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Tracking generalized tonic-clonic seizures with a wrist accelerometer linked to an online database

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ABSTRACT

Purpose: Clinical management of epilepsy and current epilepsy therapy trials rely on paper or electronic diaries often with inaccurate self-reported seizure frequency as the primary outcome. This is the first study addressing the feasibility of detecting and recording generalized tonic-clonic seizures (GTCS) through a biosensor linked to an online seizure database.
Method: A prospective trial was conducted with video-EEG (vEEG) in an epilepsy monitoring unit. Patients wore a wristwatch accelerometer that detected shaking and transmitted events via Bluetooth® to a bedside electronic tablet and then via Wi-Fi to an online portal. The watch recorded the date, time, audio, duration, frequency and amplitude of events. Events logged by the watch and recorded in a bedside paper diary were measured against vEEG, the "gold standard."
Results: Thirty patients were enrolled and 62 seizures were recorded on vEEG: 31 convulsive and 31 non-convulsive. Twelve patients had a total of 31 convulsive seizures, and of those, 10 patients had 13 GTCS. The watch captured 12/13 (92.3%) GTCS. Watch audio recordings were consistent with seizures in 11/12 (91.6%). Data were successfully transferred to the bedside tablet in 11/12 (91.6%), and to the online database in 10/12 (83.3%) GTCS. The watch recorded 81 false positives, of which 42/81 (51%) were cancelled by the patients. Patients and caregivers verbally reported 15/62 seizures (24.2% sensitivity) but no seizures were recorded on paper logs.
Conclusion: Automatic detection and recording of GTCS to an online database is feasible and may be more informative than seizure logging in a paper diary.

1. Introduction

Logs of seizure counts and characteristics in paper diaries are unreliable, so there is a need for better methods to track seizures [10]. An NINDS-sponsored conference in April 2011 recommended validation studies of epilepsy diaries and linking of electronic diaries to biosensors [1]. This is the first trial assessing the feasibility of detecting and recording generalized tonic-clonic seizures (GTCS) via a biosensor linked to an online electronic seizure diary.

Accurate information about precise timing of seizures, diurnal fluctuation, frequency, intensity and duration could facilitate treatments better tailored to the individual seizure patterns. Data collection with paper diaries presents many inherent difficulties, as it requires moderate intellectual functioning, literacy and adherence. Paper diaries are easily misplaced and cannot compensate for unrecognized seizures or false positive recordings of non-epileptic events [1,21]. Several free electronic web-based epilepsy diaries are available for use by patients and caregivers; however, active entry is still required. Additionally, patients who access these web or computer-based applications tend to be younger and better educated, thereby introducing selection bias into trials [2].

Automatic detection of GTCS based on wristwatch accelerometers is feasible [3,4]. Seizure-detection algorithms validated by patient-initiated and automatic audio recordings of sounds made by patients or bystanders have been reported [5].

The objective of this study was to test the feasibility of detecting and logging GTCS with a wrist accelerometer biosensor and linking the data to an online seizure database. The primary goal of the

Abbreviations: EMU, epilepsy monitoring unit; F, female; GTCS, generalized tonic-clonic seizures; Hz, Hertz; M, male; NINDS, National Institutes of Neurological Diseases and Stroke; vEEG, video electroencephalography.

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study was to achieve at least an 80% sensitivity of accurately capturing GTCS detected and logged by the watch-online interface compared to the gold standard of video-EEG (vEEG). The secondary outcome was to examine the sensitivity and accuracy of detection and documentation of non-seizure events by the watch-online interface compared to vEEG and to patient and caregiver reports of events.

2. Materials/methods

This was a prospective trial conducted in the Stanford Epilepsy Monitoring Unit (EMU), with patients monitored continuously using video, audio, ECG and EEG sensors. The study was performed on patients admitted for usual clinical purposes, not specifically for the study, and to provoke seizures anti-seizure medications were tapered, patients were sleep deprived and performed stationary bike exercises. The protocol and consent documents were approved by the Stanford Institutional Review Board. Adults 18 years and older who were able to give informed consent were recruited upon admission to the EMU. Patients with a seizure semiology that historically included tonic-clonic movements in at least one limb were eligible for the study, while those with a history only of non-tonic-clonic or suspected psychogenic non-epileptic events were not included. Enrolled patients wore a wireless wristwatch accelerometer (SmartWatch developed by SmartMonitor©) (Fig. 1) during their inpatient stay. This watch detects rhythmic, repetitive limb movements. Subjects were told that the watch would vibrate when it detected a seizure-like movement and were instructed to push the right center "cancel" button on the watch if they were having a non-epileptic shake event such as teeth brushing. All patients and/or caregivers were given a paper log and instructed write down all of the seizures that occurred during their inpatient admission and to rate the perceived severity of each on a scale ranging from 1 (mild) to 10 (severe). Patients and caregivers were also instructed to push a bedside button to mark an aura or seizure.

