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Performance of the InfraScanner for the Detection of Intracranial Bleeding in a Population of Traumatic Brain Injury Patients in Colombia

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Abstract

Background/Objectives: Traumatic brain injury (TBI) is a global public health concern, affecting over 60 million people annually. It is associated with high rates of mortality and disability, particularly among young and economically active individuals, and remains the leading cause of death in people under 40 years of age. Although computed tomography (CT) is the standard method for excluding intracranial bleeding (ICB), it is frequently unavailable in resource-limited settings where the burden of TBI is greatest. The InfraScanner 2000 is a near-infrared spectroscopy (NIRS) device designed to detect ICB and may serve as a triage tool in environments without access to CT imaging. This study aimed to evaluate the diagnostic performance of the InfraScanner 2000 for detecting ICB in the emergency department (ED) of a trauma center in a cohort of Colombian patients with TBI. **Methods:** This prospective study was conducted in Cali, Colombia, between December 2019 and February 2021. Adult patients presenting to the ED with blunt TBI were enrolled. InfraScanner assessments were performed according to a standardized protocol, and all participants underwent head CT within 6 h of injury. **Results:** A total of 140 patients were included. Of these, 66% were male and 34% were female. Most patients (63.57%) were between 18 and 39 years old, with a median age of 39 years (IQR: 18–86). The InfraScanner demonstrated a sensitivity of 60.0% (95% CI: 32.5–84.8), specificity of 78.4% (95% CI: 71.2–85.6), positive predictive value (PPV) of 25.0%, and negative predictive value (NPV) of 94.2% for detecting ICB. **Conclusions:** The InfraScanner 2000 showed good specificity and high NPV in identifying ICB among Colombian patients with TBI. These findings suggest it could serve as a useful triage tool to support decision-making in emergency settings with limited access to CT imaging.



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Keywords: craniocerebral trauma; Latin America; neurosurgery; TBI; traumatic brain injuries; traumatic cerebral hemorrhage

1. Introduction

Traumatic brain injury (TBI) is a major global public health concern, affecting over 60 million people annually. It is associated with high rates of mortality and long-term disability, particularly among young and economically active individuals, and remains the leading cause of death among people under 40 years of age. The burden of TBI is disproportionately higher in low- and middle-income countries (LMICs), such as those in Latin America, Southeast Asia, and Africa, where incidence rates can be up to three times greater than in high-income countries (HICs) [1–4].

In the pathophysiology of TBI, external forces applied to the cranium can cause vascular and parenchymal damage, resulting in primary brain injuries. Among these, various forms of intracranial bleeding (ICB), such as epidural and subdural hematomas, are common. These hematomas compress brain tissue, and once they exceed a critical volume, they can cause an exponential rise in intracranial pressure (ICP), potentially compromising cerebral perfusion and oxygenation, and thereby worsening brain injury [5]. Timely intervention, ideally within the first 4 h post-injury, is associated with improved outcomes [6,7].

Currently, computed tomography (CT) is the gold standard for the urgent diagnosis of ICB. It facilitates rapid identification and informs decisions regarding surgical intervention. However, in resource-limited settings, where approximately 89% of trauma-related deaths occur, access to CT scanners is often restricted. In such contexts, clinical neurological examination becomes the main diagnostic tool, despite its poor sensitivity and specificity for detecting intracranial hematomas [8].

To address this diagnostic gap, near-infrared spectroscopy (NIRS) systems have been developed, initially for use in combat environments. The InfraScanner 2000™ (InfraScan, Inc., Philadelphia, PA, USA) is a handheld device designed to detect intracranial hematomas by measuring differential near-infrared light absorption of hemoglobin between injured and uninjured areas of the brain (Figure 1). The information provided by the InfraScanner may support early evaluation of patients with suspected ICB [9,10]. The device has been studied in various settings across Africa, Asia, and Europe. These studies suggest that the InfraScanner may assist in the early detection of intracranial bleeding in prehospital or resource-constrained environments, improving triage and referral decisions.



Figure 1. The InfraScanner 2000 handheld intracranial bleeding detection system. Images courtesy of InfraScan, Inc.

