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CADTH Horizon Scan

Artificial Intelligence– Enhanced Rapid Response Electroencephalography for the Identification of Nonconvulsive Seizure

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Key Messages

What Is the Issue?

- A nonconvulsive seizure is seizure activity defined by an altered mental status, subtle limb twitches, or changes in speech. They are more difficult to identify than convulsive seizures as they do not have the distinctive motor activity associated with convulsive seizures.
- Patients in emergency departments (EDs) and intensive care units (ICUs) with suspected nonconvulsive seizures must be monitored with an electroencephalogram (EEG) to confirm diagnosis. Rapid detection of nonconvulsive seizures is crucial – a delay in treatment risks brain injury.
- There can be significant delays in accessing conventional EEG monitors and treatment because of limited supply in critical care settings, such as EDs and ICUs.

What Is the Technology?

- The Ceribell system is a rapid response point-of-care EEG designed for use in the ED and ICU to help identify patients who are having nonconvulsive seizures.
- The portable device has an artificial intelligence (AI) algorithm, Clarity, that monitors seizure activity within a 5-minute interval to determine the seizure burden during that time frame. The device alerts a bedside care provider if seizure activity occurs. This information can guide physicians' treatment plans.

What Is the Potential Impact?

- Within the ED and ICU, Ceribell could be used to increase access to EEG, allowing for faster detection of nonconvulsive seizures.
- Conventional EEG monitors are expensive and usually require a trained specialist to use and interpret findings. Most hospitals have limited access to conventional EEGs, which can lead to delays in treating patients with nonconvulsive seizures.
- In critical care settings, Ceribell may improve efficiency and patient flow by shortening time to diagnosis, preventing unnecessary treatment escalation, decreasing transfers to tertiary care hospitals.

What Else Do We Need to Know?

- The Ceribell system is not available in Canada as of this writing.



Key Messages

- The Ceribell system could improve time to treatment for patients with suspected nonconvulsive seizures due to the complexity and personnel needs of conventional EEG systems.
- Current research on the Ceribell system has mostly been retrospective with small sample sizes; therefore, the results may not be generalizable to a wider population.
- If the system is implemented in hospitals, training is required to ensure that all health care professionals in the ED or ICU know when to order the portable EEG so that the use of Ceribell is prioritized for patients with suspected nonconvulsive seizures.
- Datasets used to train AI algorithms tend to underrepresent equity-deserving groups, so implementing AI systems such as Ceribell with Clarity in health care settings could increase health care inequity for those not well represented in algorithm data.

What Is the Technology and How Does It Work?

The Ceribell system is a point-of-care EEG device.¹ The system uses an AI algorithm, called Clarity, to detect the amount of seizure activity over a 5-minute period, which indicates the seizure burden (e.g., percentage of time that EEG shows seizure activity) over that time period. Care providers can use this information to create an informed treatment plan.²

The Ceribell system ([Figure 1](#)) includes:¹

- a flexible headband with 10 electrodes that wraps around the patient’s head
- an EEG recorder powered with a battery that presents the EEG waveforms and performs AI monitoring using the Clarity algorithm
- access to a digital portal that can be accessed remotely by neurologists that provides real-time streaming of EEG data.

Non-neurologist health care professionals in the ED or ICU receive training on how to use the Ceribell system.¹ The Ceribell EEG is set up and connected to patients who are suspected of having nonconvulsive seizures by emergency physicians, nurses, or allied health staff in the ED or ICU.^{1,3} A green indication is displayed for each electrode when the device is accurately connected, and bedside monitoring can begin.³

Figure 1: Ceribell EEG Headband and Recorder



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The Clarity algorithm evaluates EEG signals over a 5-minute period.² The thresholds for seizure activity that are used by Clarity are based on those described by the American Clinical Neurophysiology Society.¹ They are 10% or greater (≥ 30 seconds of seizure activity in the last 5 minutes), 50% or greater (≥ 2.5 minutes of seizure activity in the last 5 minutes), and 90% or greater (≥ 4.5 minutes of seizure activity in the last 5 minutes).¹ If seizure activity exceeds 4.5 minutes out of the 5 minutes, the alarm rings to notify the bedside care provider of possibly or suspected status epilepticus.²

The Clarity algorithm monitors the seizure burden and the effects of treatment (i.e., medications) on the seizure burden; it does not indicate the presence of individual seizure episodes.² Once the seizure burden is determined, the care provider can assess their treatment plan and decide whether treatment should be escalated.²

Who Might Benefit? How Could This Change Care?

