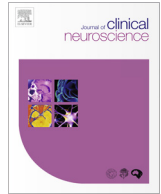




Contents lists available at ScienceDirect

Journal of Clinical Neuroscience

journal homepage: www.elsevier.com/locate/jocn

Case study

Portable near-infrared rapid detection of intracranial hemorrhage in Chinese population

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ARTICLE INFO

Article history:

Received 26 January 2017

Accepted 12 February 2017

Available online xxx

Keywords:

Intracranial hemorrhage

Traumatic brain injury

Near infrared

TBI

NIR

ABSTRACT

Background: Secondary brain injury is the main cause of mortality from traumatic brain injury (TBI). One hallmark of TBI is intracranial hemorrhage, which occurs in 40–50% of severe TBI cases. Early identification of intracranial hematomas in TBI patients allows early surgical evacuation, and can reduce the case-fatality rate of TBI. Since pre-hospital care is the weakest part of Chinese emergency care, there is an urgent need for a capability to detect brain hematomas early. The purpose of this observational study was to evaluate the performance of a near infrared (NIR) based, device to screen for traumatic intracranial hematomas in Chinese population.

Methods: Data was collected using the NIR device at the time of a computed tomography (CT) or magnetic resonance imaging (MRI) scan was performed to evaluate a suspected TBI. 85 patients were included in the per protocol population. Of the 85 patients, 45 were determined by CT scan to have intracranial hemorrhage. The CT and MRI scans were read by an independent neuroradiologist who was blinded to the NIR measurements.

Results: The NIR device demonstrated sensitivity of 95.6% (95% confidence intervals [CI] 83.6–99.2%) and specificity of 92.5% (CI 78.5–98%) in detecting intracranial hematomas larger than 3.5 ml in volume, and that were less than 2.5 cm from the surface of the brain.

Conclusion: These results confirm in Chinese population the results of previous studies that demonstrated a NIR based device can reliably screen for intracranial hematomas that are likely to be of clinical importance.

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1. Introduction

In China, trauma has become the fourth leading cause of death after heart disease, cancer, and cerebrovascular accidents, and it is the leading cause of death in adults under the age of 40. Among various traumas, traumatic brain injury (TBI) has the highest

mortality and the most serious consequences and is the most difficult to treat. It has been reported that patients who die of TBI account for 87% of all trauma deaths. The proportion of severe TBI in China is much higher than that in other countries (20% vs. 10%) [1]. TBI is frequently referred to as the ‘silent epidemic’ because complications from TBI, such as cognitive, sensory or emotional impairments may not be readily apparent. The loss of human potential, long-term impairments and disabilities associated with TBI has a tremendous impact on Chinese society. In addition, awareness about TBI among the general public is limited [2].

An estimated 3–4 million people experience traumatic brain injury each year in China or an annual rate of 230–300 per 100,000 people [3]. Another study showed that the incidence of traumatic neurological injury was 55.4 patients per 100,000 population per year in the six big cities in China and 64.1 patients in the rural areas [4]. We believe that those two reports underestimate

Abbreviations: AUC, area under the curve; CI, confidence interval; CT, computerized tomography; ΔOD , difference in optical density; ΔOD_{max} , the greatest absolute value for ΔOD among the various regions examined; GCS, Glasgow coma score; MRI, magnetic resonance imaging; NIR, near infrared; NPV, negative predictive values; PPV, positive predictive values; ROC, receiver operating characteristic; TBI, traumatic brain injury.

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<http://dx.doi.org/10.1016/j.jocn.2017.02.056>

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the size of the TBI epidemic in China as many individuals with mild TBI will not be admitted to hospitals and are often overlooked in hospital-based TBI studies [5].

Secondary brain injury, which occurs in minutes to days following primary injury, is the main cause of TBI mortality. Early identification, prevention, and correction of these events in the pre-hospital setting can lower the risk of secondary brain injury and reduce the case-fatality rate of TBI. For patients with moderate-to-severe TBI in particular, diagnosis within the first (“golden”) hour of the traumatic event is critical. Since pre-hospital care is the weakest part of Chinese emergency care, suboptimal practices in TBI management may exist in pre-hospital settings [1].

One hallmark pathological process in TBI is intracranial hemorrhage, which occurs in 40–50% of severe head trauma cases [6]. Early diagnosis and surgical evacuation of intracranial hematomas are fundamental management principles for traumatic hematomas [7]. Early identification of intracranial hematomas in TBI patients allows early surgical evacuation, which can be an important determinant of outcome. In one study, Seelig et al. 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 [8].

A practical adjunct to this goal of early identification of intracranial hematomas in the field and emergency center may be the use of a portable NIR technology. A NIR based, hand held medical screening tool (Infrascanner by InfraScan, Inc., Philadelphia, PA, USA) has been developed to screen for a brain hematoma at the site of injury [9]. In laboratory tests with phantom models of intracranial hematomas, the smallest volume of blood that can be detected with the device was 3.5 ml, and the hematoma must be within 2.5 cm of the brain surface to be detected.

In a multi-center study (431 patients) conducted with a prototype Infrascanner, sensitivity for intracranial hematomas was 88% as compared to CT scan readings [10]. Specificity in the per protocol population was 90.7%. The type of hematoma could not be determined with certainty in this 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. Leon-Carrion et al. studied the use of the Infrascanner in 35 patients with intracranial hematomas and found an overall sensitivity of 89.5% and specificity of 81.2%, as compared to CT scanning [11]. Bressan et al. evaluated 110 children at intermediate or high risk for intracranial injury. There was only one brain hematoma case in this group (it was successfully detected) [12]. The Specificity in this test was 93%. The use of Infrascanner would have led to the avoidance of ten CT scans, reducing the CT scan rate by 58.8%. Tyzo et al. evaluated 94 children with mild TBI. The Sensitivity in this test was 86.7% and Specificity was 90% [13]. The aim of the study was to propose a new protocol of screening patients using Infrascanner as a complement to repeated neurological examination and medical history review. The results of this study led to the adoption of the Infrascanner as part of the standard of pediatric care in Poland [14]. Semenova et al. evaluated the Infrascanner's ability to detect intracranial hemorrhages among 95 children having experienced mild head trauma [15]. 42 children with associated medium–high risk (GCS 13–14) received an evaluation by neurosurgeon, Infrascanner, and a CT. 53 children with associated low risk (GCS 15) received a scan with the Infrascanner and were clinically monitored for 72 h. Among the medium–high risk category the sensitivity was 100% and the specificity was 91.2%. In the low risk group, the specificity was 91.7%.

