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Clinical Evaluation of a Portable Near-Infrared Device for Detection of Traumatic Intracranial Hematomas

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Abstract

The purpose of this multicenter observational clinical study was to evaluate the performance of a near-infrared (NIR)-based, non-invasive, portable device to screen for traumatic intracranial hematomas. Five trauma centers collected data using the portable NIR device at the time a computed tomography (CT) scan was performed to evaluate a suspected traumatic brain injury (TBI). The CT scans were read by an independent neuroradiologist who was blinded to the NIR measurements. Of 431 patients enrolled, 365 patients were included in the per-protocol population analyzed. Of the 365 patients, 96 were determined by CT scan to have intracranial hemorrhages of various sizes, depths, and anatomical locations. The NIR device demonstrated sensitivity of 88% (95% confidence interval [CI] 74.9,95.0%), and specificity of 90.7% (95% CI 86.4,93.7%), in detecting the 50 intracranial hematomas that were large enough to be clinically important (larger than 3.5 mL in volume), and that were less than 2.5 cm from the surface of the brain. For all 96 cases with intracranial hemorrhage, regardless of size and type of hemorrhage, the sensitivity was 68.7% (CI 58.3,77.6%), and specificity was 90.7% (CI 86.4,93.7%). These results confirm the results of previous studies that indicate that a NIR-based portable device can reliably screen for intracranial hematomas that are superficial and of a size likely to be of clinical importance. The NIR device cannot replace CT scanning in the diagnosis of TBI, but the device might be useful to supplement clinical information used to triage TBI patients, and in situations in which CT scanning is not readily available.

Key words: head injury; intracranial hematomas; near-infrared spectroscopy; traumatic brain injury

Introduction

One hallmark pathological process in traumatic brain injury (TBI) is intracranial hemorrhage, which occurs in 45% of severe head trauma cases (Foulkes et al., 1991). There are four major types of traumatic intracranial hemorrhage: subdural, epidural, and intracerebral hematomas, and subarachnoid hemorrhage. Each of these lesions has characteristic clinical and CT scan findings, and can be present on admission to the hospital, or can occur in a delayed fashion (Silver et al., 2005).

Early diagnosis and surgical evacuation of intracranial hematomas are fundamental management principles for traumatic hematomas (Bullock et al., 2006). A practical

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adjunct to this goal of early identification of intracranial hematomas in the field and emergency center may be the use of portable near-infrared (NIR) technology.

In a pilot study (305 patients) conducted with a prototype NIR unit, sensitivity for extracerebral (epidural and subdural) hematomas was 100%, and sensitivity for intracerebral hematomas was 98%, compared to CT scan readings (Robertson et al., 1997). There were no false-positives. In 93% of late-onset lesions the NIR system detected onset more rapidly than conventional monitoring methods (ICP monitoring and repeated neurological examinations). The type of hematoma could not be determined with certainty in the pilot study; however, it was possible to detect the presence of any type of traumatic intracranial hematoma.

Other groups have reported similar experiences with the use of NIR technology to identify intracranial hematomas. Kahraman and associates (2006) studied the use of an NIR device in patients with subdural and epidural hematomas, and found an overall sensitivity of 0.87 compared to CT scanning. All patients with acute intracranial hematomas were identified. The four patients in this study in whom a subdural hematoma was not detected with the NIR device had chronic subdural hematomas for which the absorption characteristics of the blood may have been different. Francis and colleagues (2005) studied 71 patients undergoing CT scanning for a suspected brain lesion. All of the patients with a difference in optical density detected by the NIR technique had a unilateral lesion on CT scan. In two trauma centers, where 110 patients underwent evaluation with a portable NIR device prior to CT scanning, the NIR assessment had a sensitivity of 90.5% and specificity of 95.5% for extracerebral hematomas (Kessel et al., 2007).

Early identification of intracranial hematomas in TBI patients allows early surgical evacuation, which can be an important determinant of outcome. In one study, Seelig and associates (1985) showed that a delay of more than 4 h between injury and the evacuation of a traumatic subdural hematoma increased mortality and worsened outcome in survivors.

