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Original Article

CEREBO: A Portable Device for Non-invasive Detection of Intracranial Hematomas in Real Time

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ABSTRACT

Context: Brain injury has become a silent epidemic and has very low survival and recovery rates because of inaccurate triaging, especially in absence of symptoms. Therefore, a clinical assessment tool for quick onsite detection of intracranial hematoma is necessary. Aims: This study aims to assess the efficacy of the near infrared-based device CEREBO for the non-invasive detection of intracranial hematomas in traumatic head injury patients. Settings and Design: Observational, prospective, cohort, single-center study .Methods and Materials: Forty-four patients recruited from the Department of Neurosurgery of ESIC Medical Hospital, Faridabdad, between 3 and 85 years from June 2023 to June 2025 were examined by CEREBO and computed tomography (CT) scan within 72 h post-injury or first onset of symptoms to measure the desired parameters. Statistical Analysis Used: SAS 9.4. Results: The device exhibited high sensitivity (94.87%) and specificity (76.19%) for unilateral hematomas with a positive predictive value (PPV) of 93.67% and a negative predictive value (NPV) of 80%. For bilateral hematomas, the device exhibited a sensitivity of 80%, specificity of 77.78%, PPV 83.33%, and NPV 73.68%. Conclusions: This study establishes the efficacy of CEREBO to be used as a point-of-care medical screening device for detecting brain hematomas in patients who have had a head injury and is therefore recommended as an adjunct to CT scan. In the triaging or diagnosis phase, it allows for early treatment and thus helps to reduce the secondary injury resulting from the existing and delayed hematomas.

Keywords*: Traumatic Brain Injury, Intracranial Hematoma, Near-Infrared Spectroscopy (NIRS), Point-of-Care Screening, CEREBO.*

INTRODUCTION

Traumatic brain injury (TBI) affects 69 million people globally every year and more than 8 million are misdiagnosed.[1],[2],[3] This delays medical attention and hence treatment. That is why TBI is associated with very high mortality and disability rates.[3] A study by Seelig et al. revealed that the mortality due to hematomas can be reduced from 90 to 30% if hematomas are operated on within 4 h of injury.[4]The aim of the present study was to assess the efficacy of CEREBO in accurately triaging trauma patients by detecting intracranial hematomas at an early stage thereby reducing the time from injury to treatment

SUBJECT AND METHODS

This prospective observational single-center cohort study was approved by the Ethics Committee of the ESIC Medical college , Faridabad. The study included 44 patients (both male and female) who visited the neurosurgery department with a TBI within 72 h from injury or the beginning of the first symptom and were referred for a CT scan from June 1, 2023, to June 30, 2025. Patients with bruising or hematoma on the scalp or with a history of neurosurgical procedures were excluded.

Each patient or their relative gave their informed consent before starting the procedure. Once the consent was obtained, CEREBO was used to scan all accessible locations on the subject's head from the following eight lobes of the brain–frontal left, frontal right, temporal left, temporal right, parietal left, parietal right, occipital left, and occipital right [Figure 1].