The purpose of this clinical study was to evaluate the performance of this NIR based portable device, Infrascanner by InfraScan, Inc, in the detection of intracranial hemorrhage due to trauma in

Chinese population. The high incidence of TBI, and especially of severe TBI in China, coupled with suboptimal pre-hospital care, increases the special need in China for pre-hospital brain hematoma detection ability. Therefore, we believe that the first-hand sensitivity and specificity evaluation of the Infrascanner in Chinese population is necessary. The endpoint of the study was a description of the test characteristics (sensitivity, specificity, positive and negative predictive values) 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 as the gold standard.

2. Methods

2.1. Study design

The study was a single-center observational study to test the performance of the new portable NIR device to screen for intracranial hemorrhage, comparing the findings of the NIR exam to those of the admission CT or MRI scan. The endpoint of the study was a description of the test characteristics (sensitivity, specificity, positive and negative predictive values) of the portable NIR based device in the identification of hematomas within its detection limits (volume > 3.5 ml, and depth < 2.5 cm) when compared to CT and MRI scans results as the gold standard.

2.2. Theoretical basis for detection of hematomas with NIR technology

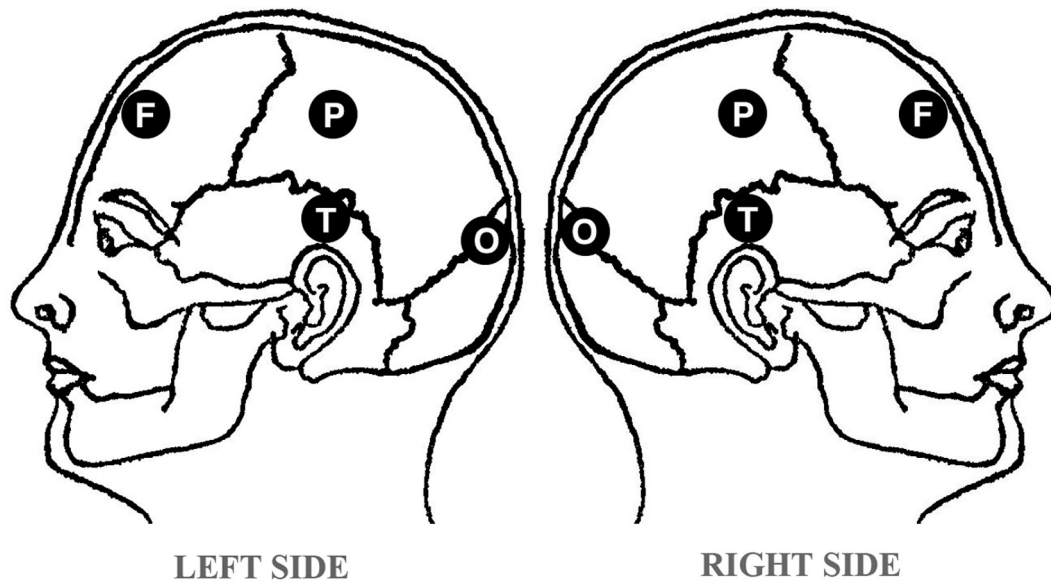
Due to its unique light-absorbing properties, hemoglobin molecules within tissue have the highest absorption rate in the NIR range (700–900 nm) [16–18]. The principle used in identifying intracranial hematomas with NIR is that extravascular blood absorbs NIR light more than intravascular blood. This is because there is a greater (usually 10-fold) concentration of hemoglobin in an acute hematoma than in normal brain tissue where blood is contained within vessels. The NIR based device, Infrascanner Model 2000 (InfraScan, Inc., Philadelphia, PA, USA), compares light absorption in both the left and right sides of the brain in four different areas. The absorbance of NIR light is greater (and therefore the reflected light less) on the side of the brain containing a hematoma, than on the uninjured side. With specified wavelength ranges, optical light source(s) or emitter(s) and a photo-detector are placed at a distance, which allows proper NIR absorption measurements in a desired volume of tissue. The used wavelength of 805 nm, the isosbestic point of hemoglobin, is sensitive only to blood volume, not to oxygen saturation in the blood.

The device is placed successively in the left and right frontal, temporal, parietal, and occipital areas of the head in a predefined sequence and the absorbance of light is recorded (see locations in Fig. 1). The difference in optical density (ΔOD) in each of the four symmetrical areas is calculated on a pair-wise basis using the following formula:

$$\Delta OD = \log_{10} \left(\frac{I_L}{I_R} \right)$$

where I_L = the intensity of reflected light on the left side of the head, I_R = the intensity of reflected light on the right side. With 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.

Intracranial hematoma detection was established when a $\Delta OD > 0.2$ units occurred in a particular pair of bilateral measurements. The presence or absence of a hematoma in a patient was determined by comparing the ΔOD_{\max} measurement to the pre-defined threshold of 0.2. When any single pair measurement



Frontal	Left/Right forehead, above the frontal sinus with medial light guide above eye pupil
Temporal	In the Left/Right temporal fossa in front of the top of the left ear
Parietal	Above the Left/Right ear, midway between the ear and the midline of the skull
Occipital	Behind the top of the Left/Right ear, between the ear and the occipital parotubérance

Fig. 1. Head locations of NIR data acquisition in patients with suspected brain injury.

indicated a difference of ± 0.2 OD or greater, the measurement pair was repeated twice to confirm the presence of a hematoma. A $\Delta OD \leq 0.2$ units was considered a negative exam. The 0.2 cut-off for the Infrascanner was set following a previous study on hematoma detection using NIR [19].