An NIR-based, hand-held medical screening tool (Infrascanner by InfraScan, Inc.) has recently been developed to screen for a brain hematoma at the site of injury. In laboratory tests with phantom models of intracranial hematomas, the smallest volume of blood that could be detected with the device was 3.5 mL, and the hematoma had to be within 2.5 cm of the brain surface to be detected.

The purpose of this clinical study was to evaluate the performance of this NIR-based portable device in the detection of intracranial hemorrhage due to trauma. The primary end-point of the study was a description of the test characteristics (sensitivity, specificity, and positive and negative predictive values [PPV and NPV]) of the portable NIR-based device in the identification of any size hematoma compared to CT as the gold standard. A secondary end-point was the description of the test characteristics of the portable NIR-based device in identification of hematomas within its detection limits (volume >3.5 mL and depth <2.5 cm), compared to CT scan results as the gold standard.

Methods

Theoretical basis for detection of hematomas with NIR technology

Due to the unique light-absorbing properties of hemoglobin, hemoglobin molecules within tissue have the highest absorption rate in the NIR range (700–900 nm; Cope, 1991; Rolfe, 2000; Strangman et al., 2002). Therefore, any change in hemoglobin concentration will be reflected in the attenuation of measured light that has interacted with the tissue of interest. The basic method for hematoma detection using NIR technology is based on differential light absorption of the left versus the right side of the brain. Under normal circumstances the brain's absorption is symmetrical. Where additional underlying extravascular blood is present, there is a greater local concentration of hemoglobin, and consequently the absorbance of the light is greater, while the reflected component is commensurately less. This differential is detectable via sources and detectors placed over symmetrical locations on the two sides of the skull. Furthermore, NIR technology is now available in small, battery-operated, and therefore easily portable designs.

Study design

The study was a multi-center observational study to test the performance of the new portable NIR device to screen for intracranial hemorrhage, by comparing the findings of the NIR exam to those of the admission CT scan.

Setting

The study was conducted in the emergency center of five trauma centers, four Level 1 trauma centers that were in the United States, and a fifth center in India.

Selection of participants

Patients of any age were eligible for the study if they were undergoing a CT scan within 12 h of a blunt or penetrating head injury at any of the five trauma centers participating in the study, between July 2006 and October 2008. Trained operators were available during hours expected to be high-volume for trauma, approximately 20 h per week. All eligible patients were enrolled during those time periods.

The criteria for obtaining a CT scan were based on the standard of care. The non-contrast CT was performed according to standard methods at the local institution. Exclusion criteria included the presence of large scalp lacerations, avulsions, or hematomas involving the NIR examination sites.

This study was performed with a waiver of informed consent approved by the local institutional review boards of the participating centers, based on the minimal risk of the study procedure. Patients who could not give informed consent for themselves were studied, because this is the population of head trauma patients that have a significant risk of having intracranial hematomas, and would most benefit from the screening device. The clinical need to emergently diagnose and evacuate intracranial hematomas precluded obtaining surrogate consent. The study procedure had minimal risk because the NIR examination was non-invasive, quick, and did not interfere with routine patient care.

Methods of measurement

The NIR device consists of two components: a sensor and a personal digital assistant (PDA). The sensor includes an 808-nm diode laser and a silicon detector. The sensor delivers NIR light to the tissue under the sensor via fiberoptics, and receives it after it has interacted with the tissue. The detector signal is then digitized and transmitted via a Bluetooth wireless link to the PDA. The PDA receives the data from the sensor, processes it further, and displays the results on its screen. The fiberoptics are designed so that they can be maneuvered between hairs to minimize the interference from thick, dark hair without shaving the hair.

Within 40 min before the CT scan was performed for clinical indications, an operator independently performed a standardized examination with the portable NIR device. Measurements were made at four pre-selected pairs of locations on the head: the frontal, temporal, parietal, and occipital regions (with a variance of ± 1 cm). At each location, the actual measurement by the portable NIR device takes up to 10 sec. The entire head scan takes less than 2 min. If the time gap between the NIR measurements and CT examinations was more than 40 min, which happened if the CT scan was delayed more than expected, then a second examination with the portable NIR device was performed within 40 min after the CT scan, with the operator still blinded to the results of the CT scan. The second exam, performed within 40 min of the CT scan, was used in the analysis.