Nonconvulsive seizures are seizure activity without motor activity, but with altered mental status and/or slight limb twitches and movements.⁴ Compared to convulsive seizures, the clinical features of which include continuous jerking and stiffening of muscles, nonconvulsive seizures are harder to identify. The clinical features of nonconvulsive seizures include cognitive impairment, an altered state of consciousness, subtle limb twitches, or changes in speech.⁴ Patients with suspected nonconvulsive seizures need to be identified quickly because a delay in treatment could lead to worsening of symptoms.⁴

EDs and ICUs rely on conventional EEG monitors that are expensive, complicated to use,⁵ and require EEG technologists to operate and interpret the results.¹

Some EDs do not have all-hours access to EEG monitors.⁵ This can delay initiation of monitoring patients with suspected nonconvulsive seizures and to subsequent delays in treatment.

A delay in treatment could lead to status epilepticus – an increased seizure burden with continuous seizure activity (without a return to normal electrical activity for at least to 30 minutes), brain and neuronal injury, increased patient morbidity, and potentially long-term cognitive disability.⁶ Consequently, it becomes harder for patients to respond to seizure medications. This can lead to a longer length of stay in the hospital, which can be costly.⁶

Due to delays in access to conventional EEG, ED physicians and intensivists often rely on clinical suspicion versus objective measurement to diagnose nonconvulsive seizures.⁶ As a result, patients with nonconvulsive seizures can be either undertreated or overtreated.⁶ Patients with subtle clinical symptoms that appear to indicate low seizure activity can be undertreated, which could lead to brain injury.^{6,7} Patients who appear to have high seizure-like activity or tendencies could be overtreated with antiseizure medication.⁷ Antiseizure medications often have adverse effects, such as sedation (which can lead to intubation in cases of

oversedation).⁶ Adverse effects can lengthen hospital length of stay and further increase costs associated with care.⁶

Some hospitals in remote or rural areas require transport and transfer of patients with suspected nonconvulsive seizures to tertiary care centres to access conventional EEG.^{3,8,9} When patients are transferred to other hospitals with no change in treatment, it can be frustrating for patients and their families, particularly when the hospital is far from their local one.⁸ This can increase the emotional toll of hospitalization for a patient and add extra costs to the families of patients to travel to a tertiary care centre.³

Using the Ceribell system at centres without consistent access to conventional EEG could help identify nonconvulsive seizures sooner and with more accuracy than relying on physician suspicion. This could alleviate problems that can be associated with delays in treatment, transport and transfer of patients, as well as undertreatment or overtreatment of patients with suspected nonconvulsive seizures. The conventional EEG requires a specialist to interpret findings, but Ceribell has been shown to be easy to use and to interpret EEG data, providing an objective measure of seizure burden at the point of care when a conventional EEG device is not available.^{6,10} The system also has a portal that neurologists can access remotely to guide treatment decisions.¹

How Is It Used in Canada?

Ceribell is not licensed for clinical use in Canada at the time of this writing. However, market authorization is expected in 2026. The system is currently being used in 2 clinical studies in Ontario (Raymond Woo, Chief Technology Officer, Ceribell, California: personal communication, October 13, 2023).

It is the first device that has been cleared by the FDA for monitoring seizure burden in the US.¹ It is used in several academic centres and community hospitals in different regions (California, Illinois, Massachusetts, Texas, and North Carolina) of the US.⁵⁻⁷

What Does It Cost?

No information regarding the cost of Ceribell was identified in Canada or elsewhere, although a subscription-based pricing structure is anticipated for Canada. The subscription would include upgrades, training, and retraining along with a cost for consumables such as the Ceribell EEG headbands (Raymond Woo, Chief Technology Officer, Ceribell, California: personal communication, October 17, 2023).