2.3. Methods of measurement

The Infrascanner Model 2000 NIR device is used for hematoma detection inpatients sustaining TBI. The NIR device consists of two components: a sensor and a charging cradle. The sensor includes an 808 nm diode laser and a silicon detector. The sensor delivers NIR light to the tissue, and receives it after it has interacted with the tissue via fiber optics mounted in a plastic, single patient use disposable shield. The fiber optics is designed so that they can be maneuvered between hair roots to minimize the interference from hair without the need to shave it (see Fig. 2). The detected signal is then digitized and analyzed by a single board computer in the scanner. The computer receives the data from the detector, processes it further and displays the results on its screen.

Within 30 min before or after the CT scan was performed for clinical indications, an operator independently performed a standardized examination with the portable NIR device. The exam, usually lasting 3 min, covers common locations for traumatic hematomas. Measurements were made at four pre-identified pairs of locations on the head: frontal, temporal, parietal, occipital regions (with a variance of ± 1 cm). At each location, the actual

measurement of the portable NIR device takes up to 10 s. The whole head scan takes less than 3 min. If the time gap between the NIR measurements and CT examinations was more than 30 min, which could happen if the CT scan was delayed more than expected, then a second examination with the portable NIR device was performed within 30 min after the CT scan with the operator still blinded to the results of the CT scan. The second exam within 30 min of the CT scan, if taken, was used in the analysis.

Operators 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 where an instructor provided a demonstration of the NIR device, followed by supervision of practice examinations on healthy individuals. Only trained operators collected data from patients in this study.

2.4. 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 between June 2015 and August 2016. Trained operators were available during regular business hours. 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. Exclusion criteria included the presence of large scalp lacerations or avulsions involving the NIR examination sites. The analyses of the performance of



Fig. 2. Portable NIR detector of intracranial hemorrhage, the Infrascanner: (a) The scanner positioned inside the charging cradle, (b) The scanner with a disposable fiber optic shield in hand and placed on a head.

the portable NIR based device were conducted using a “per protocol” population. The protocol violations that excluded the other 4 patients from the analysis were blood or lacerations on the scalp over the scan area ($n = 1$), non completion of the NIR device scan ($n = 1$), and patients with small hematomas, below the theoretical detection threshold of the NIR device ($n = 2$). Fig. 3 shows a diagram of patient retention in the study. The guidelines for neurosurgical intervention to evacuate brain hematomas 7 require bleeds of

at least 25 ml. While the minimum 3.5 ml needed for detection by the Infrascanner is a limitation on system usefulness, it still can detect hematomas that are almost order of magnitude smaller than a hematoma that will require surgical intervention. Hence, it still provides an early warning, before the hematoma had time to grow and start creating urgent risk.

The test was performed at the flagship neurosurgical center in China, and hence the patient population included more severe

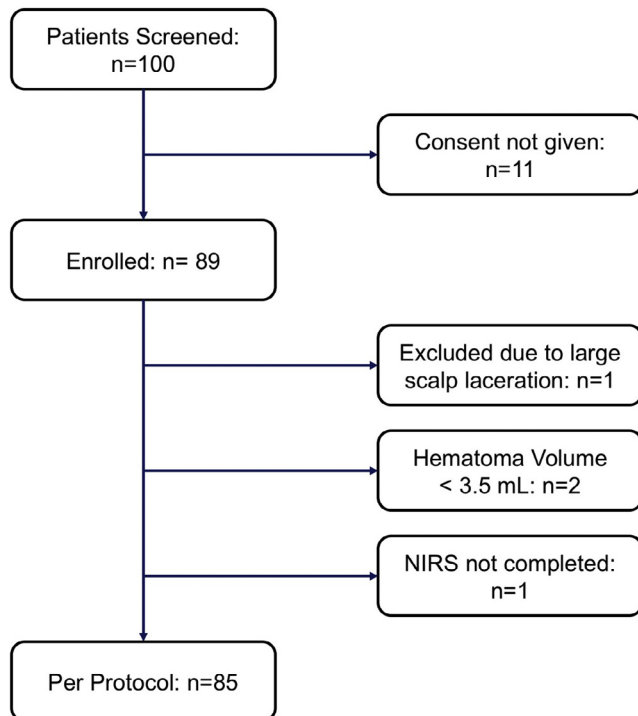


Fig. 3. Patient recruitment and retention into the study.

brain trauma cases than regular hospitals. Since there were not enough traumatic brain injury patients without hematomas we have enriched the no-hematoma group by adding: a) Patients with chronic medical diseases (such as cerebrovascular disease, diabetes and hypertension) who underwent CT, as part of their regular treatment; b) A group of 20 healthy volunteers, who underwent a 3.0T MRI scanning sequence (T1, T2 images) to avoid the radiation risk of CT scan, with Infrascanner test performed within 30 min after the MRI.

3. Results

3.1. Characteristics of the study subjects

Mostly adults were represented in this study with a range in age from 8 years to 89 years (mean of 48.3 years). Out of 85 patients, males were evaluated for suspected TBI approximately twice as often as females. The unique demographic aspect of this study population was that it included 100% Han Chinese. Characteristics that might affect performance of an optical method, such as skin and hair color, and hair thickness, were collected for the patient population. The GCS score was also collected on admission (Table 1). The mechanism of brain injury, from most frequent to least frequent, were assaults, vehicular accidents (including motorized and non-motorized vehicle accidents), falls, and unknown.