In Colombia, classified by the World Bank as an upper-middle-income country, 18.8% of the population lives in rural areas with limited access to advanced neuroimaging [11]. It is estimated that TBI is responsible for 70% of deaths due to violence and 90% of deaths from road traffic accidents in the country [12]. According to the National Institute of Legal Medicine and Forensic Sciences, more than 25,000 deaths and over 250,000 injuries related to trauma occurred in 2019 alone [12]. Given this national burden and regional disparities in access to CT imaging, the InfraScanner may represent a valuable tool for ICB detection in Colombian emergency care settings.

The objective of this study was to evaluate the diagnostic performance of the InfraScanner 2000™ in detecting intracranial hemorrhages in the emergency department of a trauma center in a cohort of Colombian patients with TBI.

2. Materials and Methods

This prospective observational study was conducted in Cali, Colombia. The study protocol was reviewed and approved by the local research ethics committee. Patients aged 18 years or older with blunt TBI diagnosed within 6 h of injury were eligible for inclusion. Enrollment began in December 2019 and concluded in February 2021. All participants, or their legal representatives when required, provided written informed consent prior to inclusion. Patients under 18 years of age were excluded in accordance with Colombian legal definitions of adulthood. Additional exclusion criteria included penetrating TBI, scalp lacerations, bruising, or subgaleal hematomas, in accordance with technical recommendations from the device manufacturer.

Data collection was carried out by healthcare providers trained in the use of the InfraScanner device and followed a standardized protocol:

1. An instructional video explaining the operation of the device was shown to eligible patients or their legal representatives, and the objectives and procedures of the study were explained to obtain informed consent.
2. NIRS measurements were performed in the emergency department according to the device's user manual, and the resulting data were recorded (Figure 2).
3. A non-contrast head CT scan was obtained for all participants and independently reviewed by a trauma neurosurgeon who was blinded to the NIRS results.
4. All data were securely stored in a restricted-access database available only to the study investigators. The data collection instrument and measured variables are presented in Table 1.

Additional data on participants' hair characteristics were collected, given the potential for these traits to affect the reliability of NIRS measurements [13]. These variables were included to evaluate whether hair characteristics had a quantifiable impact on device performance within our study population.

A statistician conducted a dichotomous analysis based on the InfraScanner's output, classifying results as either positive or negative for intracranial bleeding. CT findings were considered the reference standard for confirming the presence and location of intracranial hemorrhage (Figure 3). Diagnostic performance metrics, including prevalence, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and likelihood ratios, were calculated. All data analyses were performed using the R statistical software package.

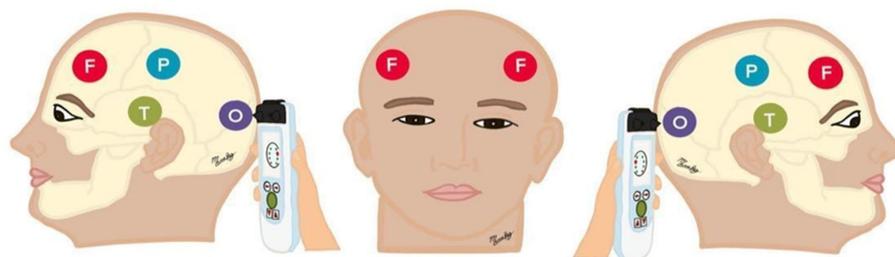


Figure 2. Anatomical reference points for InfraScanner measurements. Frontal (F): forehead above the frontal sinus. Temporal (T): temporal fossa. Parietal (P): midway between the ear and the midline of the skull. Occipital (O): midway between the ear and the occipital protuberance.

Table 1. Data collection instrument.