Operators at each study site were identified and trained both about how to use the NIR equipment, and about how to place the device in the appropriate locations for the standardized examination. This training involved a half-day site visit to the center, during which an instructor provided a demonstration of the NIR device, followed by supervision of practice examinations on normal individuals. Only trained operators contributed patients to the study.

In order to interpret the NIR examination, the absorption of light, which is related to hemoglobin content within the four scanned areas on the left side of the head, was compared with the absorption of light obtained on the corresponding locations on the right side, obtaining a difference in optical density (ΔOD) for each of the four pairs of locations on the head. The optical density measurement is a logarithm of the measured light intensity: $OD = \log_{10} I$. For each examination the ΔOD for each of the four brain regions was recorded, and the ΔOD_{max}, defined as the greatest absolute value for ΔOD among the various regions examined, was recorded. The presence or absence of a hematoma was determined by comparing the ΔOD_{max} measurement to a pre-defined threshold of 0.2. This threshold was determined based on a pilot study in TBI patients (Robertson et al., 1997), and a pilot study with healthy volunteers. Variability due to accidental hair compression is one of the reasons that the detection threshold of the Infrascanner was set to 0.2 (to maximize specificity). The other factor in determining the detection threshold was the distribution of hematoma signals (to maximize sensitivity). In each head region where the ΔOD was more than the threshold of 0.2, the measurement was repeated to confirm the finding, and to reduce the chances of a false reading due to hair trapped under the lightguides.

A neuroradiologist from an independent clinical site separate from the five hospitals involved in patient scanning evaluated all of the CT scans and entered the results in a database. The matching NIR device recordings were entered in the same database by the clinicians at the five clinical sites. In order to eliminate any possible bias, the neuroradiologist was blinded to the NIR measurements, and the clinicians who entered the NIR device measurements were blinded to the CT scan readings in the database. An independent statistician compared the performance of the portable NIR-based device in hematoma detection using CT scan results as the gold standard.

The primary end-point of the study was a description of the test characteristics (sensitivity, specificity, and positive and negative predictive values) of the portable NIR-based device in the identification of any size hematoma compared to CT as the gold standard. A secondary end-point was the description

Table 1. Summary of Patient Demographic Characteristics

Characteristic	*All subjects enrolled (n = 431)*	*Per protocol subjects (n = 365)*
Age (y)		
Mean	37.4	36.7
Median	35	35
Range	1–89	1–88
Gender		
Male	323 (74.9%)	273 (74.8%)
Female	108 (25.1%)	92 (25.2%)
Race		
Caucasian	119 (27.6%)	85 (23.3%)
African-American	108 (25.1%)	96 (26.3%)
Asian	129 (29.9%)	117 (32.1%)
Hawaiian	1 (0.2%)	1 (0.2%)
Hispanic	74 (17.2%)	66 (18.1%)
Skin color		
Light	131 (30.4%)	98 (26.8%)
Dark	148 (34.3%)	125 (34.2%)
Black	152 (35.3%)	142 (38.9%)
Hair color		
Bald	3 (0.7%)	3 (0.8%)
Light	80 (18.6%)	59 (16.1%)
Dark	167 (38.7%)	141 (38.6%)
Black	180 (41.8%)	161 (44.1%)
Unknown	1 (0.2%)	1 (0.3%)
Hair thickness		
Bald	5 (1.2%)	5 (1.3%)
Thin	90 (20.9%)	72 (19.7%)
Normal	259 (60.1%)	221 (60.5%)
Thick	76 (17.6%)	66 (18.1%)
Unknown	1 (0.2%)	1 (0.2%)
Mechanism of injury		
Fall	180 (41.8%)	160 (43.8%)
Accident	185 (42.9%)	153 (41.9%)
Assault	51 (11.8%)	41 (11.2%)
Gunshot wound	11 (2.6%)	8 (2.2%)
Other	4 (0.9%)	3 (0.8%)
Initial GCS score		
3–8	107 (24.8%)	89 (24.4%)
9–12	37 (8.6%)	32 (8.8%)
13–15	287 (66.6%)	244 (66.8%)
Mean time between NIR exam and CT scan	25.2 min	19.6 min

NIR, near-infrared; GCS, Glasgow Coma Scale; CT computed tomography.