The watch and watch-online interface were programmed to detect shaking events and record the date, start and end times, duration, mean shake frequency and amplitude of abnormal movements, along with associated audio. As a positive control to ensure that the equipment was properly functioning at the time of enrollment, an abnormal test movement was simulated, registered by the watch and instantly uploaded to the watch-online portal.

Fig. 1. Wristwatch accelerometer.

All parameters for each detected event were transmitted via Bluetooth® to a bedside electronic tablet and then via WiFi to an online cloud-based seizure database. Watches were exchanged with fully charged devices every 2 days to prevent battery failures.

Thresholds for shake detections are programmable and, for the purpose of this study, were set to a sensitivity of 4 on a scale of 10, with 10 being the least sensitive, and a requirement for at least 7 s of shaking. When the abnormal motion ended, the watch recorded an additional 30 s to register any recurrent repetitive movements. The entire duration of the abnormal movement was recorded from 7 s before watch detection to 30 s after end of the shaking. Data were automatically transferred to the online portal. Each abnormal motion was recorded as graphical data of shake intensity on a two gravitational (2 g)-force acceleration scale ranging from -2 g to +2 g, corresponding to numerical values -128 to +127 (Fig. 2). The watch recorded shaking frequency as the number of times per second that the accelerometer signal crossed the zero level. The shaking frequency was then reported as low (<5 Hz), medium (5–10 Hz) or high (>10 Hz). Each second of event data was categorized into five levels of peak-to-peak amplitudes where maximum excursion of shake amplitude ranged from 0 to 255 acceleration units. The categories were grouped as low (<120), low-medium (120–160), medium (160–200), medium-high (200–240) or high (>240). Amplitude data then were aggregated for the entire event duration and percentage contributions of each amplitude level were

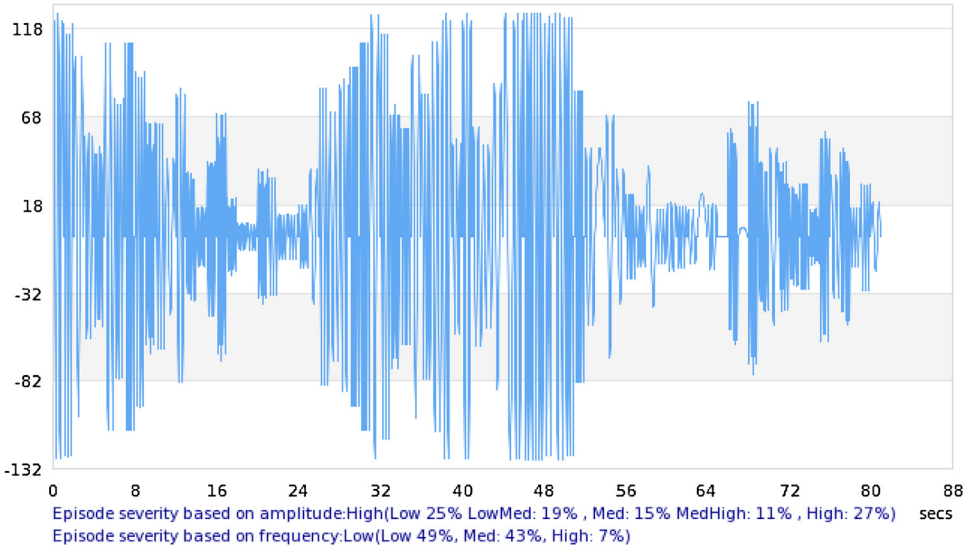

Fig. 2. Case 20 accelerometer data from a GTC. *X*-axis = time in seconds, *Y*-axis = +2 g (+127) to -2 g (-128) force.