Variable	Options
Health center	South/North/East/Referral Center
Sex	Male/Female
TBI Type	Blunt/Penetrating
Time and date of the trauma	DD/MM/YY and time
Time and date of the NIRS measurement	DD/MM/YY and time
Positive NIRS	Yes/No
Hair type	Straight/Curly wavy/No hair
Hair color	Black/Blond/White/Brown/Other/No hair
Hair length	Short/Medium/Long/No hair
Subgaleal hematoma	Yes/No
Scalp laceration	Yes/No
Time and date of the CT scan	DD/MM/YY and time
Intracranial hematoma on the CT scan	Yes/No
Type of hematoma	Subdural < 1 cm/Subdural > 1 cm/Epidural < 30 cc/Epidural > 30 cc/ Intraparenchymal hematoma/Subarachnoid hemorrhage
Location of the hemorrhage on the CT scan	Frontal/temporal/parietal/occipital
Laterality of the hemorrhage on the CT scan	Left/Right
Midline shift on the CT scan	Yes/No
Clinical conduct after ER	Discharge/Surgical management/Nonsurgical management
Hematoma volume	In cubic centimeters (mL)
Hematoma depth	In centimeters (cm)
Glasgow coma scale at time of initial presentation	3–15

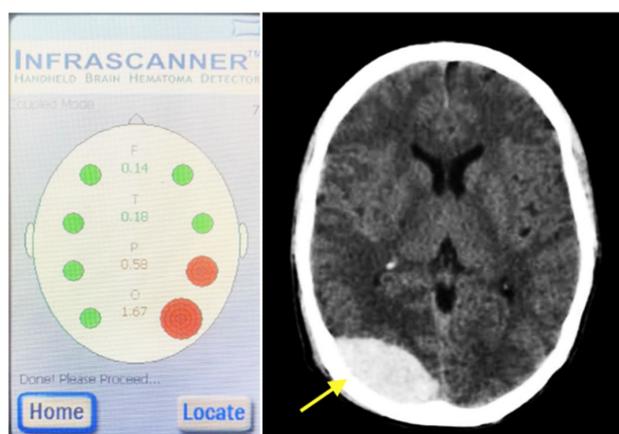


Figure 3. Positive InfraScanner measurement (red circles on the left side of the image) and the corresponding CT scan presenting a right-sided occipital extradural hemorrhage (yellow arrow). Note that the InfraScanner view is oriented from the top of the patient’s head (as if looking down from the crown), while CT images are usually interpreted from the feet upward. This explains why the same lesion appears on opposite sides in the two modalities.

3. Results

A total of 140 patients were included in the study. Overall, 66 percent were male and the median age was 39 (18–86 years), with most patients being 18–39 years old (63.57%). Mild TBI was the most common presentation (60%) and only two patients presented with severe TBI (13.3%). Additional patient characteristics are listed in Table 2.

Table 2. Patient characteristics.

Characteristics	Total (n = 140)	Population Mean (μ)
Age	n (%)	
18–39 years	89 (63.57)	28
40–59 years	27 (19.28)	49
60–79 years	19 (13.57)	67
>80 years	4 (3.85)	84
No data	1 (0.71)	1
Gender		
Female	47 (33.57%)	
Male	93 (66.42%)	
Hair type		
Straight	70 (50)	
Curly	59 (42)	
Wavy	5 (4)	
No hair	6 (4)	
Hair color		
Black	93 (66)	
Blond	15 (11)	
White	18 (13)	
Brown	7 (5)	
Other	1(1)	
No hair	6 (4)	
Length		
Short	78 (56)	
Medium	32 (23)	
Long	24 (17)	
No hair	6 (4)	
GCS (patients with positive CT scan)		
14–15 (mild TBI)	9 (60)	
9–13 (moderate TBI)	4 (26.6)	
≤8 (severe TBI)	2 (13.3)	

Of the 140 patients in the study, 82 (58.57%) had soft tissue injuries in the head that did not compromise the measurement points (Table 3). Subgaleal hematoma was the most common presentation (48.34%).

Table 3. Relationship between InfraScanner results and CT scan findings for the identification of intracranial bleeding.