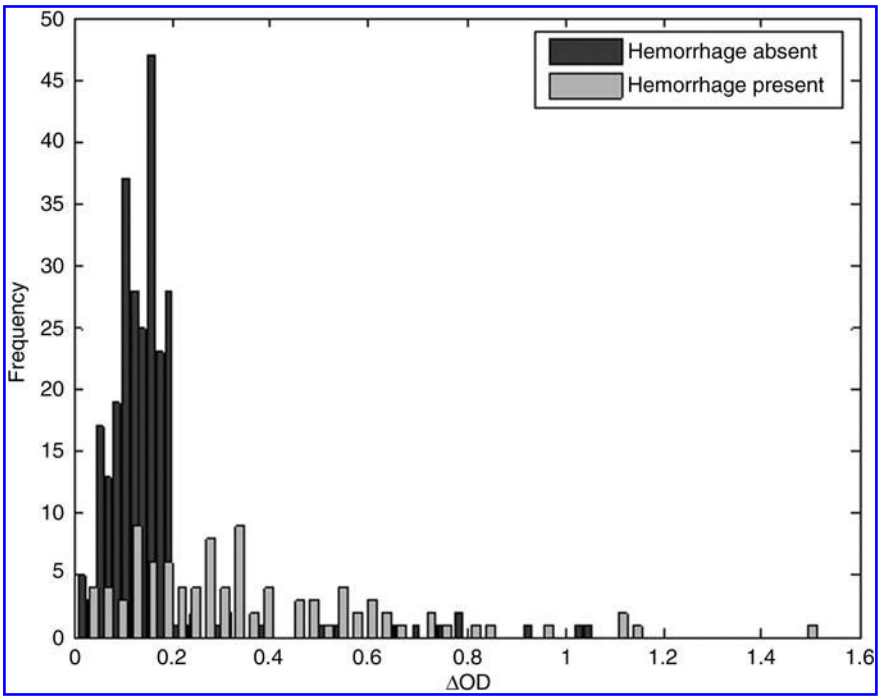

FIG. 1. Distribution of difference in optical density (ΔOD) for patients with intracranial hemorrhage present ($n = 96$), and intracranial hemorrhage absent ($n = 269$).

of the test characteristics of the portable NIR-based device in identification of hematomas within its detection limits (volume >3.5 mL and depth <2.5 cm), compared to CT scan results as the gold standard. Other exploratory analyses were performed to examine factors such as hematoma type and size, and study site.

Primary data analysis

The analyses of the performance of the portable NIR-based device were conducted using a "per-protocol" population. Patients were excluded from the analysis if they had large scalp lacerations or hematomas or blood on the scalp over the scan area. Patients were also excluded from the analysis when the NIR device malfunctioned (e.g., because it was not charged), when symmetrical bilateral measurements were not made, or when the NIR examination was not performed within 40 min of the CT scan.

Results

Characteristics of the study subjects

All age groups were represented in this study, with a range in age from 1 to 89 years (Table 1). Demographics were similar for patients among the different clinical sites, and the 365 per-protocol cases were representative of the whole group. Out of 431 patients, males were evaluated for suspected TBI approximately three times more often than females. Characteristics that might affect performance of an optical method, such as race, skin and hair color, and hair thickness, were represented in significant numbers in the patient population. The mechanism of brain injury, from most frequent to least frequent, were vehicular accidents (including motorized and non-motorized vehicle accidents), falls, assaults, gunshot wounds, and others (such as sports-related accidents and birth trauma).

The per-protocol population, as defined in the methods section, included 365 patients. The protocol violations that excluded the other 66 patients from the analysis were time between NIR exam and CT scan >40 min ($n = 39$), blood or lacerations on the scalp over the scan area ($n = 11$), asymmetric placement of the NIR device ($n = 13$), measurement by untrained operators ($n = 2$), and use of an uncharged NIR system ($n = 1$). In the per-protocol group, there were 31 (32.2%) subdural hematomas, 23 (24%) epidural hematomas, 29 (30.2) intracerebral hematomas or contusions, and 13 (13.5%) patients with subarachnoid hemorrhage, for a total of 96 (26.3%) patients with intracranial hemorrhage. The remaining 269 patients did not have intracranial hemorrhage.