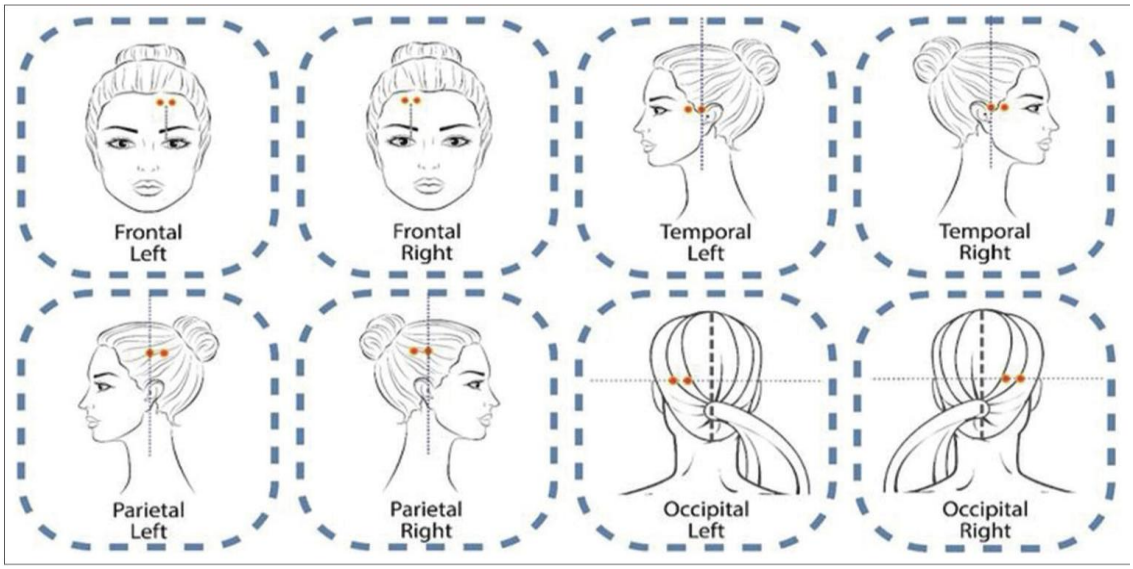

Figure 1: Measurement Locations for scan using CEREBO

Eight patients were examined before the CT scan and the other 36 patients, post to the CT scan. The number of datasets collected was impacted by the number of CT scans each patient was recommended. The duration between the CEREBO and CT scan can be seen in [Figure 2]

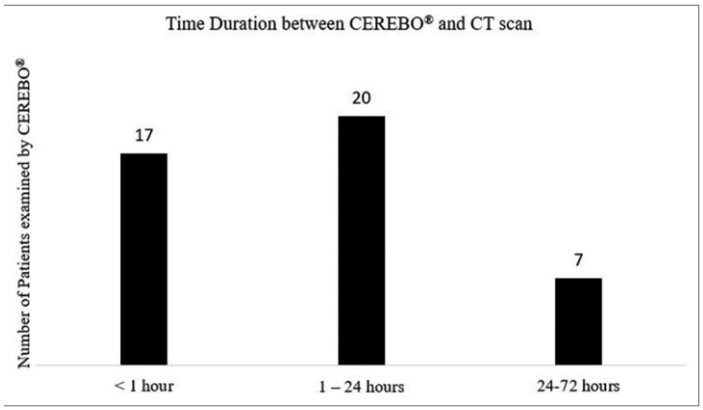

Figure 2: Duration between the CEREBO and CT scan. The time period was divided into three categories: less than 1 hour, between 1 to 24 hours and 24 to 72 hours

CEREBO principle and operation

CEREBO uses near-infrared light to calculate the optical density (OD) in different regions of the brain. The light emitter and receiver are spaced 3.5 cm apart, allowing the intensity of light to be measured from a depth corresponding to intracerebral hemorrhages. CEREBO works by comparing the OD values of the right and left hemispheres of the brain in four different regions. The absorption rate of near-infrared light on the hematoma side of the brain is greater than that on the contralateral non or smaller hemorrhagic side, thus it reflects less light. A hemorrhage was confirmed if the absolute value of OD ratio was greater than 0.1, otherwise, it was considered non-hemorrhagic or smaller hemorrhagic.

CEREBO is an easy-to-use device [Figure 3], which takes less than 30 min of training. It guides the operator at every step. While in use, the screen displays the instruction on the display so that the operator can refer at any given point in time. Also, the device is pre-installed with a “How to Use” help video, thus, making the process simple for the operator. The major focus of the device training is the identification of lobe location. The device needs to be placed in contact with the scalp at the lobe location to scan it. In our study, the average scan time per location was 32.5 ± 8.84 s. [Figure 3]

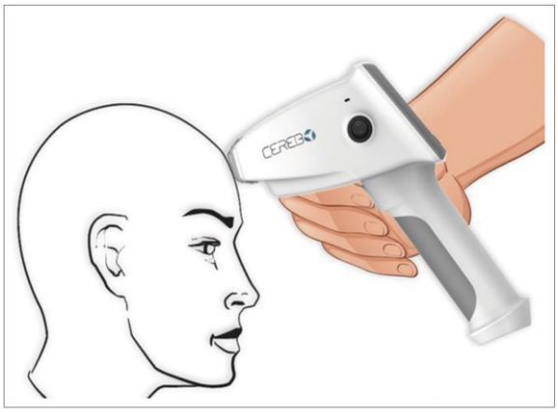

Figure 3: Examination of the left frontal lobe using CEREBO. The device is kept perpendicular to the lobe and then the button is triggered to initiate the scan

The operating steps are as follows: (I) Place the disposable cap on the head of CEREBO and switch on the "POWER" button (II) Select "START SCAN" on the home screen (III) Select "LOCATION" using the navigation keys (IV) Press "TRIGGER" button to initiate the scanning (this will be indicated by a buzzer as well as by a LED blinking green light) (V) Scan at least two contralateral locations and then long press "OK" to generate the color-coded result on the display where green indicates non-hemorrhagic lobe, whereas red indicates hemorrhagic lobe [Figure 4]