The per protocol population, as defined in the methods section, included 85 patients. In the per protocol group, there were 17 (20%) subdural hematomas, 10 (11.8%) epidural hematomas, and 18 (21.1%) intracerebral hematomas for a total of 45 (52.9%) patients with intracranial hemorrhage following an acute traumatic brain injury. The remaining 40 patients had GCS of 15 and did not have intracranial hemorrhage. Out of this group, 20 subjects were healthy volunteers, serving as additional negative control. Those healthy volunteers were scanned in an MRI as the gold standard.

3.2. Procedure

This study was performed with patients admitted to the Department of Neurosurgery, Beijing Tiantan Hospital, Capital Medical University, Beijing, China. The Hospital Institutional Review Board approved this study and all procedures were in accordance with the Declaration of Helsinki guidelines.

A neuroradiologist evaluated all of the CT and MRI scans and entered the results in a database. In order to eliminate any possible bias, the neuroradiologist was blinded to NIR measurements and the clinicians who entered the NIR device measurements were blinded to the CT and MRI scans readings in the database. An independent statistician compared the performance of the portable NIR based device in hematoma detection using CT and MRI scans results as the gold standard.

Overall sensitivity and specificity analyses were performed, using comparisons between NIR and CT/MRI scan results. True positives, false positives, true negatives and false negatives were counted and used to estimate both sensitivity (true positives/true positives + false negatives) and specificity (true negative/false positive + true negative). Positive predictive values (PPV = true positive/true positive + false positive), negative predictive values (NPV = true negative/true negative + false negatives) and the respective 95% confidence intervals (CI) were also calculated.

3.3. Main results

The distribution of ΔOD_{\max} values for all 85 per protocol patients is illustrated in Fig. 4, separated by whether or not intracranial hemorrhage was identified on the initial CT or MRI scan. The ΔOD_{\max} for the 40 cases where no intracranial hemorrhage was identified on the initial CT scan ranged from 0.07 to 0.42, but 92.5% of the cases were ≤ 0.20 , which was pre-defined as the threshold for identification of intracranial hemorrhage. Of the 45 cases where intracranial hemorrhage of size larger than the detection ability of the Infrascanner (3.5 ml) was identified on CT scan, 43 cases had a ΔOD_{\max} greater than the predefined threshold of 0.2, for an overall sensitivity of 95.6%. Table 2 shows the full performance data for all per protocol cases. PPV was 93.5% and NPV was 94.9%.

The diagnostic performance of a test, or the accuracy of a test to discriminate diseased cases from normal cases is evaluated using receiver operating characteristic (ROC) curve analysis. The area under the ROC curve (AUC) is a measure of how well a test can distinguish between two diagnostic groups (hematoma/normal). Using the information in Fig. 4, we were able to construct the ROC curve for the Infrascanner test in detection of intracranial hemorrhage (illustrated in Fig. 5). The AUC was 0.97, which means that this is an excellent test to differentiate between patients with an intracranial hemorrhage and those without it.

Fig. 6 shows three examples of pathological CTs of intracranial hematomas detected by Infrascanner in the study sample. Figs. 6 (a and b) show examples of the detection of unilateral bleeds, while Fig. 6(c) shows an example of the detection of bilateral hematoma. Although it was a bilateral frontal lobe cerebral hemorrhage, the amount of bleeding on both sides was substantially different. The NIR method, which is looking for blood volume asymmetry, was able to detect it.

3.4. Limitations

Several limitations for identifying intracranial hematomas with NIR were observed in this study. First, the size, type, and location of the hematoma cannot be as precisely determined as with a CT scan. Second, because the NIR examination relies on absorbance in the contralateral brain locations for comparison, bilateral

Table 1
Demographic and clinical characteristics of study subjects ($n = 85$).

Characteristic		Subjects			
		CT positive	CT negative	MRI negative	All patients
Age (years)	Range	23–89	8–79	21–49	8–89
	Mean	55.5	50.3	29.9	48.3
Sex	Male	31 (69%)	12 (60%)	12 (60%)	55 (65%)
	Female	14 (31%)	8 (40%)	8 (40%)	30 (35%)
Race	Han	45 (100%)	20 (100%)	20 (100%)	85 (100%)
Skin color	Light	28 (62%)	15 (75%)	14 (70%)	57 (67%)
	Dark	17 (38%)	5 (25%)	6 (30%)	28 (33%)
Hair color	Black	24 (53%)	10 (50%)	18 (90%)	52 (61%)
	Brown	10 (22%)	7 (35%)	2 (10%)	19 (22%)
	Light	11 (24%)	3 (15%)	0 (0%)	14 (16%)
Hair thickness	Thick	8 (18%)	3 (15%)	6 (30%)	17 (20%)
	Normal	24 (53%)	12 (60%)	11 (55%)	47 (55%)
	Thin	13 (29%)	5 (25%)	3 (15%)	21 (25%)
GCS	3–8	5	–	–	5
	9–12	8	–	–	8
	13–15	32	20	20	72