	Positive CT Scan	Negative CT Scan	Total
Positive InfraScanner test	9	27	36
Negative InfraScanner test	6	98	104
Marginal totals	15	125	140

A total of 15 patients (10.71%) had an ICB identified on a CT scan. Nine of these patients had a positive InfraScanner result, and six had a negative result. With these results, we found the InfraScanner test to have a sensitivity of 60.00% and a specificity of 78.40% in detecting ICB. A positive predictive value (PPV) of 25% and a negative predictive value (NPV) of 94.23% were found (Tables 3 and 4).

Table 4. Sensitivity, specificity, positive predictive value, negative predictive value, and likelihood ratios of the InfraScanner compared to CT scan for the detection of intracranial bleeding.

Variable	Value	CI 95%
Sensitivity	60.00%	35.20–84.8
Specificity	78.40%	71.19–85.61
PPV	25.00%	10.85–39.15
NPV	94.23%	89.75–98.71
LR+	2.73	1.63–4.73
LR–	0.51	0.27–0.95
Prevalence	0.1071	-
Pre-test Prob.	0.1071	-
Odds pre-test	0.1199	-
Odds post-test (+)	0.3273	-
Post-test probability (+)	0.2466	16–36%
Odds post-test (–)	0.0611	-
Post-test probability (–)	0.0576	3–10%

Of the 15 patients with a positive cranial CT, 3 underwent surgical management and 12 received non-surgical management. On the CT image of the three patients who underwent surgical management, the first patient had a subdural hematoma greater than 1 cm; the second patient had a subdural hematoma greater than 1 cm and an intraparenchymal hematoma; and the third patient had a subdural hematoma less than 1 cm and a subarachnoid hemorrhage. The most common hemorrhages in true positives were subarachnoid hemorrhages and subdural hematomas (Tables 5 and 6).

Table 5. True positives (TP): findings in patients with both InfraScanner and CT scan positive for intracranial bleeding, including lesion location, presence or absence of subgaleal hematoma, hemorrhage volume, depth, and type.

InfraScanner Results			CT-Scan				GCS	
Result	Location (Positive Side)	Subgaleal	Result	Type(s) of Intracranial Hemorrhage	Location	Volume of Bleeding		Depth of Bleeding
Positive	Parietal (L)	No	Positive	tSAH	Temporal (R)	N/A	1.4	8
					Temporal (L)	N/A	2.3	
Positive	Frontal (R) and temporal (R)	Frontal (R) and temporal (R)	Positive	EDH	Temporal–Parietal–Occipital (R)	9	1.6	15
					Parietal–Occipital (L)	1.8	1.2	
Positive	Frontal (R)	Frontal (R) + frontal (R) fracture	Positive	IPH	Frontal–Temporal (R)	N/A	1.5	15
Positive	Temporal (L)	No	Positive	tSAH	Temporal (L)	N/A	1.4	15
Positive	Frontal (L)	Parietal (R)	Positive	Subdural Contusion	Temporal–parietal–Occipital (L)	0.9	1.4	14
					Temporal–Parietal(L)	N/A	1.1	
Positive	Parietal and occipital (L)	No	Positive	tSAH	Temporal (L)	N/A	2.5	15
Positive	Temporal and Parietal (R)	Temporal and parietal (R) + temporal–parietal fracture (R)	Positive	Subdural EDH tSAH	Temporal–Parietal (R)	0.6	0.8	15
					Temporal–Parietal (R)	21	1	
					Temporal–Parietal (R)	N/A	0.8	
Positive	Frontal (R)	No	Positive	Subdural Contusion	Parietal (R)	0.3	1.2	12
					Parietal (L)	N/A	1.4	
Positive	Frontal, parietal, occipital (L)	No	Positive	Subdural	Frontal–Temporal–Parietal–Occipital (L)	2.13	Front: 0.8; Occipital: 0.7; Parietal: 0.6	14
Positive	Parietal (R)	Frontal (L)	Positive	tSAH	Frontal (R)	N/A	1.09	15

TSAH: subarachnoid hemorrhage; IPH: intraparenchymal hemorrhage; EDH: epidural hematoma; N/A: not applicable; L: left; R: right.

Table 6. False negatives (FN): findings in patients with negative InfraScanner and positive CT scan results for intracranial bleeding, including lesion location, presence or absence of subgaleal hematoma, hemorrhage volume, depth, and type.