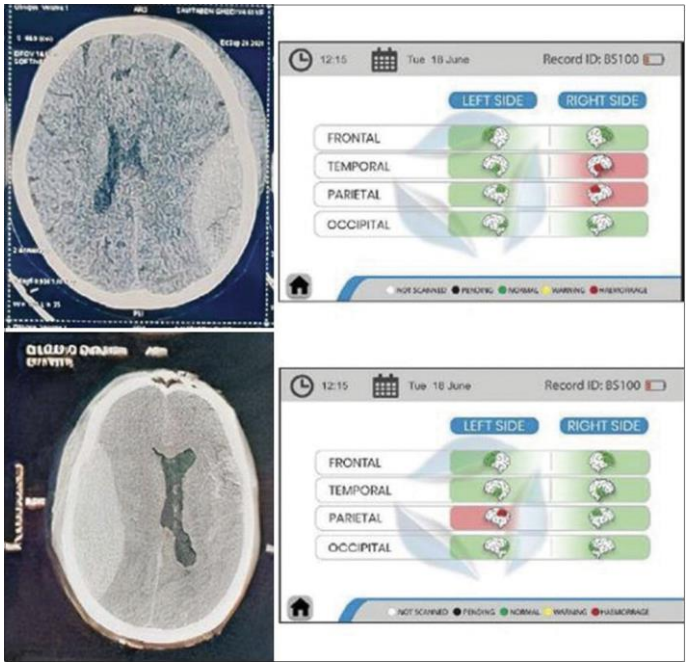

Figure 4: Comparison of Pathological CT scan with the CEREBO result - right tempo-parietal hematoma and left parietal hematoma

Data collection and statistical analysis

A subject number was uniquely assigned to each patient whose head was scanned using the CEREBO, along with his/her age, gender, date, and type of injury, Glasgow Coma Scale (GCS) score, date of CT scan, date of CEREBO scan, duration of the scan, and CEREBO measurement (output and input).

Each contralateral lobe pair examined was considered an independent case for analysis. The specificity, sensitivity, positive predictive value (PPV), negative predictive value (NPV), and accuracy of the device to detect intracranial bleeding in comparison to the reference examination, CT scan was calculated using descriptive statistics on SAS 9.4 statistical software. Results were categorized into true negatives, true positives, false negatives, and false positives based on the normative derived 95% confidence interval (CI). Further, a t-test was used to determine a significant relationship between the two groups—hemorrhagic and non-hemorrhagic; $P < 0.005$ was considered to be statistically significant. For the purpose of clinical parameter computation, the contralateral lobe pairs were categorized into unilateral and bilateral intracranial hemorrhages. Another categorization was done based on the depth of hematoma into epidural, subdural, intracerebral, and subarachnoid hemorrhages.

RESULTS

The demographic data of the participants are outlined in [Table 1]

Table 1: Baseline and demographic characteristics

Characteristics	Number (%) or Mean±SD		
Total number of patients	44		
Age	39.2±19.05		
	Median (37)		
	Range 3.0 to 85.0		
Male patient	29 (65.91%)		
Female patient	15 (34.09%)		
Non-traumatic patients	5 (11.36%)		
(GCS Score)	**Mild**	**Moderate**	**Severe**
	2 (40.00%)	3 (60.00%)	0 (0.00.%)
Traumatic patients	39 (88.64%)		
(GCS Score)	**Mild**	**Moderate**	**Severe**
	8 (20.51%)	19 (48.72%)	12 (30.77%)

*(GCS - Glasgow Coma Scale)

GCS scores were recorded, and the patients were classified into mild, moderate, and severe TBIs. Statistically significant difference in OD values of left and right hemispheric lobes was seen between the hemorrhagic (M = 0.33, standard deviation [SD] = 0.21) and non-hemorrhagic patients (M = 0.04, SD = 0.03); t (119) = 6.972, P < 0.001. [Figure 5]

