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Epihunter Absence: Phase 3, prospective, multicenter validation study.

Introduction

Epihunter's mission is to enable people with a brain disorder to participate more fully in society. Epihunter's first product is epihunter Absence, which combines wearable EEG data with AI algorithms that run on a smartphone to automatically and in real-time detect and signal absence seizures. Epihunter Absence is available in Europe, Australia and New Zealand as a medical device.

Self-reporting of absence seizure frequency is highly unreliable. Research showed that patients report only 6% of all EEG verified absences[1]. Nevertheless, therapeutic decisions are in many cases based on info from seizure diaries or patient-reported seizure frequency.

This abstract presents the results of a phase 3[2] prospective multicenter validation study of epihunter Absence. The study ran in 4 different centers: UZ Leuven (Leuven, Belgium), Filadelfia (Dianalund, Denmark), Institute of Neurology and Neuropsychology (Tbilisi, Georgia), and Boston Children's Hospital (Boston, US) and was funded by a grant from the Epilepsy Foundation (US).

Materials & methods

The study compared electrographic seizures (EGS) as registered during the clinical video EEG with seizures automatically detected by epihunter Absence. The clinical and wearable EEG were recorded simultaneously. EGS were identified by experts, defined as at least 5 seconds of spike-waves (SW) in the standard EEG signal, regardless of clinical manifestations.

102 subjects (57 female, 45 male) were included in the study. They had a median age of 10 years (4-28) and a variety of epilepsy types (CAE: 33, JAE: 24, IGE: 14, EMA: 2, GGE: 1, unclassified: 28).

Results

During the study, 309.4 hours of joint hospital and wearable EEG were recorded. 39 subjects had 364 absence seizures; 63 subjects had no seizures.

The device showed a median sensitivity per subject of 92.90% (IQR: 66.7%-100%) and a median false-alarm (FA) rate per recording of 0 FA/h (IQR: 0-0.61FA/h). 65% of all subjects didn't show any false alarm. The median F1 per subject is 0.82. The average sensitivity was 79.12% (95%CI: 75%-83%) and the average FA rate 0.59/h. The average F1 score is 0.75.

Sensitivity (median)	False-alarm rate (median)
92.90% IQR: 66.7%-100%	0 FA/h IQR: 0-0.61 FA/h

Table 1: Main study results

Conclusion

As far as we know, this is the first Phase 3 validation study of a wearable device for absence seizure detection. Moreover, epihunter Absence is the first real-time absence seizure detection device that is commercially available in Europe, Australia and New Zealand.

This study has shown that epihunter Absence is a tool to consider for the automatic detection of absence seizures.

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[1] Keilson et al, Pediatr Neurol. 1987; 3:273–6, Swinnen et al, Epilepsia. 2021; 62(11):2741-52
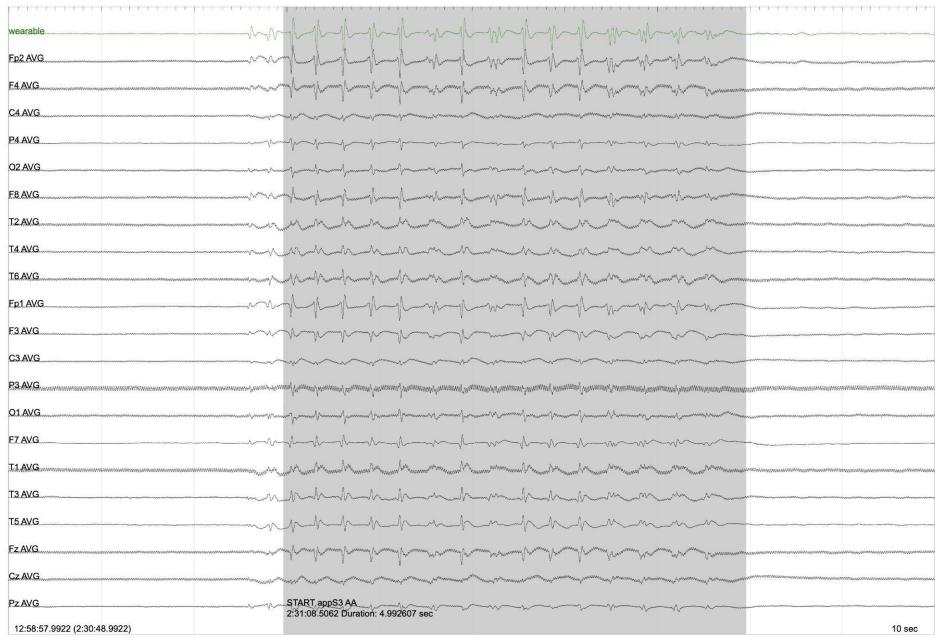[2] Beniczky et al, Epilepsia 2018; 59:9-13

Figure 1: Joint visualisation of wearable (green, top) and clinical (black) EEG and automatically detected seizure (gray area)