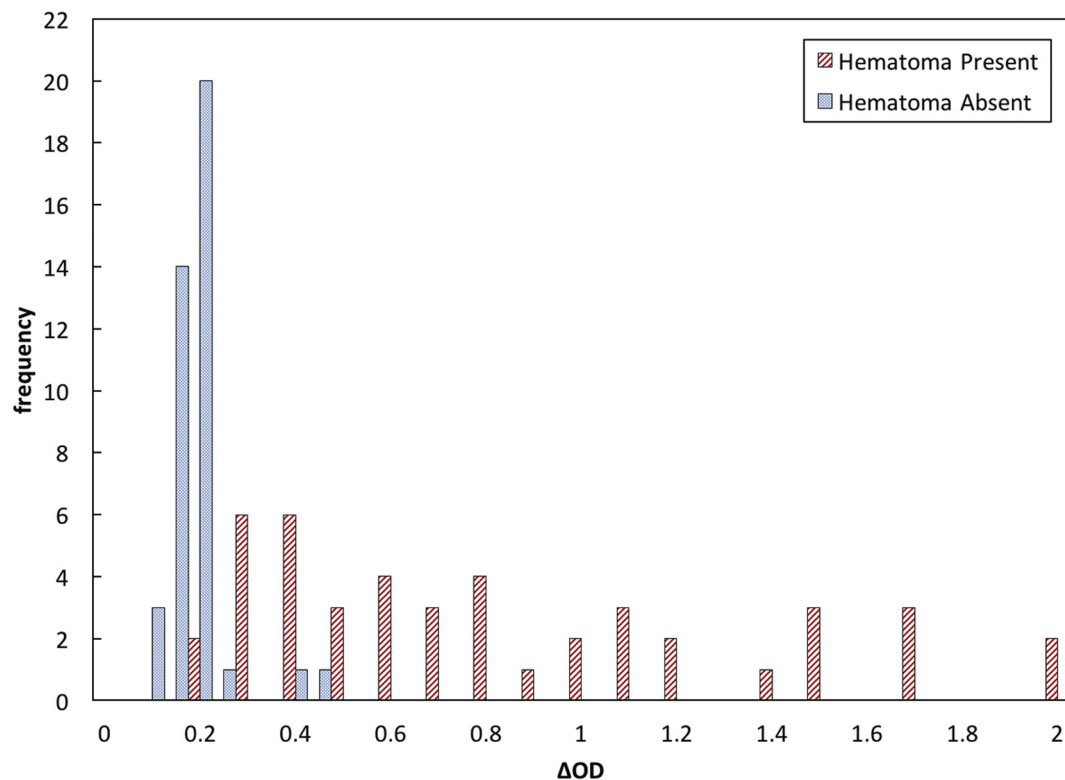


Fig. 4. Distribution of difference in optical density (ΔOD) for patients with intracranial hemorrhage present ($n = 45$), and intracranial hemorrhage absent ($n = 40$).

Table 2
NIR device performance.

Epidural, Subdural, and Intracerebral Hematomas, volume > 3.5 ml and distance < 2.5 cm from brain surface (85 patients, 45 with intracranial hematomas within NIR detection limits)			
Specificity (95%CI)	Sensitivity (95%CI)	NPV (95%CI)	PPV (95%CI)
92.5% (78.5–98%)	95.6% (83.6–99.2%)	94.9% (81.4–99.1%)	93.5% (81.1–98.3%)

Abbreviations: PPV = positive predictive value, NPV = negative predictive value, 95%CI = Exact 95% confidence interval.

lesions could be difficult to identify with this technology. This circumstance occurred on two occasions in the 85 patients and must be kept in mind. Fig. 7 shows those two cases of bilateral frontal

lobe hemorrhage, with the amount of bleeding similar on both sides of the head, as well as similar distance of the bleed from the scalp.

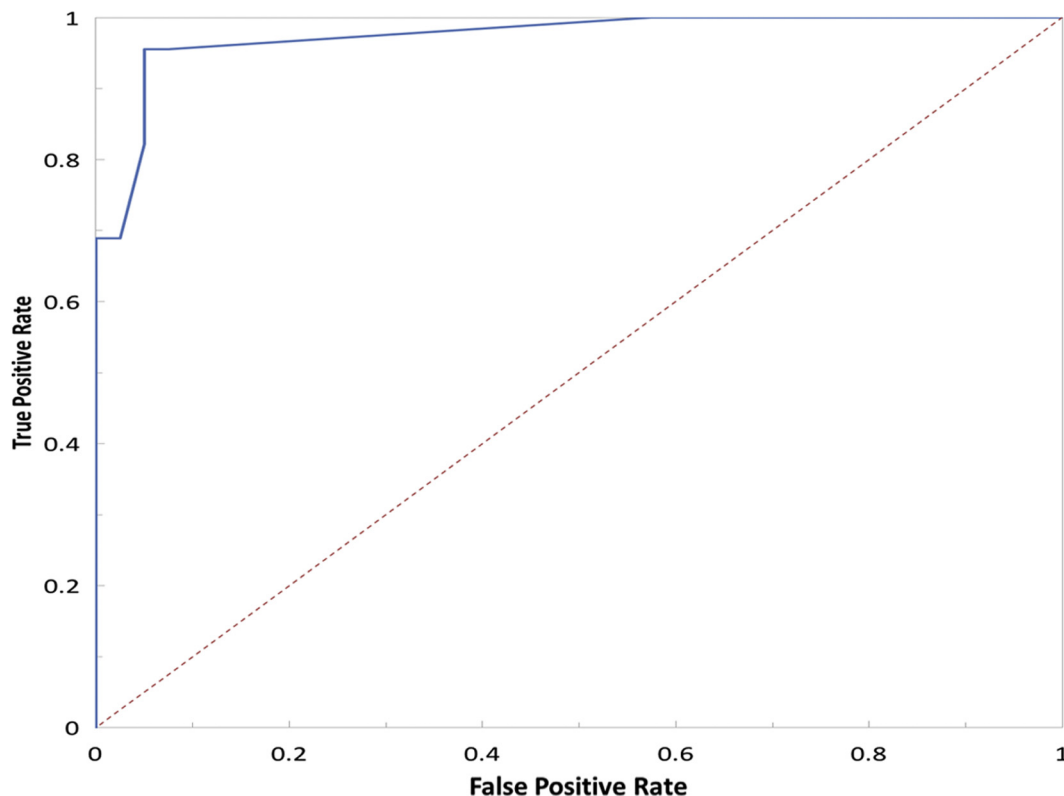


Fig. 5. Receiver operating characteristic (ROC) curve for the Infrascanner test in detection of intracranial hemorrhage.