Economic models have predicted that implementing the rapid EEG in EDs and ICUs could reduce hospital costs.¹¹ Compared with conventional EEG devices and EEG specialists, modelling predicts that the Ceribell system could reduce the length of stay and hospital transfers in more remote areas, which could lead to cost-savings.¹¹

A cohort study including 22 uses of the Ceribell system found that costs associated with setting up and implementing the devices in a hospital were lower than the costs associated with interhospital transfers and current standard of care.³ Likewise, studies have reported that time to treatment with the Ceribell EEG, including time to initiation and interpretation, was less than the time recorded with conventional EEG monitors.^{1,5} Assuming the evidence continues to show effectiveness, implementation of the Ceribell system could lead to an increase in efficiency in EDs and ICUs, allowing health care staff to treat more patients.⁵

Community hospitals that have implemented the Ceribell system have noted that training of health staff in the ED and ICUs was easy and well accepted.^{5,6} Training sessions could be done in person or online.^{5,6} There was no mention of special training requirements, implying implementation of the point-of-care EEG can be easily facilitated and managed.

What Is the Evidence?

The 9 studies that examined the use of the Ceribell system that we identified were nonrandomized;^{1,3,5-7,10-13} 5 studies were retrospective.^{1,3,5,12,13} No randomized controlled trials were identified. Sample sizes were small. There were few economic evaluations that were conducted, namely cost-benefit analyses.¹¹ The manufacturer either funded and supported the work or reviewed the manuscripts, providing critical feedback for most studies. All studies identified included adult participants; the average age of participants was mid to late 50s.

Diagnostic Test Accuracy of the Clarity AI Algorithm

A retrospective review was used to test the ability of the Clarity AI algorithm to measure seizure burden in adult patients at risk of seizures.¹ In this study, 353 EEG recordings from 249 people were evaluated for possible seizures with Clarity and the results were compared to expert neurologists' opinions.¹

For the 17 people who had seizures, the algorithm was good at identifying those seizures.

**The higher the seizure burden, the more accurate the algorithm was.¹
The study authors suggested that the algorithm was reliable for extreme cases of seizure burden but not for milder cases with shorter seizure activity.¹**

Clarity was found to have 99% negative predictive value, indicating it was good at predicting the patients who did not have seizures.¹ Overall, Clarity was able to detect seizures in the patients with high seizure activity and was able to rule out seizures, both of which could impact treatment decisions.¹

Another study conducted to compare the quality of EEG signals recorded with the rapid response EEG to signals recorded with a conventional EEG monitor found that the quality was similar in both a controlled laboratory and ICU setting.¹⁴

How Does Ceribell Compare the Standard of Care?

Two prospective observational studies^{6,7} found the use of the Ceribell rapid response EEG in the ICU (N = 181) and ED (N = 44) setting was associated with faster diagnosis time, a change in clinical management, less treatment escalation, and faster patient discharge compared with the standard of care.

ICU Setting

A multicentre study included 5 academic hospital ICUs in different regions of the US. In this study, physicians monitored 181 adult patients with brain injury who were suspected of having nonconvulsive seizures.⁶ The study compared physicians' own clinical judgment with the rapid response EEG data provided by Ceribell.⁶ Overall, Physicians found the device was easy to use and it improved their confidence in diagnosis and treatment (including increases or decreases in antiseizure medication).⁶

Monitoring with Ceribell tended to:⁶

- improve the correct detection of seizure activity (sensitivity increasing from 77.8% to 100%)
- improve the correct detection of the absence of seizure activity (specificity increasing from 63.9% to 89%)
- shorten the amount of time to results (approximately 5 minutes vs. approximately 2.75 hours to 4.8 hours with conventional EEG).