Main results

The distribution of ΔOD values for all 365 per-protocol patients is illustrated in Figure 1, separated by whether or not intracranial hemorrhage of any type and size was identified on the initial CT scan. The ΔOD for the 269 patients in whom no intracranial hemorrhage was identified on the initial CT scan ranged from 0 to 1.05, but 90.7% of the cases were <0.20, which was pre-defined as the threshold for identification of intracranial hemorrhage. The variability in these non-hemorrhage cases was greater than in the pilot trial. The main reason for the variability is probably accidental hair compression, which happens even if the user tries to wiggle the optical fibers through the hair.

Of the 96 cases in whom intracranial hemorrhage of any size and type was identified on CT scan, 66 cases had a ΔOD greater than the pre-defined threshold of 0.2, for an overall

Table 2. Near-Infrared Device Performance

Specificity (95% CI)	*Sensitivity (95% CI)*	*NPV (95% CI)*	*PPV (95% CI)*	*Prevalence*
All intracranial hemorrhage types and sizes (365 patients, 96 with intracranial hemorrhage)				
90.70% (86.4–93.7)	68.70% (58.3–77.6)	89.00% (84.6–92.3)	72.50% (62.0–81.1)	26.30%
Epidural, subdural, and intracerebral hematomas and contusions, volume > 3.5 mL and distance < 2.5 cm from the brain surface (365 patients, 50 with intracranial hematomas within NIR detection limits)				
90.70% (86.4–93.7)	88% (74.9–95.0)	97.60% (94.6–99.0)	63.70% (51.2–74.7)	15.60%

PPV, positive predictive value; NPV, negative predictive value; 95% CI, exact 95% confidence interval; NIR, near-infrared.

sensitivity of 68.7%. Table 2 shows the full performance data for all of the per-protocol cases. Specificity was 90.7%, NPV was 89.0%, and PPV was 72.5%.

The type and size of the intracranial hemorrhage was the major factor that affected the performance of the NIR device. Figure 2 shows the distribution of ΔOD values by type and size of hemorrhage. Most of the 30 ΔOD values <0.2 in patients with intracranial hemorrhage (the false-negatives) occurred in cases in whom the characteristics of the hematoma were outside the detection limits of the NIR device ($n = 20$), or were subarachnoid hemorrhage ($n = 4$).

The ΔOD values in the subarachnoid hemorrhage cases, in whom the volume of blood could not be estimated, was quite variable, and ranged from 0.03 to 0.86. The distribution of ΔOD values for epidural, subdural, and intracerebral hematomas and contusions within the NIR device detection limits (>3.5 mL and <2.5 cm from the brain surface) is shown in black. Of the 50 cases with a hematoma within the detection limits, 44 had a ΔOD value >0.2, for a sensitivity of 88%. The full performance data for this subgroup of cases is also shown in Table 2. Specificity was 90.7%, NPV was 97.6%, and PPV was 63.7%.

The median volume of blood in the individual hematoma cases was 8.6 mL, and varied tremendously, from a low value of 0.1 mL to a high value of 133 mL. The distribution of hematoma volumes is shown in Figure 3. The effect of hematoma volume on the sensitivity of the NIR measurements for the epidural, subdural, and intracerebral hematoma and contusion cases is shown in Table 3. When only very-large-volume hematoma cases were included in the analysis (>70 mL) the sensitivity was 100%, and all of the hematomas were detected. When hematoma volume was >25 mL, which might in some circumstances indicate a hematoma that would require surgical evacuation, the sensitivity was 93.3%. When smaller hematoma cases were included in the analysis, the sensitivity dropped significantly. There was not a significant difference in performance of this portable NIR-based device at the different locations of the medical centers.

