an average sensitivity per patient of 78.83% (95% confidence interval [CI] = 69.56%–88.11%), median sensitivity per patient of 92.90% (interquartile range [IQR] = 66.7%–100%), and overall sensitivity across all seizures of 79.12% (95% CI = 74.58%–83.18%). The average false detection rate in all 102 patients was .53/h (95% CI = .32%–.74%). For the total recording duration (309.4 h), the false detection rate was .59/h. Almost two thirds of the patients (64.7%) did not have any false detection at all. The median F1 score per patient was .823 (IQR = .57–1). For the total recording duration, the F1 score was .74. Supplementary Document 1 shows the STARD flowchart of the study.

The feasibility of the automated behavioral testing triggered by the automated seizure detection was tested in 36 seizures from six patients. Supplementary Document 2 shows video-EEG examples with automated behavioral testing during electrographic absence seizures. In 30 seizures, the automated behavioral testing documented nonresponsiveness and in six seizures, it documented responsiveness, verified by the clinical video-EEG recording (Supplementary Document 2).

4 | DISCUSSION

In this phase 3, large, prospective, multicenter, blinded clinical validation study, using a predefined algorithm and cutoff values, we achieved an average sensitivity of 78.8%, median sensitivity of 92.9%, and median F1 score of .82 per patient, for real-time, automated detection of absence seizures, with a wearable device incorporating dry EEG electrodes. The vast majority of the patients (almost two thirds) did not have any false alarms. To the best of our knowledge, this is the first phase 3 trial to demonstrate the accuracy of a wearable device for automated detection of absence seizures.

Previously published phase 0–2 studies reported somewhat better results, with sensitivity of automated absence seizure detection between 94% and 99%, and false detection rates between zero and .9 per hour.[4,11–17] Results of retrospective analyzes always appear to be better than the prospective ones. When algorithms are trained on the recorded dataset and then evaluated using cross-validation, overfitting may occur, especially when the sample size is small. Furthermore, optimizing the cutoff value to the already recorded dataset gives an overly optimistic view of the performance of the algorithm. The performance of our fully automated detection is comparable to the recently published semiautomated detection of absence seizures, where experts evaluated the automated detections, achieving a median sensitivity of 83% and an F1 score of .87.[4]

Absence seizures are relatively common; they affect .7–4.6 in 100 000 individuals across the general population,[25] and they bear a significant burden on the patient's quality of life due to constraints in everyday life.[26] Therapeutic decisions are currently based on seizure self-reporting, which is unreliable, as both overreporting and underreporting have been documented, and this may change in time within the same patient, making any estimation extremely difficult. Therefore, an objective estimation of seizure burden, using a fixed algorithm and fixed cutoff value, has high potential clinical relevance, even when not perfectly accurate, as it is stable in time, making possible an objective assessment of within-patient change of the seizure burden.

The benefit of long-term EEG monitoring to assess the therapeutic response in patients with absence seizures has been well documented.[27,28] However, visual evaluation of long-term EEG monitoring using full-array EEG and clinical equipment is time-consuming, obtrusive, usually limited to 24 h, and often performed in the hospital.

Using automated seizure detection and a wearable EEG device with dry electrodes, which can be mounted by parents/caregivers in the home environment of the patient, potentially can circumvent these difficulties, providing better patient care. The huge impact on the global health care system of the recent pandemic clearly demonstrated the importance of extending patient management to the home environment. Teleconsultations of patients with absence seizures would benefit from data on seizure burden derived from automated EEG analyses using wearable devices in the home environment of the patients. This is the main use case we envisage for our device.

Previously published automated seizure detection systems using wearables (not only for absence but also for other seizure types) monitor changes in biosignals, but do not involve automated behavioral testing.[8] Although these automated detections can accurately identify seizure activity, they are uninformative about important seizure characteristics, such as impairment of consciousness. Many experts expressed concerns that increased use of wearable detection devices will flood the clinicians with detections of uncertain clinical significance. Linking automated seizure detection to automated behavioral testing can potentially alleviate this problem. Automated behavioral testing triggered by automated seizure detection, based on full EEG array in an epilepsy monitoring unit, has been previously reported in two patients.[29] Here, we demonstrated the feasibility of this approach using wearable devices. To the best of our knowledge, ours is the first study incorporating automated behavioral testing into a wearable seizure detection device. The potential of this approach for other seizure types is considerable.

In conclusion, this phase 3 clinical trial demonstrated that absence seizures could be detected with a fully automated algorithm, embedded into a wearable device. Linking automated behavioral testing to automated seizure detection may provide useful information for characterizing seizures. Use of home EEG recordings using wearables and automated signal analysis may provide useful information for management of patients with absence seizures by telemedicine.

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CONFLICT OF INTEREST

D.L. and T.B. are employees, founders, and shareholders of Epihunter. The institution of S.A.L. received funding from Epihunter, for part of her salary, during the study. The institution of G.J. and S.K. received funding from Epihunter to compensate for the time of the technicians. S.B. and A.R. served as scientific consultants for Epihunter, during the study. The remaining authors do not have conflicts of interest related to this work. 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 in the online version of the article at the publisher's website.

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