The authors found that use of Ceribell led to timely and more accurate assessments of seizure burden.⁶

ED Setting

Emergency physicians at 2 ED sites (an academic and a community hospital) monitored adult patients (N = 44) suspected of nonconvulsive status epilepticus.⁷ Use of Ceribell ruled out seizure burden causing the treatment plan to change in 53% of patients.⁷ Use of Ceribell also enabled faster discharge of 21% of the patients due to the faster nature of getting and interpreting the EEG results with the device.⁷ The authors concluded that using the rapid EEG in the ED may result in faster diagnosis and could lead to quicker discharges and fewer unnecessary treatments.⁷

Lessons From Hospitals That Implemented Ceribell

The Ceribell EEG system has been validated in the ICU and/or ED at various academic and community hospitals. One study was prospective;¹⁰ 4 studies used a historical control to determine whether Ceribell would be useful at the centres.^{3,5,12,13}

- The use of Ceribell resulted in similar diagnostic information that matched data and interpretation with the conventional EEG system.¹⁰
- Implementation of Ceribell resulted in a 3.29-fold increase in the number of EEGs ordered in a community hospital ICU and ED that previously had 1 EEG monitor divided between inpatient and outpatient settings.⁵
- At an academic¹³ and a community hospital,⁵ implementation of the rapid EEG decreased the time between ordering the EEG and using it to monitor patients, with the community hospital⁵ reporting a decrease of 8 hours.

- Using the Ceribell system reduced the time between diagnosis and treatment.³
- Implementation resulted in a decrease of treatment escalation to antiseizure medications in various settings.^{10,12,13}
- In a hospital where EEG was not available, use of Ceribell reduced the number of transfers to a tertiary care centre.³
- Nurses and physicians found the Ceribell system easy to use.^{5,10} Nurses also felt with the use of remote real-time monitoring of Ceribell, they had more time to spend on patients “on the ground.”⁵

Overall, in community and academic settings, Ceribell seemed to improve the efficiency of detecting nonconvulsive seizure activity in the ICUs and EDs that implemented it.

Safety

One study reported scalp irritation and bruising with the use of the headband in 1 patient; however, the patient had thrombocytopenia. Symptoms resolved after treatment with anticoagulants.⁶

Issues to Consider

Study Types

Most of the studies we identified had positive conclusions related to the Ceribell system; but most were retrospective, had small samples, and had ties to the manufacturer. The retrospective nature of the studies makes it difficult to compare the groups who were monitored with the rapid EEG system and the conventional EEG system.⁵ Therefore, despite promising results of the rapid EEG system, it is difficult to determine whether wider use of Ceribell would lead to improved efficiency and costs for hospitals. Although some studies were conducted in multiple geographical regions,⁶ smaller sample sizes reduce generalizability of the results. Most of the research was connected to the manufacturer, which has a stronger potential for bias than if not. It becomes challenging when interpreting results to distinguish product advertisement from beneficial effects of implementing the service.

Adequate Training

A quality improvement study conducted in an ED investigated whether educating non-neurologists would have an effect on the appropriate use of Ceribell.¹⁵ Researchers found that education did not change EEG ordering habits of health care professionals who acquired the Ceribell system.¹⁵ Instead, they found non-neurologists continued to order Ceribell for patients who did not meet the criteria for nonconvulsive status epilepticus, such as patients with convulsive status epilepticus.¹⁵ If Ceribell becomes available in Canada, it will be important to train all health staff that work in EDs and ICUs on what the appropriate use is for ordering the portable device to monitor patients. Patients with suspected nonconvulsive seizures should be prioritized for monitoring with the device. Without training, there could be overuse or overordering of the device for

patients who do not need it, which could have downstream effects on costs and allocation of resources.¹⁵ Hatcher et al.¹⁵ proposed creating an ordering algorithm to avoid this problem.

Access to High-Speed Wi-Fi

Using Ceribell in rural and remote areas has the potential to reduce the burden on patients and hospitals associated with interhospital transfers to access conventional EEGs. However, the lack of high-speed Wi-Fi in rural areas poses a potential risk.^{16,17} Ceribell has a portal that expert neurologists can use to review EEG data and monitor patients remotely.¹ Physicians need quick, secure, and Health Insurance Portability and Accountability Act (HIPAA)–compliant Wi-Fi to access the portal.¹ The Wi-Fi in rural areas tends to be slower with limited bandwidth, which can affect neurologists' ability to review the EEG data remotely.¹⁶ This can impact care in EDs and ICUs where non-neurologist staff rely heavily on remote neurologists. There may be delays in treatment, which could increase the morbidity of people with suspected nonconvulsive seizures.⁶

Challenges With AI Acceptability and Algorithms

Some health care professionals could resist using AI.¹⁸ The introduction of AI in hospital settings has the potential to change the type of expertise needed for health care professionals to use certain medical devices.¹⁸ This could be felt as a positive for some (potentially reducing workloads and increasing capacity for some health care professionals) or as a potential threat to others (potentially worrying that roles or number of people in a department could be reduced or eliminated).

