Childs Nerv Syst
DOI 10.1007/s00381-013-2314-2

ORIGINAL PAPER

The use of handheld near-infrared device (Infrascanner) for detecting intracranial haemorrhages in children with minor head injury

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Received: 25 September 2013 / Accepted: 22 October 2013

Abstract
Objective A handheld device using near-infrared technology (Infrascanner) has shown good accuracy for detection of traumatic intracranial haemorrhages in adults. This study aims to determine the feasibility of use of Infrascanner in children with minor head injury (MHI) in the Emergency Department (ED). Secondary aim was to assess its potential usefulness to reduce CT scan rate.
Methods Prospective pilot study conducted in two paediatric EDs, including children at high or intermediate risk for clinically important traumatic brain injury (ciTBI) according to the adapted PECARN rule in use. Completion of Infrascanner measurements and time to completion were recorded. Decision on CT scan and CT scan reporting were performed independently and blinded to Infrascanner results.
Results Completion of the Infrascanner measurement was successfully achieved in 103 (94 %) of 110 patients enrolled, after a mean of 4.4±2.9 min. A CT scan was performed in 18 (17.5 %) children. Only one had an intracranial haemorrhage that was correctly identified by the Infrascanner. The exploratory analysis showed a specificity of 93 % (95 % CI, 86.5–96.6) and a negative predictive value of 100 % (95 % CI, 81.6–100) for ciTBI. The use of Infrascanner would have led to avoid ten CT scan, reducing the CT scan rate by 58.8 %.
Conclusions Infrascanner seems an easy-to-use tool for children presenting to the ED following a MHI, given the high completion rate and short time to completion. Our preliminary results suggest that Infrascanner is worthy of further investigation as a potential tool to decrease the CT scan rate in children with MHI.

Keywords Minor head injury · Near-infrared spectroscopy · CT scan · Children

Introduction

Minor head injuries (MHI) continue to be a major problem in paediatrics, representing one of the most common reasons for visits to the Paediatric Emergency Department (PED) [19, 5, 7], however only a small number are at risk of identifiable poor outcome [6, 14, 22].

The use of head CT for the detection of traumatic intracranial injuries in children should be balanced against the risks related to radiation [1, 18, 21], and risk of sedation of uncooperative patients [4, 17]. In addition, it leads to an increased resource utilization [20].

Despite recent availability of high-quality clinical decision rules to assist decision-making on CT scan in paediatric MHI [6, 14, 22], the rate of unnecessary neuroimaging is far from being optimal [16].

In the study centres we implemented the rule by the Paediatric Emergency Care Applied Research Network (PECARN) [14] that provides differentiated algorithms for

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Published online: 14 November 2013

children younger and older than 2 years of age (Fig. 1) This rule, derived and validated in the largest multicentre study with high methodological standards, appears to be the best rule to accurately identify children at very low risk of clinically important traumatic brain injuries (ciTBIs) for whom a CT scan can safely be avoided. For children at intermediate and high risk of ciTBI however, the rate of CT scan is still considerable with a rate of unnecessary CTs of approximately 20 % in our setting [2], and more than double in the United States [14].

In the effort of further optimizing the use of head CT scan in children with MHI new management strategies should be investigated, such as the additional use of non-radiating tools for the identification of patients with potentially clinically important intracranial haemorrhages.

Near-infrared spectroscopy (NIRS) technology devices have shown good accuracy for the detection of traumatic intracranial haemorrhages in adults [8–13, 15], with a sensitivity ranging from approximately 70 to 100 % and a specificity equal or greater than 80 %.

Promising results have also recently been reported in children [3, 25]. However, data are still limited and no studies have specifically assessed the feasibility of NIRS technology in detecting intracranial haemorrhages in the most challenging group of children with MHI in the emergency department (ED) setting.

The aim of this study was to determine the feasibility of use of NIRS technology for children with MHI in the ED. We hypothesised that the use of a handheld, non-radiating, painless, near-infrared technology device (Infrascanner) would be time efficient, and could be easily used in a busy ED also in young children.

As a secondary aim we explored whether Infrascanner could help reduce the number of unnecessary CT scan in this population and is worth of further larger multicenter studies.