As shown in Figure 4, the information provided by the NIR exam supplemented the clinical information provided by the neurological examination. The baseline prevalence of intracranial hematoma in the per-protocol population was 27%. In patients with an abnormal neurological examination (Glasgow Coma Scale [GCS] score <15), the PPV was 47%. In

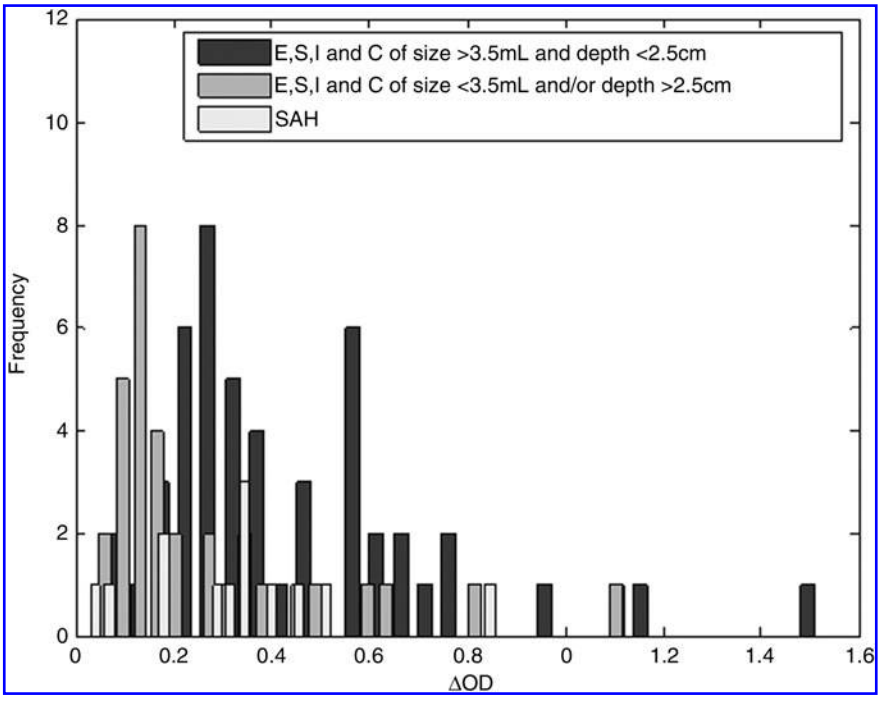

FIG. 2. The distribution of difference in optical difference (ΔOD) values for all hemorrhage categories (E, epidural hematoma; S, subdural hematoma; I, intracerebral hematoma; C, contusion; SAH, subarachnoid hemorrhage).

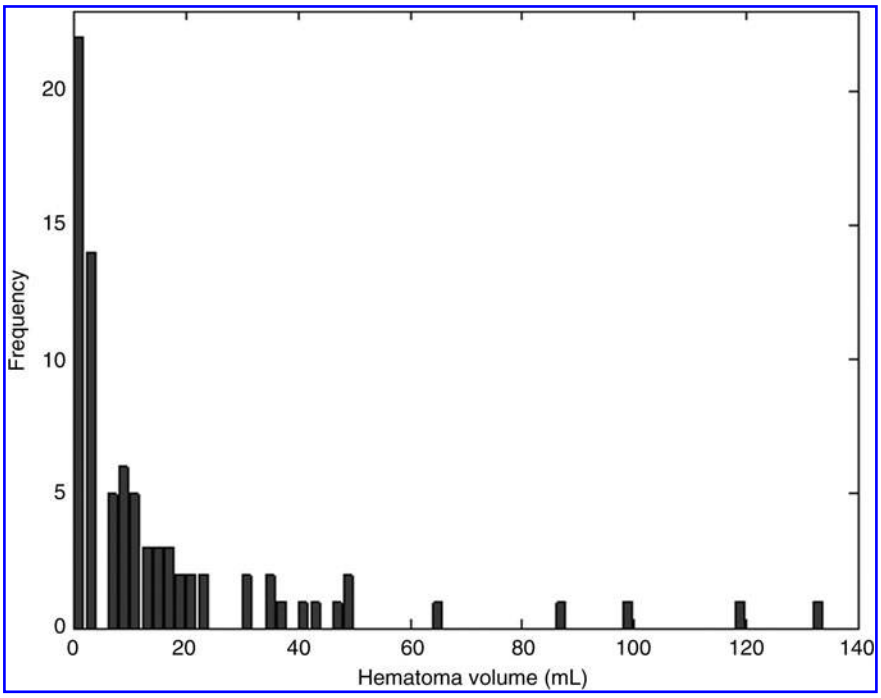

FIG. 3. The distribution of the volumes of the 83 epidural, subdural, and intracerebral hematomas, and contusion cases.

patients with a ΔOD >0.2 regardless of the neurological examination, the PPV was 63%. However, in patients with an abnormal neurological examination and with a ΔOD >0.2, the PPV was 80%.