With the development of AI, there has been an issue with datasets used to train algorithms in all sectors.¹⁸ Health care datasets tend to underrepresent equity-deserving groups as well as groups with disabilities or rare diseases.¹⁸ This is because racialized people and people with rare medical conditions are usually underrepresented in clinical trials and medical research. As a result, implementation of AI systems in health care has the potential to worsen inequities in health care.^{19,20}

Related Developments

There are several point-of-care EEG devices emerging to help facilitate diagnosis and treatment of patients with seizures. Some use AI algorithms to help with function but not all rely on AI.

- Zeto EEG, which has been cleared by the FDA, monitors seizure burden and activity in children and adults using seizure detection software.²¹ Hospitals that have implemented the device are satisfied with the ease of use, increased efficiency, and its ability to be used in remote rural areas.²¹
- An AI model, called Standardized Computer-based Organizing Reporting of EEG-Artificial Intelligence (SCORE-AI) was developed to distinguish EEG recordings and classify abnormal EEG recordings into categories that can be used to guide clinical decision-making.²² A diagnostic study to validate the SCORE-AI found it was able to accurately categorize EEG abnormalities and performed as well as human experts.²²

- A research team in Europe conducted a feasibility study of a rapid EEG used for children with suspected nonconvulsive status epilepticus, in a pediatric ED.²³ Physicians found the device to be useful in diagnosing seizures and found that applying the electrodes on children was mostly “easy.”²³
- A research team in Boston also developed an emergency EEG device called StatNet that could be used by health care personnel who were not extensively trained.²⁴ Information regarding the trial results was unavailable.

A research team designed a study to explore the relationship between Ceribell and delirium status.²⁵ Rapid behavioural assessment tools used for identifying tend not to perform as well in clinical practice as they do in research settings; therefore, if found to be effective, Ceribell could be a tool for identifying patients with delirium in the ICU.

Looking Ahead

The use of Ceribell was associated with shorter hospital stays, a change in treatment plan, fewer escalations to antiseizure medications, and a decrease in patient transfers.^{3,5,10,12,13} Using the point-of-care EEG also improved diagnosis of nonconvulsive seizures.^{5,6} Evidence suggests that Ceribell could avoid delayed treatment for patients with suspected nonconvulsive seizures with accessing conventional EEG systems; however, these studies have been small. Independent randomized controlled trials with larger sample sizes are needed to further determine the usefulness of Ceribell.

Ceribell offers a clinical decision support tool for health care professionals as they treat patients with suspected nonconvulsive seizures in EDs and ICUs. If additional trials find it to be effective, it could positively impact hospital systems by allowing for more rapid diagnosis of nonconvulsive seizures, improving the likelihood of positive patient outcomes, and making care more efficient in EDs and ICUs.

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Appendix 1: Methods

Literature Search Strategy

An information specialist conducted a literature search on key resources including MEDLINE, Embase, and PsycInfo through the Ovid platform; the Cochrane Database of Systematic Reviews; the International HTA Database; the websites of Canadian and major international health technology agencies; as well as a focused internet search. The search approach was customized to retrieve a limited set of results, balancing comprehensiveness with relevancy. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. Search concepts were developed based on the elements of the research questions and selection criteria. The main search concepts were rapid or AI-based EEG, for point-of-care or ED, and nonconvulsive seizures; or the Ceribell Rapid Response EEG. The search was completed on September 20, 2023, and limited to English-language documents published since January 1, 2017. Regular alerts updated the database literature searches until November 6, 2023.

Selection Criteria

One author screened the literature search results and reviewed the full text of all potentially relevant studies. Studies were considered for inclusion if the intervention was Ceribell or point-of-care EEG. Conference abstracts, abstracts of texts not found, and grey literature were included when they provided additional information to that available in the published studies.

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