InfraScanner Results			CT-Scan					GCS
Result	Location (Positive Side)	Subgaleal	Result	Type(s) of Intracranial Hemorrhage	Location	Volume of Bleeding	Depth of Bleeding	
Negative	N/A	Temporal (L)	Positive	Subdural	Temporal (R)	0.6	0.48	14
Negative	N/A	No	Positive	Subdural	Frontal (R)	0.1	1.9	12
			Positive	tSAH	Frontal (L)	N/A	1.15	
Negative	N/A	No	Positive	tSAH	Occipital (R)	N/A	1.0	13
					Occipital (L)	N/A	2.6	
Negative	N/A	No	Positive	IPH	Frontal–Parietal (R)	N/A	Front: 2.03; Parietal: 0.7	3
			Positive		Frontal–Parietal (L)	N/A	Front: 1.2; Parietal: 3.2	
Negative	N/A	Occipital (R)	Positive	Contusion	Frontal (L)	N/A	1.8	10
				tSAH	Temporal (L)	N/A	2.6	

SAH: subarachnoid hemorrhage; IPH: intraparenchymal hemorrhage; N/A: not applicable; L: left; R: right.

4. Discussion

This study aimed to evaluate the diagnostic performance of the InfraScanner 2000™ for detecting intracranial hemorrhages in adult patients presenting with TBI to the emergency department of a trauma center in Colombia.

This cohort included a relatively heterogeneous group of patients in terms of age and sex who presented with blunt TBI, with mild TBI being predominant. Of these, only a little more than ten percent presented some type of ICB evident in the CT scan, which coincides with what is reported in the medical literature, in which it is estimated that in this type of trauma, around 90% of head CTs will be normal [14–16].

Patients presented extradural hematomas (EDH), traumatic subarachnoid hemorrhages (tSAH), subdural hematomas (SDH), cerebral contusions, and intraparenchymal hemorrhages (IPH). Calculating the exact sensitivity and specificity for detecting each type of bleeding with the InfraScanner device is complicated by the simultaneous presence of several types of bleeding, which makes it difficult to determine whether the device would accurately detect a particular type in the absence of the others. However, the device seems to be more effective in detecting EDH than other types of hematomas, as has been shown in similar studies [8]. Nonetheless, the small number of positive CTs in our study limits the scope of this observation and necessitates conducting larger studies focused on more severe injuries to draw such conclusions.

The mean volume of focal bleeding detected by the InfraScanner was 5.10 mL, while that of the cases not detected by the device was 0.35 mL. These measurements reinforce what was seen in other studies, where the effectiveness of the device had a direct relationship with the volume of intracranial bleeding. In our case, we did not take any measurements of the volume of the tSAH. Considering that there are several true-positive and false-negative cases, it remains to be resolved whether the volume of this type of bleeding could also have a relationship with the effectiveness of the device in detecting these cases.

A previous pilot study of 35 patients in a level I trauma center in Spain described a sensitivity of 89.5% and a specificity of 81.2% in detecting intra- and extra-axial hematomas using the InfraScanner system [8]. Another observational study used the InfraScanner in 102 patients with penetrating or closed TBI at a military general hospital in China. They demonstrated a sensitivity of 100% (95% [CI] 82.8–100%) and specificity of 93.6% (95% CI 85–97.6%) in detecting intracranial hematomas > 3.5 mL in volume and <2.5 cm from the surface of the brain in patients who presented within 12 h after the initial trauma [17]. A cohort study of 205 patients who presented within the first hour of injury at a major

trauma center in London found the InfraScanner had a sensitivity of 75% and specificity of 50.43% [18].

Our results demonstrated that the InfraScanner in this sample of the Colombian population, within the first 6 h of the TBI event, had a sensitivity of 60.00% (CI 32.5–84.8) and a specificity of 78.4% (CI 71.19–85.61). We found that the sensitivity was limited, with a wide confidence interval, which we attributed to the low number of patients with positive CT scans, and a much larger sample size is needed to reach a precise estimate. The system had a specificity of 78.4%, which is also lower than in some previously published studies [8,9,17,19–21].