Discussion

This study confirms the findings of previous investigations demonstrating that NIR technology can be used to screen for the presence of intracranial blood from a simple examination of the difference in optical density between the area involved in the hemorrhage and the uninvolved site on the opposite side of the head (Robertson et al., 1997). Unlike previous studies, this protocol assessed the performance of the NIR device to identify all types of intracranial hemorrhage. While the sensitivities for identifying extracerebral (subdural and epidural) hematomas in the studies by Kahraman and colleagues (2006) and Kessel and associates (2007) were 87% and 90.5%, respectively, the sensitivity in the present study for all types of intracranial hemorrhage was only 68%. The size and type of intracranial hemorrhage present seemed to be the major factor affecting the performance of the NIR-based device.

The portable NIR-based device demonstrated high sensitivity (88%) and specificity (90.7%) in detecting traumatic intracranial hematomas >3.5 mL in volume and <2.5 cm from the surface of the brain. With hematomas >25 mL in volume, a size that would be likely to cause mass effect and to require surgical evacuation (Bullock et al., 2006), the sensitivity was 93.3%. With very small hematomas (<3.5 mL), or hematomas that are more distant (>2.5 cm) from the brain surface, the sensitivity was lower. The clinical usefulness of this technology to identify hematomas therefore will depend on the type of brain disorder being examined. For TBI, for which the majority of the hematomas are subdural or epidural, and in which many intraparenchymal hematomas involve the surface of the brain, the sensitivity should be good.

Table 3. Sensitivity and Specificity for Epidural, Subdural, and Intracerebral Hematomas and Contusions of Different Volumes

			Hematoma absent		*Hematoma present*	
Volume	*Specificity (95% CI)*	*Sensitivity (95% CI)*	*False-positive* (n)	*True-negative* (n)	*True-positive* (n)	*False-negative* (n)
>70 mL	90.7% (86.4–93.7)	100% (46.3–100)	25	244	5	0
>25 mL	90.7% (86.4–93.7)	93.3% (66.0–99.7)	25	244	14	1
>10 mL	90.7% (86.4–93.7)	91.6% (76.4–97.8)	25	244	33	3
>3.5 mL[a]	90.7% (86.4–93.7)	88% (75.0–95.0)	25	244	44	6
>1.5 mL	90.7% (86.4–93.7)	73.1% (60.7–82.9)	25	244	49	18
All	90.7% (86.4–93.7)	68.7% (57.4–78.2)	25	244	57	26

[a]These hematomas were >3.5 mL volume and <2.5 cm from brain surface. 95% CI, exact 95% confidence interval.