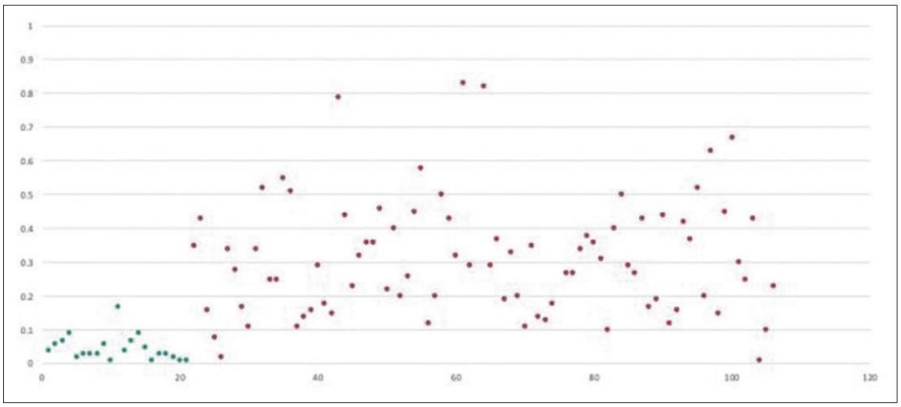

Figure 5: Difference in the Optical Density obtained using CEREBO Patients with no hemorrhage are denoted in green and the ones with hemorrhage are shown in red shows the calculated absolute optical difference in the study participants clusters—hemorrhagic and non-hemorrhagic.Patients were classified into two groups—unilateral (74.29%) and bilateral (25.71%) hematomas. The accuracy indexes derived from the patients with unilateral and bilateral hematomas demonstrated high sensitivity and good specificity [Table 2] and [Table 3].

Table 2: Clinical analysis for unilateral hemorrhage obtained from CEREBO®

Lobe location	PPV (%)	NPV (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
Frontal	96.77	75.00	96.77	75.00	94.29
Occipital	81.82	87.50	90.00	77.78	84.21
Parietal	94.12	75.00	94.12	75.00	90.48
Temporal	95.00	75.00	95.00	75.00	91.67
Total	93.67	80.00	94.87	76.19	90.91

*PPV - Positive predictive value, NPV - Negative predictive value

Table 3: Clinical analysis for bilateral hemorrhage obtained from CEREBO®

Lobe location	PPV (%)	NPV (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
Frontal	88.89	75.00	88.89	75.00	84.62
Occipital	75.00	71.43	60.00	83.33	72.73
Parietal	80.00	75.00	80.00	75.00	77.78
Temporal	83.33	75.00	83.33	75.00	80.00
Total	83.33	73.68	80.00	77.78	79.07

*PPV=Positive predictive value, NPV=Negative predictive value

Patients were also categorized based on the following hematoma groups—subdural (45.63%), epidural (19.42%), subarachnoid (13.59%), and intracerebral (12.62%). CEREBO could detect these intracranial hematomas with high sensitivity [Table 4]

Table 4: Clinical analysis for different depths of hemorrhages obtained from CEREBO®

Type of hematoma	PPV (%)	NPV (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)
Subdural	83.93	88.24	92.16	76.93	85.56
Epidural	68.97	93.75	90.91	76.93	81.97
Intracerebral	59.09	93.75	86.67	76.93	79.63
Subarachnoid	60.87	96.77	93.33	76.93	81.48

*PPV=Positive predictive value, NPV=negative predictive value

DISCUSSION

The novel concept of an optoelectronic sensor system to detect an intracranial hematoma non-invasively improves the existing methods of patient classification into non-hemorrhagic and hemorrhagic cases. The triaging or classification of trauma patients is predominantly done in hospital settings; currently, there is a need for field-deployable systems that do not need an expert data interpretation for the detection of intracranial hematoma in prehospital settings such as ambulances. Although this technology solution is predominantly designed to detect unilateral hematoma, it could be applied to detect bilateral hematomas. Nevertheless, there is a knowledge gap, which remains unfulfilled. This study demonstrates the capability of CEREBO a portable rapid non-invasive screening device, to detect both unilateral and bilateral traumatic intracranial lesions and intracranial hematomas. In this respect, we aimed to provide the data about the efficacy and accuracy of CEREBO to detect unilateral and bilateral intracranial hematoma in both pre-CT and post-CT examinations.