Overall, our results are broadly consistent with previous reports that highlight the high negative predictive value (NPV) of the InfraScanner, as shown in Table 7. However, the heterogeneity in reported sensitivity, specificity, PPV, and NPV across studies suggests that direct comparison between populations is challenging and may be influenced by differences in patient selection, injury severity, timing of evaluation, and device protocol.

Table 7. Diagnostic performance reported in comparable published studies.

Study Number	Author, Country, Year and Reference	Sample Size	Sensitivity	Specificity	PPV	NPV
1	Gopinath et al., USA, 1993 [21]	56	100%	100%	100%	100%
2	Hennes et al., Germany, 1997 [22]	212	95.9%	28.9%	64.6%	83.9%
3	Francis et al., India, 2005 [19]	71	77.8%	100%	100%	93%
4	Kahraman et al., Turkey, 2006 [20]	60	86.7%	100%	100%	88.2%
5	Kessel et al., Israel, 2007 [23]	110	67.9%	95.1%	82.6%	89.7%
6	Ghalenoui et al., Iran, 2008 [24]	148	88.9%	77.7%	69.6%	92.4%
7	Coskun et al., Turkey, 2010 [25]	253	86.4%	54.5%	15.3%	97.7%
8	Leon-Carrion et al., Spain, 2010 [8]	35	89.5%	81.3%	85%	86.7%
9	Robertson et al., USA and India, 2010 [9]	319	88%	90.7%	63.7%	97.6%
10	Akyol et al., Turkey, 2016 [26]	151	85.7%	66.6%	11.1%	98.9%
11	Xu et al., China, 2017 [13]	85	95.6%	92.5%	93.5%	94.9%
12	Peters et al., Netherlands, 2017 [27]	60	92.9%	72.7%	81.3%	88.9%
13	Trehan et al., India, 2018 [28]	100	58.9%	42.9%	65.5%	35.7%
14	Liang et al., China, 2018 [17]	102	100%	93.6%	82.8%	100%
15	Yuksen et al., Thailand, 2020 [29]	47	100%	44.4%	35.5%	100%

Taken together, our findings support the notion that the InfraScanner may be more useful as a rule-out tool in patients with suspected mild TBI, rather than as a definitive diagnostic or localization method for intracranial bleeding. In this context, it may serve as a triage aid, helping to identify patients unlikely to benefit from CT imaging in low-resource or prehospital environments.

We believe that the main limitation of our study is the rigid exclusion criteria that limited patient selection and may have produced a sample bias. This resulted in a sample of mostly mild TBI injuries consisting of traumatic subarachnoid hemorrhage. More severe cases, likely patients with subdural or epidural hematomas, could have been excluded due to their high prevalence of associated scalp injuries (lacerations, bruises, and subgaleal hematomas) in the areas where the InfraScanner measurements were to be performed. Additionally, due to the SARS-CoV2 outbreak in Colombia during the time of the study, the referrals at the study institution were limited because of mobility restrictions, causing a decrease in the regular flow of TBI patients across the entire hospital network.

5. Conclusions

The InfraScanner system for detecting ICB in this population of TBI patients has high specificity and fair sensitivity. Based on these results, the system is effective in ruling out true-negative cases. It is important to note that this method is not intended to replace CT when available but serves as a triage tool for identifying patients who require immediate transfers for urgent head CT and neurosurgical consultation. The system can be valuable when included in algorithms for managing trauma patients in less-resourced settings where CT is not available.

Author Contributions: A.M.R. was responsible for the conceptualization and methodology of the study. All the remaining authors contributed to data acquisition, analysis, and the construction of the manuscript. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of the MEDITECH Foundation under Act No. 001 of 2022 on 17 February 2022.

Informed Consent Statement: Written informed consent has been obtained from the patients to publish this paper.

Data Availability Statement: The datasets generated during and/or analyzed during the current study are available upon request.

Conflicts of Interest: The authors declare no conflicts of interest.

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