An important confounding factor for NIR technology with TBI patients is injury to the scalp. Blood contained within a scalp hematoma can also alter the OD and cause a false positive result with this technology. The presence of a scalp laceration or hematoma was an exclusion criterion for this study. Despite the effort to exclude open scalp injury, subgaleal hematomas are less obvious and can contribute to false positives. Fig. 8 illustrates such false positive case, with a scalp hematoma, but without intracranial hemorrhage.

4. Discussion

The most significant results of this pilot study are that the hand-held near-infrared Infrascanner demonstrates excellent sensitivity and specificity in detecting intra- and extra-axial traumatic hematomas and, even more importantly, it is able to detect small hematomas (<25 ml) within the first 12 h following injury. Data shows that the Infrascanner demonstrated high sensitivity (95.6%) and specificity (92.5%) in detecting traumatic intracranial hematomas >3.5 ml in volume and <2.5 cm from the surface of the brain. Its on-site capacity to identify patients that have suffered an intracranial hematoma may be considered very high.

This study confirms the findings of previous investigations demonstrating that NIR technology can be reliably 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 [8,11–13,15,19–21]. The sensitivity for identifying intracranial hematomas in the studies by Robertson et al. [8] and Leon-Carrion et al. [11] was 88% and 89.5% respectively. Robertson had close to 40% of the patients with black skin and only 27% of patient had light skin. In the Chinese population that we enrolled in the study we had no patients with black skin and 67% of the

patients had light skin. We anticipate that since the NIR method has some sensitivity to skin color, the sensitivity in patients with lighter skin should be better. This can partially explain the higher sensitivity we observed in this study, which had skin color distribution similar to the study in Spain, by Leon-Carrion. Robertson also noted that for patients with larger bleeds the sensitivity was higher (93.3%). Unlike the previous studies, this study was performed at a national Neuro-center in China and therefore had substantially higher prevalence of patients with brain hematomas in general and larger bleeds in particular. Comparing Fig. 3 in Robertson et al. [8] with Fig. 9 here, showing the distribution of the volume of the intracranial hemorrhages observed, reveals that in the current study there was a higher rate of larger hematomas than in the Robertson study. The higher prevalence of larger hematomas can provide an additional explanation for the higher sensitivity we observed in this study.

The specificity in the studies by Robertson et al. and Leon-Carrion et al. was 90.7% and 81.2% respectively. Unlike prior studies, the Infrascanner used in this study included a new “Guided Mode”. This is a new upgraded user interface that helps the operator follow the scanning protocol and assists in performing the measurements correctly. The use of this software helped increase scanning protocol compliance and reduced user errors. Rigorous operator training coupled with the use of the Guided Mode contributed to lower false positive rate, or the higher specificity observed in this study, as compared to prior research.

The clinical usefulness of this technology to identify hematomas will depend on the type of brain disorder being examined. For TBI, where the majority of the hematomas are subdural or epidural, and where many intraparenchymal hematomas involve the surface of the brain, the sensitivity should be good.

This study demonstrates that the Infrascanner is a useful tool in the initial examination and screening of patients with head injury. It has utility as a preliminary exam given within 12 h post-injury,

