DAY-TO-DAY LIFE RESULTS OF THE mjn-SERAS MEDICAL DEVICE FOR EARLY SEIZURE DETECTION.

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Abstract text
Purpose: For patients with drug-resistant epilepsy, an alert system that can predict seizure onset through a medical device could significantly enhance safety and independence. Artificial Intelligence (AI) leverages forecasting models for early seizure detection. This post-market study, part of the EIT Health Amplifier project, showcases the initial application of the in-ear EEG medical device, mjn-SERAS, integrated with an AI algorithm in daily life activities.
Method: Fifteen individuals previously diagnosed with drug-resistant epilepsy participated in a study conducted from May 2021 to April 2024 in an ambulatory environment. The study collected a total of 9,130 hours of data over 1,587 days, recording xxx seizures. The validation split study involved continuous monitoring, with a combined usage of all devices amounting to 3,590 hours and a total of 168 seizures recorded. All devices are CE marked in accordance with Europe's Medical Device Directive (MDD).
Results: The final accuracy of the individual models averaged 82%, with a sensitivity of 72% for the number of seizures detected. The specificity, measured in hours over the total usage days, was 97%. The False Alarm Rate (FAR) per day during interictal periods was 0.50 when considering the total number of false positive alerts. When assessing only interictal days with false alarms, the FAR per day was 0.37.
Conclusion: The results highlight a disparity between hospital records and daily life, showing a correlation quality of 70%. This discrepancy reveals challenges that necessitate enhancements in EEG recording, filtering, and algorithms. Current studies, such as SERAS-Home funded by EIT Health, must evaluate the implications of early warnings for users and explore the potential enhancements in quality of life. Developing patient-specific AI models for early seizure detection emerges as a crucial objective, particularly for individuals with drug-resistant epilepsy.

Keywords
Keyword 1: SEIZURES
Keyword 2: FORECASTING
Keyword 3: EARLY DETECTION
Keyword 4: mjn-SERAS
Keyword 5: MEDICAL DEVICES

Late Breaker Affirmation
Please specify why this is a late breaker abstract Results performed in April-May with the actual AI algorithms during the EIT Health project, are very interesting for the day-to-day using of wearables devices for predicting seizures. We can observe devices working on RWD, ambulatory system.

General
1. I confirm that I have previewed this abstract and that all information is correct. I am aware that the content of this abstract can be modified or corrected up to the abstract submission deadline, 2 February 2024. I accept that the abstract will be published exactly as submitted.: Yes
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