Detection of generalised tonic-clonic seizures by a wireless accelerometry device: a prospective, multicentre, double-blind study

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Summary

Purpose: to investigate the reliability of detecting GTCS by a portable, wireless accelerometry device placed on the wrist.

Methods: 73 consecutive patients (age: 6 – 68 years; median: 37 years) at risk of having GTCS and who were admitted to the long-term video-EEG monitoring unit (LTM) were recruited in three centres. The reference standard was considered the seizure identified by experienced clinical neurophysiologists, based on the video-EEG recordings and blinded for the accelerometry device data. Seizure time-points automatically detected by the accelerometry device were compared with the reference standard. Patients were monitored for 17 – 171 hours (mean: 66.8).

Results: Thirty-nine GTCS were recorded in 20 patients. The device detected 35 seizures (89.7%). In 16 patients all seizures were detected. In three patients more than 2/3 of the seizures were detected. Seizure was not detected at all in a patient who only had one seizure. The mean of the sensitivity calculated for each patient was 91%. The mean detection latency measured from the start of the focal seizure preceding the secondarily GTCS was 55 s (95% CI: 38- 73 s). The rate of false alarms was 0.2/day.

Significance: Our results suggest that the wireless wrist accelerometry device detects GTCS with high sensitivity and specificity. Patients with generalised tonic-clonic seizures (GTCS) have an increased risk for injuries related to seizures and for sudden unexpected death in epilepsy (SUDEP). A portable automatic seizure detection device will be an important tool for helping these patients

Fig. 1A+B

DEVICE: A watch-like device with a 3-axis acceleration transducer (sensor), a microprocessor and a rechargeable battery (Figure 1A). The sensor measures the acceleration of any movement in the wrist, whether this is in the x-, y- or z-direction. The device has 2-way radio communication to a table placed or portable control unit (Figure 1B). The sensor is to be used round the clock with a recharge of the build-in battery once every 24 hour.

An example of actual measurements for a patient are shown in figure 2, where x-axis is blue, y-axis green and z-axis red. At the end of the time-epoch, a seizure is recorded. Figure 3 is focused on the measurements during this seizure.

The algorithm is based upon precise acceleration measurements of the patient's wrist for detecting generalized T/C seizures. Ongoing calculations determine whether movements are seizure-like or normal, high values are given to seizure-like movements and at a fixed alarm threshold, an alarm is triggered. The algorithm is fully automatic; no device settings must be carried out.

PATIENTS: Total = 73. Admitted to long-term video EEG monitoring in 3 epilepsy centres: Danish Epilepsy Centre (Dianalund, Denmark), Bethel Epilepsy Center, (Bielefeld, Germany), Rigshospitalet University Hospital (Copenhagen, Denmark)

- Gender:
  - All patients: 39 male; 34 female
  - Patients with seizures (20 patients): 13 male; 7 female
- Age:
  - All patients: 6 – 68 years (mean=36.2; median=37)
  - Patients with seizures (20 patients): 13 – 63 years (mean=37.3; median=39)

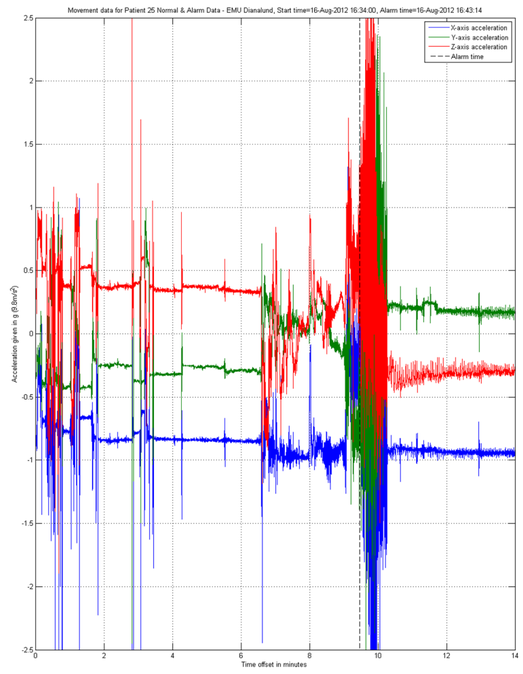

Fig. 2

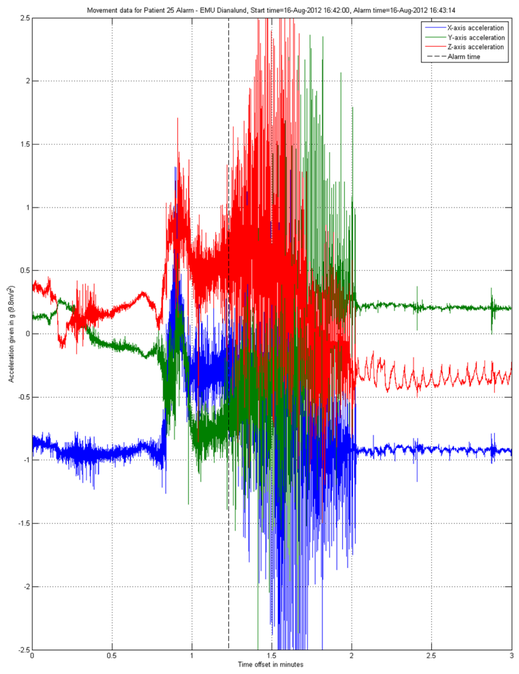

Fig. 3

RECORDING TIME: 4,878 hours (17 – 171; mean=66.8; median=72)

SEIZURES (reference standard = video-EEG)

- Secondarily-GTCS: 39 seizures in 20 patients (1 -5; mean=1.95; median=1)
- Other seizures: 149 (SPS:37; CPS/psychomotor:31; focal tonic:6; hypermotor:6; absence:1; myoclonus:60; PNES:8). None of them triggered an alarm.

SENSITIVITY for GTCS:

- For all GTCS: 35/39 = 89.7%
- Per patient (with seizure): mean 91% (95% CI=80% - 100%). In 16 patients: all seizures were detected. In three patients more than 2/3 of the seizures were detected (but not all of them). Seizure was not detected at all in one patient who only had one seizure.

LATENCY OF ALARM – as measured from the clinical start of the focal seizure

- mean 55 s (95% CI=38 -73 s)

RATE OF FALSE ALARMS:

- altogether: 40 false alarms (16 out of the 73 patients)
- rate: 0.0082/hr; 0.2/day
- per patient: mean 0.17/day (0.05 – 0.28)
- In two patients 6 false alarms occurred when they brushed their teeth with the arm where the sensor was placed, although instructed not to do so. Thirty-four false alarms occurred during voluntary rhythmic movements of the arms (playing cards, playing backgammon and winding up the cable of the amplifier).

DEVICE DEFICIENCY:

- Device deficiency was recorded 15 times.
- Only one event occurred that lead to the termination of the recording. This occurred in the first patient and was due to a system error which subsequently was corrected and has not occurred afterwards. Another system error led to a transient interruption of the recording. However this was rapidly corrected and the recording was continued.
- Eleven events were caused by battery failure (discharged in shorter time than 24 hrs). During the study, all measured data were transmitted by blue tooth connection to the computer, and this demands more energy. In the commercially available product, only the alarm triggers are transmitted, which considerably decreases the energy consumption).

SIDE EFFECTS

Only recorded in one patient: the device triggered a mild allergic reaction on the skin.

Epi-Care® free epilepsy alarm is developed and manufactured by Danish Care Technology ApS, Energivej 3, DK-4180 Sorø