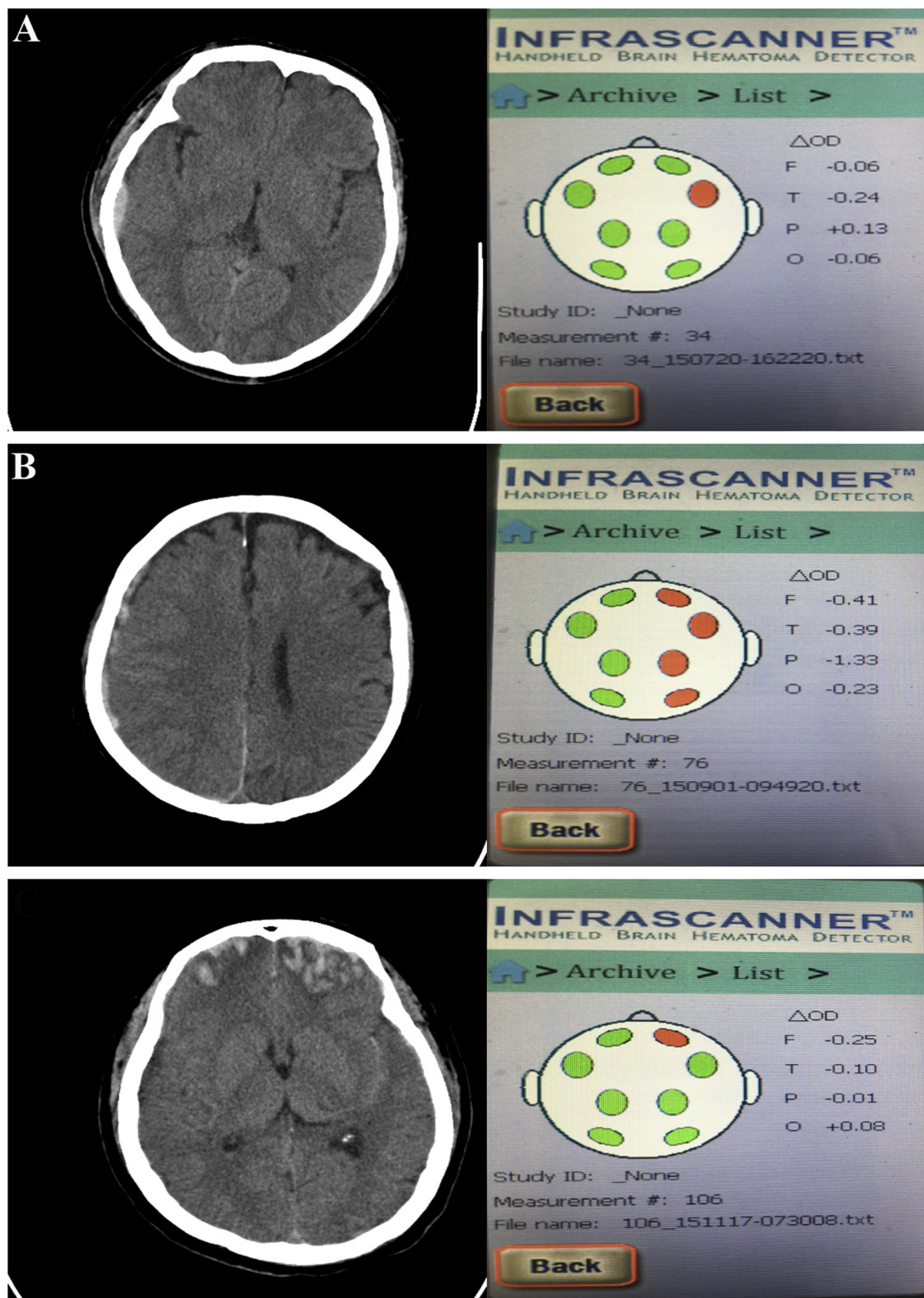


Fig. 6. Examples of pathological CT scans and Infrascanner readings: (a) Right temporal epidural hematoma, (b) Right frontal and temporal subdural hematoma, (c) Bilateral frontal intracerebral hemorrhage.

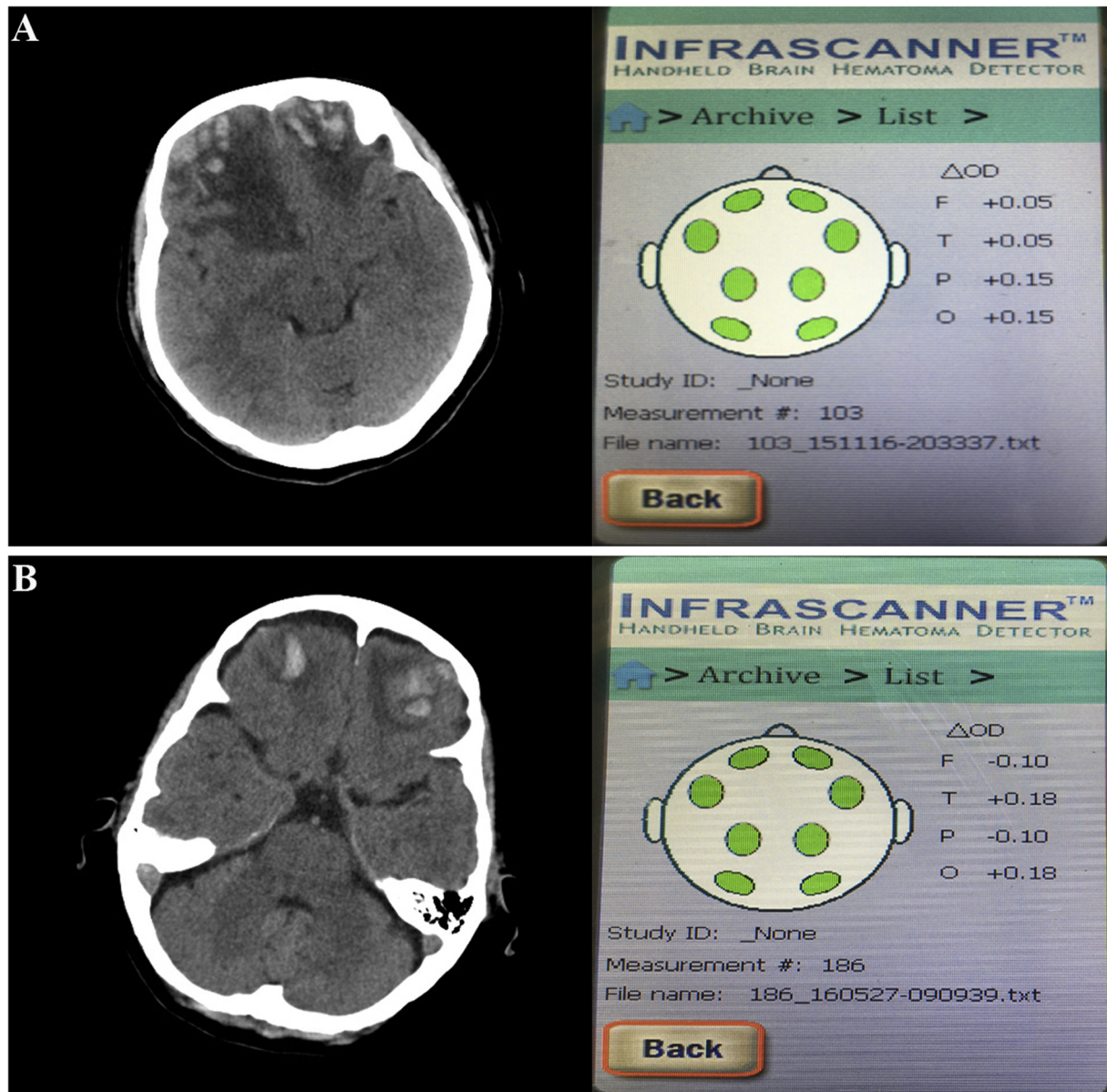


Fig. 7. Two cases of bilateral brain contusions, where Infrascanner was negative: (a) Bilateral frontal intracerebral hemorrhage, (b) Bilateral frontal intracerebral hemorrhage.

when a CT scan is not available or as an adjunct to CT scans. The Infrascanner's high specificity and high NPV suggest that the device could supplement clinical information, such as neurological status, mechanism of injury and hemodynamic stability, all of which are used in the field to triage patients to a trauma center and in the emergency unit to determine the urgency and/or need for subsequent imaging studies. The output of the NIR device gives an indication of the presence of an intracranial hematoma (yes or no) and a value of OD in the 4 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 volume of the hematoma, as well as other brain characteristics such as midline shift, hernia, etc [7]. Hence, the Infrascanner is not indicated as a substitute for a CT scan, nor can the NIR technology replace CT scanning when it is readily available. However, a positive NIR exam could give higher priority for imaging, even in an otherwise low risk patient, particularly in cases where the detection is made prior to hospitalization in places or situations where CT scans are not

available or in cases of mass TBI casualties such as natural or man-made disasters. It is a simple and quick test to perform. NIR technology uses non-ionizing and safe light, and is especially suitable for use in radiation sensitive patient groups such as children and pregnant women.

