Abstracts

Performance of Clarity, an Automated Seizure Detection Algorithm, in a Large Retrospective Dataset

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Authors :
Presenting Author: Suganya Karunakaran, PhD – Ceribell, Inc.

Archit Gupta, PhD – Ceribell, Inc.
Ali Marjaninejad, PhD – Ceribell, Inc.
Tanaya Puranik, MS – Ceribell, Inc.
Baharan Kamousi, PhD – Ceribell, Inc.

Rationale: Clarity, an automated seizure detection algorithm, uses point-of-care electroencephalogram (POC EEG) to provide continuous seizure burden (SzB) monitoring and bed-side alerts for suspected status epilepticus (SE). Since its release in 2020, Clarity has been regularly updated to improve performance in diverse seizure types. In this study, we evaluated the performance of Clarity's latest version in a large retrospective labeled dataset.

Methods: We analyzed a retrospective dataset containing 1148 POC EEGs collected from more than 10 hospitals. All epochs from each EEG recording were annotated by two or more Epileptologists into patterns such as Normal/Slow, Highly Epileptiform Patterns (non-seizure) (HEP), Seizure, or Status Epilepticus (SE). The reviewer's label that best represented a consensus among all reviewers was chosen as the final label for a file. The most severe category among all the epochs in the consensus label was assigned as the ground truth categorization of a file. The latest version of Clarity was run post-hoc on each of these recordings to obtain a maximum SzB per file. We identified cases in which the ground truth was SE and all cases in which Clarity would provide an SE alert (maximum SzB ≥90%) to determine the frequency of true positive, false negative, and false positive cases.

Results: In this dataset, there were 21 recordings with SE as the ground truth categorization and Clarity output indicated seizure burden ≥ 90% for 20 of them, demonstrating a sensitivity of 95%, specificity of 97%, negative predictive value of 99.9% and positive predictive value of 39% for SE detection. Of the cases that had seizure burden greater than 90% and were not categorized as SE, three-fourths of the cases were categorized as either seizures or highly epileptiform activity. Out of 28 recordings with ground truth categorization of seizures, not meeting criteria for SE, 3 were missed by the algorithm (Clarity seizure burden was 0) showing a sensitivity of 89.3% and specificity of 71% for seizure detection.

Conclusions: Clarity has a high level of sensitivity and specificity to identify suspected SE. It also has high sensitivity to short seizures and high negative predictive value to rule out SE or seizures.

These results suggest that Clarity can accurately monitor suspected SE in acute care practice, providing initial guidance to the bedside team to either escalate care or rule-out ongoing seizures.

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Neurophysiology

Performance of Clarity, an Automated Seizure Detection Algorithm, in a large retrospective dataset

Suganya Karunakaran PhD, Archit Gupta PhD, Ali Marjaninejad PhD, Tanaya Puranik MS, Baharan Kamousi PhD

Background

- The FDA-cleared **Ceribell seizure-burden monitoring algorithm, Clarity,** automatically and continuously monitors point-of-care EEG (POC EEG) and provides a seizure burden every 10 seconds. Seizure burden is the load of seizure activity in the last 5 minutes (Figure 1). [1]
- When the seizure burden (SzB) is equal or greater than 90%, it provides visual and auditory alerts at the bedside and on the online EEG portal (Figure 2). [2]
- One of the major advantages of AI algorithms like Clarity is that they have the potential to continuously improve performance over time.
- In this analysis, we evaluated the performance of Clarity's latest version in a large retrospective labeled dataset.

Methods

Dataset: Retrospective dataset of 1148 POC EEGs from 10+ hospitals.

Annotations:

- Epochs from each EEG were annotated by 2 or more expert Epileptologists into patterns such as a) Normal/Slow, b) Highly Epileptiform Patterns (non-seizure) (HEP), c) Seizure, or d) Status Epilepticus (SE).
- A reviewer's label best representing a consensus among all labels was chosen as "ground truth" per file.
- The most severe category in the file was assigned as ground truth categorization of a file.

Ground truth determination				
Status Epilepticus	Seizure	HEP	Normal/Slow	Total
21	28	195	904	1148

Analysis:

- Files in which Clarity would provide an alert for suspected SE (maximum Szb ≥90%) were identified and compared with ground truth.

Figure 1. Clarity analyzes the EEG and outputs seizure burden value every 10s

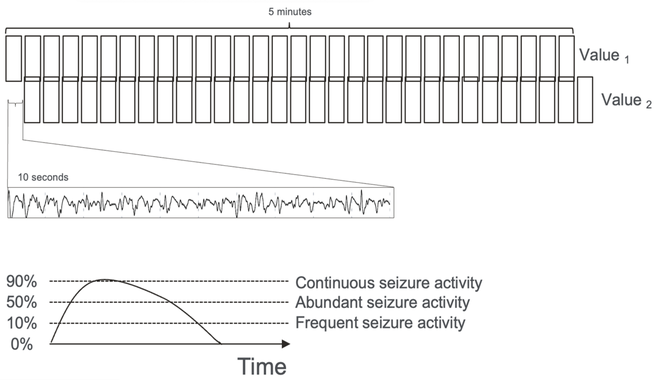
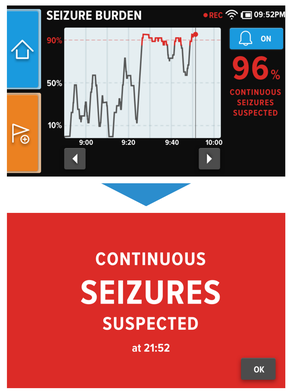


Figure 2. Seizure burden display and alert on Ceribell device when SzB >= 90%



Results

Table 1. Clarity performance in this dataset

	Ground truth determination				
Clarity v7.0 Seizure Burden	Status Epilepticus	Seizure	HEP	Normal/Slow	Total
≥90%	20	3	21	7	51
1-89%	1	22	80	216	319
0%	0	3	94	681	778
Total	21	28	195	904	1148

95% Sensitivity
Accurately detecting status epilepticus

97% Specificity
Accurately identifying non-status cases as not status epilepticus

99.9% Negative Predictive Value
Accurately ruling out status epilepticus

Conclusions

- Clarity V7.0 has a high level of sensitivity and specificity to identify suspected Status Epilepticus (≥90% threshold)
- In the single missed case of status epilepticus (highlighted orange in Table 1), Clarity still had >30% seizure burden.
- Of the cases with false positive suspected SE alerts, 77% were categorized as seizures or HEP by experts.
- The high negative predictive value of the algorithm for 90% SzB indicates that suspected SE cases can be ruled out accurately within minutes of EEG recordings and thus can help optimize treatment and interventions in critical care settings.
- Clarity V7 has 89.3% sensitivity and 71% specificity for short seizure detection (≥1% threshold)
- Two of the 3 seizures that were missed by Clarity (highlighted green in Table 1) were focal (in 4 channels) and very short, lasting 1 minute each.
- The negative predictive value (NPV) for 0% SzB ruling out the presence of status epilepticus or any seizure was 99.6%.

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All authors are employees of and have financial interest in Ceribell, Inc.

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