Assessment of a Mattress Monitor with a Ferro-Electret Sensor as a Nocturnal Detection System for Movements Associated with Tonic-Clonic Seizures - A Clinical Investigation of the Emfit® Tonic-Clonic Seizure Monitor

Identification of the devices

Medical device under investigation:
- Name: Emfit® Tonic-Clonic Seizure Monitor
- Model: D-1090-2G
- Serial numbers: 10902G005978, 10902G005979, 10902G005982, 10902G008068
- Firmware: t63 v1.3.0
- Accessory: Emfit® Bed Sensor L-4060SL t

Other essential devices used for investigation
- Emfit® model IP-9150 with DVM Suite software for recording alarm events
- Video EEG monitoring devices: Neurofax (Nihon Kohden America Inc., CA)

Authors of report

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Investigators and administrative structure of investigation

Stephan Schuele, MD, MPH – Principal Investigator
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All investigators are based out of the Northwestern Memorial Hospital, Chicago, IL, USA.

Objectives

Sudden Unexplained Death in Epilepsy (SUDEP) is a devastating epilepsy-related event, usually seen in the context of a Generalized Tonic-Clonic (GTC) convulsion in an unattended patient. The exact mechanism of SUDEP is not known, but is thought to involve cardiac and respiratory factors (Nei 2010). Several ways of preventing SUDEP have been identified, and these include seizure control, stress reduction, physical activity, family's ability to perform CPR, and nocturnal supervision (Scorza 2010). This study was aimed to investigate the Emfit® Tonic-Clonic Seizure Monitor as an alarm system that can alert caregivers to movements associated with generalized convulsive seizure activity and therefore potentially avoid nocturnal SUDEP.

The Emfit® bed sensor is made of ferro-electric electromechanical film (Emfit® -film) which is a quasi-piezoelectric material that responds to mechanical stress. Specifically, permanently charged layers of polypropylene are separated by air voids and orthogonal mechanical pressure changes the thickness of these voids, subsequently creating an electric charge that can be measured as a voltage. The change in voltage is proportional to the change in force (Rajala 2010). Therefore, if a patient is exerting force on the mattress during a seizure, the under-mattress sensor will detect the force and translate it into a voltage signal. That is then linked to an Emfit® monitor with digital signal acquisition. Special algorithms are developed for detecting tonic-clonic seizure and signaling audible alarm. This sensor has already been shown to accurately detect periodic limb movement (Rauhala 2008) and disordered breathing during sleep (Tenhunen 2010). As of now, there have been no studies performed comparing the Emfit® monitor with electrographically confirmed tonic-clonic seizures.

References:

1. Curr Neurol Neurosci Rep. 2010 Jul; 319-26. Sudden unexpected death in epilepsy. Nei M, Hays R.
2. Epilepsy Behav. 2010 Jul; 137-8.What can be done to reduce the risk of SUDEP? Scorza FA, Arida RM, Terra VC, Cavalheiro EA.
3. J Neurosci Methods. 2009 Mar 30; 157-61. Periodic limb movement screening as an additional feature of Emfit® sensor in sleep-disordered breathing studies. Rauhala E, Virkkala J, Himanen SL.
4. Lancet Neurol. 2008 Sept 22; 1021-31. Sudden unexpected death in epilepsy: current knowledge and future directions. Tomson, T, Nashef L, Ryvlin P.
5. Procedia Engineer. 2010 Sept 5; 862-865. PVDF and EMFi sensor materials. Rajala S, Lekkala J.
6. Sleep Breath. 2010 Oct 20. Increased respiratory effort during sleep is non-invasively detected with movement sensor. Tenhunen M, Rauhala E, Virkkala J, Polo O, Saastamoinen A, Himanen SL.

Subjects

Patients admitted for continuous monitoring were recruited from our Epilepsy Monitoring Unit over a 12 month period. Recruitment was done prior to video electroencephalography (vEEG) hook up and the Emfit® sensor was placed under the mattress and connected to an Emfit® monitor for patients who consented. Standard vEEG recording took place with additional information being recorded from the Emfit® monitor. Background information recorded included age, age at onset, handedness, gender, weight, number of previous and current anti-epileptic drugs, MRI findings, and epilepsy type.

Methodology

In the clinical trial Emfit®'s under mattress bed sensor model L-4060SL was attached by tape to a 2 mm thick polypropylene plate. This was done to facilitate repeated placement and removal from under the mattress for each new patient. The sensor has a 9 ft long cable that connects to the electronic monitor D-1090-2G. When a patient is present, the sensor produces a small voltage signal, ranging from a few micro-volts to a few volts depending on the force of movement. The electronic device acquires signals and determines frequency, strength, and duration of movement. Sensor output feeds into the monitor device and GTC notifications are produced based on these three factors. In the home setting, caregivers can be alerted in two ways. First, by sounding an alarm (which was disabled during the trial as to not cause disturbance to the patient) and second via the device's dry-contact output. In the trial this output was connected to Emfit®'s IP-9150 device, which has an input for connecting auxiliary devices. IP-9150 is an IP based device, which connects to a computer over a LAN (local area network). Hundreds of devices can be connected to one computer for centralized monitoring purposes. In this study, three devices were connected to a computer. The computer was running Emfit®'s DVM Suite software, which can store all data into a SQL database. A small parsering software was used to collect data from the SQL database, which then exported all alarms from a desired time window into an excel sheet. Alarms listed in the excel sheet appeared as "Alarm via X4" and could then be recorded on a data collection sheet. Data collected from the Emfit® monitors were reviewed and compared to video EEG findings. Patient events were categorized into GTC seizures, other clonic seizures, other motor seizures, non-motor clinical seizures, non-epileptic behaviors, and no visible changes on video or to direct testing.