Recent data shows that hematoma expansion is associated with early neurological deterioration [22]. 38% of patients suffer intracerebral hematoma progression during this time period and it has been related to a worse prognosis. The Infrascanner may be an adjunct tool in the intensive care units for long-term follow-up of patients with intracranial hemorrhage for early detection of postoperative re-bleeding or hematoma expansion.

Several limitations of the device design should be acknowledged in addition to the ones mentioned in results section. Symmetrical bilateral hematomas could be difficult to identify with this technology. In this study, two false negative patients had symmetrical bilateral frontal lobe hemorrhages, with similar volume and location of bleeding on both sides of the head. But, as we found in another case (Fig. 6(c)), the Infrascanner can detect bilateral



Fig. 8. Patient with right temporal-parietal scalp hematoma without intracranial hemorrhage.

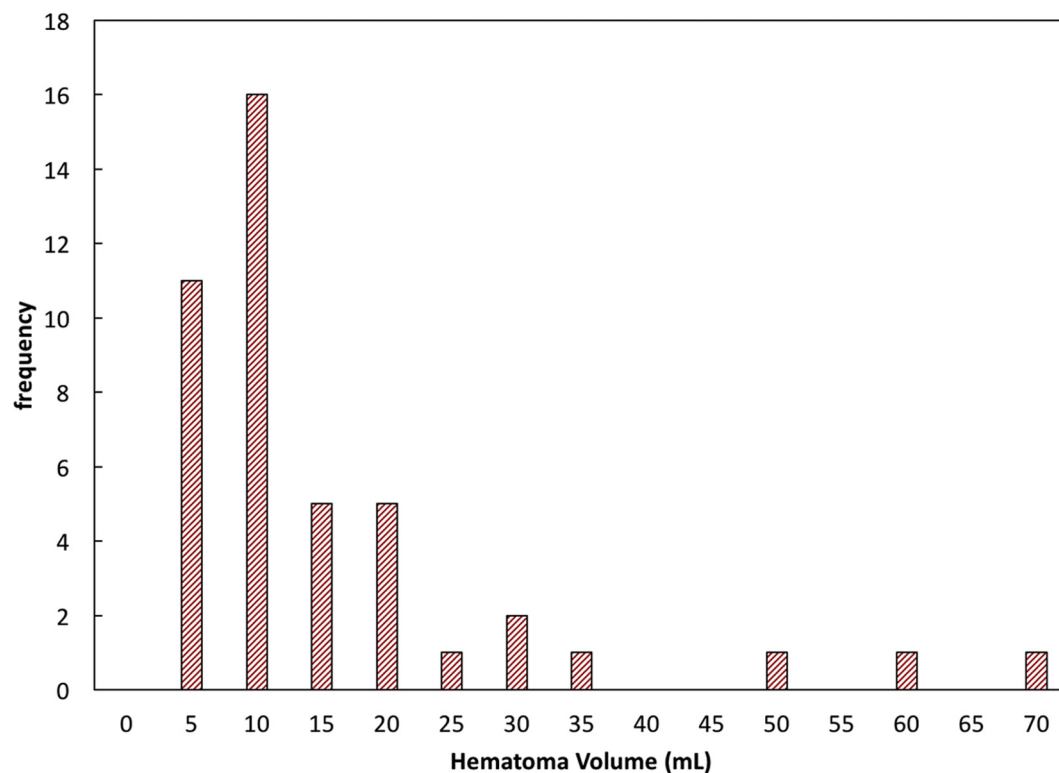


Fig. 9. Distribution of the volume of the intracranial hemorrhages observed.

intracranial hemorrhage when there is an obvious hematoma volume difference between the two sides of the head. While less common in TBI patients, NIR method might miss deep bleeds (more than 2.5 cm from brain surface) as well as small contusions of less than 3.5 ml volume.

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 [19,20], probably because the hemoglobin breakdown products in a chronic hematoma do not have the same light absorption characteristics as hemoglobin in NIR.

In addition to scalp injury there are several other sources for false positives, such as high neck clothes, thick and dark hair, scalp displacement as well as restless and non-cooperative patients.

5. Conclusions

In conclusion, the study showed that the Infrascanner is a suitable portable device in Chinese population for detecting pre-operative intracranial subdural, epidural and intracerebral hematomas in remote locations, emergency rooms and intensive care units. It could aid paramedics, emergency room physicians and hospital staff, permitting better triage decisions, earlier treatment and reducing secondary brain injury caused by acute and delayed hematomas. The device has the potential to reduce the use rate of CT scans, and to reduce the risk of radiation to children, pregnant women and other sensitive patient groups. Future studies will be needed to confirm the ability of NIR technology to reduce the use rate of CT scans.

Disclosure

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflict of interest declaration

The authors report no conflicts of interest.

Acknowledgments

The following individuals helped with data collection: Neurosurgeons Dezhi Li, Yu Wang, Jiayi Qiu, Yu Xin, Huanguang Liu and Peng Kang, and Nurses Lei Wang and Qian Li.

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