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Day-to-day life impact of the early seizure detection, using forecasting models in real time with mjn-SERAS device

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Introduction

Approximately 33% of epilepsy cases are resistant to medication, resulting in frequent and unpredictable seizures. An alert system before the onset of seizures could enhance safety and independence for these patients. Early seizure detection, a focal point in Artificial Intelligence healthcare algorithms, employs forecasting models in medical devices. This technical study presents the initial application of the in-ear EEG medical device mjn-SERAS with an AI algorithm in a real-world setting. The study assesses the device's capability to record EEG, process the data, and issue an alert preceding a seizure.

Methods

Thirteen devices were utilized with individuals previously diagnosed with drug-resistant epilepsy, capturing data from May 5, 2023, to January 11, 2024. The technical study involved continuous monitoring over eight months, encompassing a total of 116 days with ictal occurrences. The combined usage of all devices amounted to 810 hours of recording, averaging 7 hours per day. Notably, 193 seizures were documented. All devices bear the CE mark in accordance with Europe's Medical Device Directive. Warnings were evaluated in four time intervals: up to 15 minutes before user-confirmed seizures, 15 to 30 minutes before seizures confirmed by the user or MJN's dashboard, 30 to 120 minutes before seizures confirmed by MJN's dashboard, and more than 120 minutes before seizures, deemed unrelated to the seizure event.

Results

The distribution of seizure warnings indicates 39% within the preceding 15 minutes, 24% between 15 and 30 minutes, and 18% more than 30 minutes before the seizure. Notably, 19% are categorized as false positives on the same day but occurring more than 120 minutes before the seizure event.

The average warning lead time is 7 minutes for alerts within 15 minutes before a seizure, 26 minutes for the 15 to 30-minute interval, and 77 minutes for warnings beyond 30 minutes before a seizure event.

Data recording before the seizures has been a main factor, 46% of seizures have a correct pre-ictal period recorded, 40% of seizures have a pre-ictal with few incidences but processable and 14% of seizures have an incorrect pre-ictal recording due to artifacts, loss of data, disconnecting or other incidences not processable by the algorithm.

For algorithm training, the quantity of validated seizures is crucial. Users experiencing more than 10 seizures can achieve an average performance of 82% on ictal days, whereas users with fewer seizures fall below the 50% threshold. Criteria, such as having more than 10 validated seizures and less than 10% of incorrectly recorded days where insufficient pre-ictal data is captured, are considered in the evaluation process.

Conclusions

The results underscore the disparity between hospital records and daily life, revealing challenges that necessitate enhancements in EEG records and algorithms. Future studies, such as SERAS-Home, must evaluate the implications of early warnings for users and explore hypotheses regarding the potential enhancement in the quality of life. Developing patient-specific AI models for early seizure detection emerges as a crucial objective, particularly for individuals grappling with drug-resistant epilepsy.