Measures were taken to protect participant confidentiality. Subjects were assigned a study identification number and study identification numbers were linked to patient names and medical record numbers in a password-protected database. No substantial risk was seen due to participation in this study. There was also no cost or direct benefit. During this study, monitors were provided by Emfit®. After the study is complete, they will be returned to the company.

Investigation Initiation and Completion Dates

Current Investigation Dates: March 15, 2011 – March 15, 2012. Investigation End Date: March 15, 2012.

Results

Fifty one patients were included in the study, with 31 being female and 20 being male. Their weight ranged from 47-144kg with a mean of 78.8kg and their ages from 18-81 with a mean of 37.6. Age at epilepsy onset ranged from birth to 75 with a mean of 26.8. Number of AED's ranged from 0-5 with a mean of 1.6, and the number of prior AED's ranged from 0-16 with a mean of 1.6 as well. This population included 5 patients with generalized epilepsy, 30 with focal epilepsy, and 16 patients with a diagnosis of non-epileptic events.

18 GTCs occurred in 13 patients (5 patients had 2 GTCs each) with focal epilepsy. 16 of these 18 resulted in true alarms, and 8 of these occurred while the patient was awake and the other 8 while asleep. The two missed GTCs occurred during wakefulness and none were missed during sleep. Of these 13 patients, 9 were female and 4 were male, their weight ranged from 50 to127kg, and ages from 20 to 81 years.

93 other events occurred. None of them triggered an alarm. These included 19 other motor seizures, specifically, atonic, myoclonic, and automotor seizures and five staring spells. There were also 14 subclinical seizures and 11 epileptic subjective paroxysmal behaviors. Of note, one of 44 non-epileptic subjective paroxysmal behaviors was a convulsive non-epileptic seizure. Other non-epileptic paroxysmal events included pseudo-syncope, dizzy feelings, hot flashes, panic attack, strange sensations, slurred speech, word finding difficulty, hearing voices, and memory loss.

All 21 false alarms occurred during wakefulness with 18 of those being due to rhythmic activity. These activities included bouncing, scratching, flossing, tapping, scrubbing, nodding, laughing, and getting into bed. It is unclear what caused the other 3 wakeful false alarms. In two of them, the patient was seen to be looking around and in the other no movement was noted.

In summary, during a total of 3741 hours of vEEG monitoring 132 events transpired with 37 Emfit® alarms being activated. This alarm set included 16 true positives, 93 true negatives, 21 false positives and 2 false negatives. A further subset concentrated on nocturnal events, which included 8 true positives, 20 true negatives, 0 false positives, and 0 false negatives making this device 100% sensitive and 100% specific to events occurring out of sleep.

State	Sensitivity	Specificity	PPV	NPV
Awake	0.80	0.78	0.28	0.97
Sleep	1.00	1.00	1.00	1.00
Overall	**0.89**	**0.82**	**0.43**	**0.98**

Discussion

Our data show that the device was able to identify 16 out of 18 overall GTCs and all 8 GTCs that occurred at night. The importance of this finding is that missing night time GTCs can have disastrous consequences when compared to missing day time GTCs. The two undetected GTCs occurred both in patients who had one other GTC that occured in the following 2 to 5 hours. The false negative alarms during wakefulness are most likely due to the patient's upright positioning aided by multiple pillows while in bed. Both situations are a consequence of the sensor being tested in hospital beds, and would likely not be occur with home use and was also not seen during night time.

86% of day time false positives were due to rhythmic patient movements, which in a home setting could be easily cancelled by the caregivers. No false positives occurred during sleep which is important because they would lead to constant attending to a patient who is not seizing. As expected, atonic, myoclonic, automotor, staring, and subclinical seizures as well as auras were not picked up by the device. Non-epileptic seizures and most notably one convulsive pseudo-seizure that occur did not trigger an alarm implying the device's specificity to epileptic convulsions.

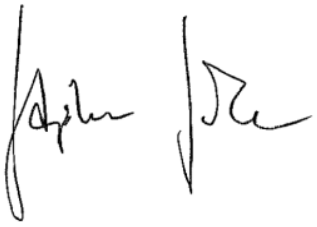
Potential Applications

The Emfit® device appears very useful in the scenario of nocturnal generalized convulsion detection which can be utilized in the home or in the EMU setting. Its audible alarm capability can alert caregivers to assist their loved one during a seizure much faster and easier, especially during the night time. Based on our findings to date, the Emfit® monitor is an effective method of GTC detection and may be a novel way of preventing SUDEP.

Signature

Place and date of issue: Chicago, IL, April 12, 2012

Name, function, signature:



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