Seizure detection devices: the newest gadgets on the block

Melissa Tsuboyama, MD 2020 Michael J. Bresnan Child Neurology Course





Disclosures

- No relevant financial disclosures
- No ties to any of the companies or products that will be mentioned



Non-FDA cleared technology

- Many of the sensors in this talk are not FDA-cleared and have not been validated in children
- Some sensors in this talk are not considered medical devices.





Utility of Seizure Detection Devices (SDD)



- Inpatient EEGs detect up to 29x the number of seizures reported by families (and 7x the number of those observed by nursing)
- Self/Family-reporting is unreliable
- And patients/families know they are missing seizures!

Zhao and Lhatoo, 2018; Bruno et al., 2020





Is seizure detection or seizure count useful?

- AED management
- Patient safety/SUDEP
- Patient/caregiver peace of mind, increased independence
- Clinical trials for new treatments





Ideal device

- □ 100% sensitivity & specificity*
- □ Detects all seizure types
- ☐ Cheap/affordable
- ☐ Cosmetically blends in/wearable
- ☐ Automated/Limited user input/action required
- □ Long battery life
- ☐ User-friendly interface

- *People with epilepsy (PWE), caretakers, physicians:
 - Sensitivity > 90%
- False alarm rate (FAR) < 1/sz
 detected and 1/week for sz-free
 PWE

Van de





- EEG
- sEMG
- Electrodermal activity (EDA)
- EKG
- Accelerometry (ACM)
- Motion detection

- Seizure alert dogs
- Skin temperature
- Respiratory monitor
- Pulse oximetry
- Multimodal



Embrace2 Watch

- Multimodal
 - Gyroscope
 - ACM*
 - EDA*
 - Temperature
- Detects GTCs
- Latency: ~30 sec

- Sensitivity
 - EMU: 98%
 - Real world rest: 97%
 - Real world active: 87%
- FAR
 - EMU: 0.94/24 hours
 - 1.35/24h in pediatrics
 - Real world: 0.58/d





Dept HHS (US FDA), 2019; Caborni et al., 2017.



^{*}Biggest contributors to detection algorithm



Features:

- FDA-cleared (Ages 6+)
- Rechargeable (~48h)
- GPS
- Water-resistant

Requires:

- Rx for watch
- Subscription for seizure detection and caregiver notification

Troubleshooting tips:

- Wear on <u>non-</u>
 <u>dominant hand</u> if
 bilateral tonic clonic
 seizures
- Turn Rest Mode <u>OFF</u> when active*
- Ensure <u>snug fit</u> of adjustable band

https://www.empatica.com/embrace2/

* FDA clearance is with Rest Mo





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SPEAC system

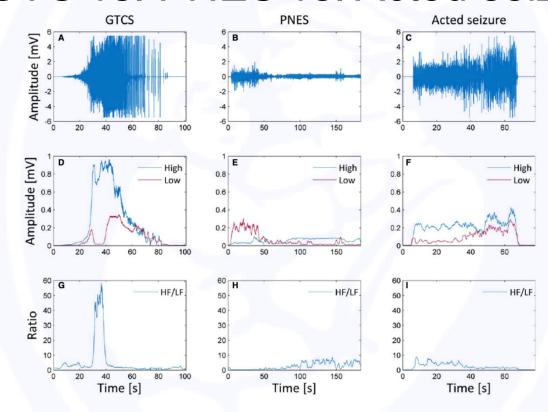
- Sensing Portable sEMG Analysis and Characterization system
- Detects GTCs
- Differentiates seizure vs PNES
- Accurate placement important

Beniczky et al., 2018, Halford et al., 2017



- Sensitivity: 94-95%
- FAR: 0.67/24h or 1.44-2.52/24h
- Latency: 5.3 7.7 sec

GTC vs. PNES vs. Acted seizure



Adapted from Beniczky et al., 2014









Features

- FDA-cleared (18+)
- Upper arm circumference ≥14 cm
- Recharge every 12 hours
- Portal w/data analysis for physician
- Has audio/microphone

Equipment

- Two sEMG monitors
- Arm band
- Laptop
- Wireless router
- Adhesive patches

https://speacsystem





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EmFit

- Flexible sensor under mattress connected to monitor
- Uses piezoelectric transducer to measure repetitive motion
 - Ballistocardiography
- Latency: 9 sec
- Performs best during sleep state, FAR 0.18/24h (awake)



Narechania, et al., 2013, Van Poppel, et al., 2013





Number and Types of Seizures Occurring During the Study Period, and Number Detected by the Emfit Movement Monitor.

Seizure type	Seizures captured	Seizures causing alarm activation	Seizures in sleep	Seizures in sleep causing alarm activation
Generalized tonic-clonic	16	12 (75%)	13	(1 (84.6%)
Simple motor	7	4 (57%)	4	2 (50%)
Complex partial with motor involvement	12	3 (25%)	2	2 (100%)
Tonic	11	3 (27%)	2	0
Myoclonic-tonic	12	I (8.3%)	2	0
Complex partial without motor involvement	9	`0 ′	1	0
Myoclonic	- 11	0	4	0
Total	78	23 (29.5%)	28	15 (53.6%)

45 subjects:

14 mo-28 years (7.8-115.3 kg, 24 males)

26 subjects, 78 seizures

Adapted from Van Poppel, et al., 2013





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Seizure Detection Devices Melissa Tsuboyama MD

SmartWatch Inspyre

App that is compatible with Android or Apple Watch

Features:

- Sends alert to designated caregivers w/GPS coordinates
- User activated help alert
- Can automatically record audio upon onset of event
- Provides graphical visualization of abnormal movement patterns, duration, severity of shaking

Requires:

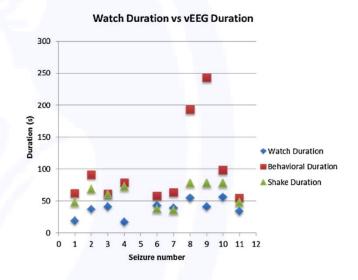
Smart phone, activation and subscription fees





SmartWatch Inspyre

- EMU 62 szs
 - 13 GTC
 - -49 non-GTC
- Sensitivity 92% (12/13 GTCs)
- Underestimates duration of seizures
- 81 false positives, 50% canceled by patient



Velez et al., 2016





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ePatch

- Algorithm based on short term HR variability
- For patients with marked autonomic changes (>50 bpm change in ictal HR)
- Sensitivity 87%
 - 20/23 seizures: included <u>8 focal impaired awareness</u>
 seizures and <u>2/4 focal aware seizures</u>
- FAR 0.9/24h (0.22/night)
- Up to 14d continuous monitoring



ePatch

Bi•Tel

Jeppesen et al., 2020



Other commercially available technology

- Motion detector cameras
- Pulse oximeter/heart rate monitors

Other wearable technology in the pipeline

- Epilog EEG
- Eysz eye movements
- Byteflies multimodal





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We are making progress, but have quite a ways to go!



Seizure Detection Devices Melissa Tsubovama MD

Application in Clinical Practice

- Semiology is key!
- Ties in with SUDEP counseling
- Appropriate counseling
 - Devices do not prevent SUDEP
 - Devices are not 100% accurate/sensitive/specific
 - Do provide an extra layer of monitoring
 - Can provide additional data
- DannyDid Foundation Grant Program:
 - https://www.dannydid.org/epilepsy-sudep/devices-technology/





Questions?