According to the World Health Organization (WHO) estimate, TBI is the major cause of death and disability in the world today. The high burden of mortality and morbidity makes TBI pressing public health and medical problem. Therefore, low and middle-income countries have a higher prevalence of risk factors for TBI and insufficiently prepared health systems to deal with the associated health outcomes.[5]

In the United States, in 2010, TBI was known to have an economic impact of about $76.5 billion, including both indirect and direct costs.[6],[7]An intracranial hemorrhage is a serious threat, regardless of the cause, which could be a fall at home, a road traffic accident, or battleground injury, to name a few. A lag in hematoma removal can increase the death risk and harm the functional capacity of those who survive. Hematomas often enlarge within 3 h of damage and can persist for up to 12 h post-injury.[8] Time from injury to surgery has been a crucial factor in the functional recovery of patients with hematomas.[9],[10],[11] As a result, a precise and timely diagnosis is critical to the treatment's success. The patient's examination via GCS along with the medical history is the most preferred examination today, especially in asymptomatic patients to decide if further analysis by CT scan is required. A CT scan helps to localize the bleeding and reveal the primary causes of intracranial hemorrhage (ICH).[12]

F.F. Jobsis was the first to use near-infrared light to monitor hypoxia events in a cat's brain and exposed heart in 1977.[13] With the introduction of portable near-infrared spectroscopy (NIRS) instruments, it will be possible now to triage these patients even in the case of high responsiveness as indicated by GCS. Within clinical medicine, NIRS-based non-invasive devices can have two potential applications that are related but distinct. First, the NPV helps screen and rule out lesions in patients who do not have CT access and decide whether patients require to be sent to a large trauma center. Second, the PPV may screen the patients and help clinicians diagnose and treat cerebral hematomas that require immediate evacuation such as the burr holes at a hospital with no facility for CT imaging or even in the pre-hospital setting if in case, transfer periods are significantly longer.[14]

In developed countries, where CT scans are routinely used to diagnose effectively the epidural hematomas (EPH), subdural hematomas (SDH), and intracerebral hematomas, the mild head injuries with GCS scores greater than 13 are often missed. However, developing countries are known to face the issue of the unavailability of CT scans. In addition, the available scanners are present in small numbers, dispersed across dangerous terrain with limited transportation and emergency services. Also, CT scans cannot be done against the prescribed frequency because of exposure to ionizing radiation, and a single scan costs the equivalent of several months' worth of income for those who need them the most. Thus, when TBI is prevalent, with brain imaging being vital to survival, obtaining this type of imaging is often impossible. The main discovery seen is that the near-infrared CEREBO can identify hematomas with high accuracy when compared with the gold standard CT scan. It likewise demonstrates the ability to recognize true negatives, thus, distinguishing patients who have not endured an intracranial hematoma. This implies that CEREBO has immense potential to be deployed at the point of care in efficiently affirming the presence or absence of an intracranial hematoma in TBI patients.

CEREBO was found to be reliable at detecting intracranial hematomas from all brain lobes including frontal, occipital, parietal, and temporal hematomas. Although CEREBO is not intended to replace CT scans, it may be beneficial in instances where CT scans are unavailable to study deep tissues non-invasively and bring hospital-grade diagnosis to the point of care. This is especially relevant because nearly half of patients with a head injury who get CT scanning within 2 h after damage, especially those with cerebral contusions, are suspected to have early progressive bleeding.[15]According to new research, hematoma expansion is linked to early neurological impairment; 38% of patients experience intracerebral hematoma growth during this time, resulting in a bad prognosis.[16]

CEREBO has certain limitations. Proper contact between the device and the scalp and identification of measurement location are required to obtain accurate measurements. Because scalp hematomas may cause false-positive NIRS readings, the head scanning protocol avoids measurements through scalp hematomas, measuring near, but not in, scalp injuries.[17]

In our study, the hematomas detected via the CEREBO examination were greater than or equal to 2 mL in blood volume and at a distance of 3–3.5 cm from the brain. These results included four false negatives in unilateral and five in the bilateral scans. This may be attributed to hair absorption, bleed volume, bleed depth, or bleed age in case of unilateral hematomas and similar absorption on the contralateral sides for bilateral hematomas, thereby making it difficult for CEREBO to detect them.

There were no adverse effects seen with the device. It is extremely safe to use at all ages, even for pregnant and lactating mothers as there is no use of radiation. CEREBO is an easy-to-use device with minimal training. Within 72 h of injury or onset of initial symptoms, it can be utilized as an addition to CT scans or in the preliminary assessment, resulting in a shorter period from injury to treatment.

CONCLUSION

CEREBO is a rapid portable point-of-care battery-operated device that detects preoperative intracranial hematomas in intensive care units and emergency rooms. It could help paramedics, emergency room physicians, and hospital staff by allowing for early detection and hence treatment and preventing subsequent harm caused by hematomas that are present or delayed. It would be useful to put the CEREBO to test in the intensive care unit (ICU) to see if periodic NIRS measurements can be utilized to track the progression of cerebral hematomas post-surgery

Conclusion

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest
There are no conflicts of interest.

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