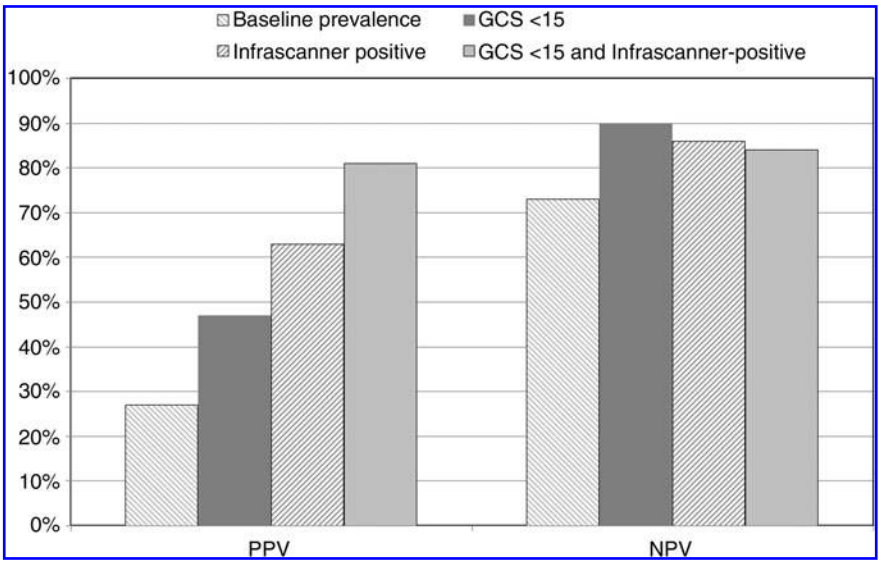

FIG. 4. Positive predictive value (PPV) and negative predictive value (NPV) for all patients, for patients with Glasgow Coma Scale score (GCS) <15, and for patients with NIR exams showing a difference in optical density (OD) >0.2. The combination of the NIRS exam and the clinical neurological examination yielded a better PPV than either characteristic alone (NIR, near-infrared).

The PPV of the NIR examination was 63.7% and the NPV was 97.6%. For these predictive value calculations, it should be noted that for rare disorders, the major determinant of the predictive value of the test is the prevalence of the disorder in the population tested (Altman and Bland, 1994). Regardless of the test's sensitivity and specificity, if the population is at low risk of having the disorder, positive results are more likely to be false-positives, decreasing the PPV. Likewise, if prevalence is low, negative results are likely to be true-negatives, increasing the NPV. Since the prevalence of intracranial hematomas was 15.6% in the population studied, the predictive values have only limited usefulness.

Several limitations of the study design should be acknowledged. One confounding factor for NIR technology with TBI patients is injury to the scalp. Blood contained within a scalp hematoma can alter the ΔOD and cause a false-positive result with this technology. The presence of a scalp laceration or hematoma was an exclusion criterion for this study, and was also one of the common reasons for excluding cases from the per-protocol analysis. In clinical practice, however, patients with scalp injuries need to be evaluated for head injury, and would be more likely to have a false-positive result with this technology. This may be a limitation in generalizing the results of this study to all TBI patients.

The study protocol also specified that the portable NIR-based device exam must have been performed within 12 h of head injury. This time requirement for data collection was chosen because the NIR method relies on the absorption characteristics of acute blood. As previous studies have suggested, chronic subdural hematomas cannot be reliably detected with this method (Kahraman et al., 2006; Robertson et al., 1997), probably because the hemoglobin breakdown products in a chronic hematoma do not have the same absorption characteristics.

Hair, especially when thick and darkly colored, has been a difficult issue complicating past studies using NIR technology to detect intracranial hematomas (Kahraman et al., 2006; Robertson et al., 1997). Shaving areas of the head to obtain a more accurate NIR examination would be an impediment to clinical application of the device. The fiberoptic lightguides of the NIR device, which can be worked in between hairs, was designed to minimize the significance of this problem.

A limitation of the previous pilot study was that all of the NIR measurements were performed by one experienced investigator using a prototype device that required calibration and manual calculation of the ΔOD, which would be cumbersome in an emergency setting (Robertson et al., 1997). The portable NIR device's simplified and dedicated design has made the NIR technique more useful in the setting of the trauma emergency department. Although some training was required to properly do the NIR examination with the portable device, there was no difference in performance among the difference sites participating in the study.

The output of the NIR device gives an indication of the presence or absence of an intracranial hematoma, and a value of ΔOD in the four brain regions examined. This would not be sufficient information alone to make a definitive diagnosis or to make a decision about treatment. Surgical decisions require additional information about the location, type, and size of the hematoma, as well as other brain characteristics such as midline shift and other indications of mass effect (Bullock et al., 2006). The findings from the NIR device also cannot detect other traumatic processes such as diffuse axonal injury or cerebral edema. Thus a severe TBI could exist in the presence of a normal NIR exam.

Nevertheless, the high specificity and high NPV of the NIR examination suggest that the device might be useful to supplement clinical information, such as the neurological status, the mechanism of injury, and hemodynamic stability, which are used in the field to triage patients to a Level 1 trauma center, and in the emergency department to determine the urgency and/or the need for subsequent imaging studies. The portability of the NIR device might be particularly useful in military applications and other austere conditions. The NIR technology

cannot replace CT scanning when it is readily available, but the finding of a positive NIR examination might suggest a higher priority for imaging, even in an otherwise low-risk patient. Future studies will be needed to confirm the role of this NIR technology in the screening and treatment of TBI.

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Author Disclosure Statement

No competing financial interests exist.

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