Methods

Study design and setting

A prospective observational pilot study was carried out over a 9-month period (June 2011–February 2012) in the PED of the Woman's and Child's Health Department of Padova Hospital and over 7 months (September 2012–March 2013) in the Paediatric Unit of Treviso Hospital, in Italy. The PEDs of Padova and Treviso share clinical protocols and they collaborate in common research projects. Their yearly census is approximately 25,000 and 15,000 visits of children younger than 15 years. Both study centres use an adapted version of the

ciTBI predictors	Age < 2 years of age	Age ≥ 2 years of age
High-risk	Altered mental status[a] Palpable skull fracture	Altered mental status[a] Signs of basilar skull fracture
Intermediate-risk	Severe injury mechanism[b] Loss of consciousness > 5 secs Non-frontal hematoma Not acting right as per parents	Severe injury mechanism[b] Any loss of consciousness Vomiting Severe headache Amnesia[c]
Very low risk	None	None

[a] GCS 14, agitation, sleepiness, slow response or repetitive questioning
[b] Motor vehicle crash with patient ejection, death of another passenger or rollover, pedestrian or bicyclist without helmet struck by motorized vehicle, falls (of >3 feet for children < 2 years of age or > 5 feet for children ≥ 2 years) or head struck by high impact object
[c] Predictor added at the study sites, based on consensus, in the adapted PECARN rules in use

***ciTBI**: death from traumatic brain injury, neurosurgery, intubation for more than 24 h for traumatic brain injury, or hospital admission of 2 nights or more associated with traumatic brain injury on CT (defined as: intracranial haemorrhage or contusion, cerebral oedema, traumatic infarction, diffuse axonal injury, shearing injury, sigmoid sinus thrombosis, midline shift of intracranial contents or signs of brain herniation, diastasis of the skull, pneumocephalus, skull fracture depressed by at least the width of the table of the skull)*

Fig. 1 PECARN minor head injury age-based clinical prediction rules: high, intermediate and very low risk groups for clinically important traumatic brain injury (*ciTBI*)

PECARN rule for the management of children with MHI (Fig. 1).

Inclusion and exclusion criteria

A convenience sample of children younger than 15 years of age presenting to the ED following a MHI at high or intermediate PECARN risk of ciTBI were enrolled [2, 14]. Neurologic or bleeding disorders were part of the inclusion criteria, as children with these conditions are more likely to undergo CT scan, independent of their risk group. According to the instructions of the manufacturer, only children who sustained the head injury within the 12 h prior to presentation were eligible to undergo the Infrascanner measurement. This time restriction was recommended to warrant optimal sensitivity.

Exclusion criteria were: performance of neuroimaging at another hospital before assessment in the study PEDs, low risk of intracranial injury or trivial injury, as defined by the PECARN study [14], large scalp lacerations or blood over one or more sites of NIRS measurement or suspicion of abuse (for the most likely subacute/chronic nature of possible intracranial injuries), previous craniotomy [12].

Definitions

MHI: blunt head injury with GCS≥14 at the time of ED assessment.

ciTBI: death from head injury, neurosurgery, intubation for more than 24 h for the head injury or hospital admission of two nights or more associated with traumatic brain injury on CT scan [14] (defined as: intracranial haemorrhage or contusion, cerebral oedema, traumatic infarction, diffuse axonal injury, shearing injury, sigmoid sinus thrombosis, midline shift of intracranial contents or signs of brain herniation, diastasis of the skull, pneumocephalus, skull fracture depressed by at least the width of the table of the skull).

Trivial injuries: ground-level falls or walking or running into stationary objects, and no signs or symptoms of head trauma other than scalp abrasions and lacerations [14].

Study outcomes

Feasibility of NIRS technology: defined as

- Completion of Infrascanner measurements: performance of the measurements in all the four pre-selected pairs of locations (frontal, temporal, parietal and occipital regions).
- Time to completion: time to complete all the measurements, including repeat of the measurements in case of a positive result (see below).

Possible usefulness of NIRS technology in reducing CT scans: defined as

- Ability to predict negative CT scans in children with negative NIRS
- Ability to predict children without ciTBI as assessed by either CT scan or results of follow-up for children who did not undergo CT scan on initial assessment.

Clinical evaluation and management

Decisions on CT scan and disposition (discharge, observation in ED, length of observation or hospitalization) were made independently by the treating physician, who was blinded to the Infrascanner measurements results. Treating physician's decision-making on whether to CT scan was not influenced by the Infrascanner results. CT scan findings were reported by an attending neuroradiologist who was unaware of the current study and Infrascanner measurements results.

Data collection and study procedures

In both centres, patients were enrolled only when a study operator was available, i.e., weekdays during day time (8 am–6 pm). The electronic data system of each PED was monitored to identify eligible patients.

Data on demographics, mechanism of injury, clinical findings, PECARN risk group and disposition were prospectively collected at the time of initial assessment in the ED. Information on hair characteristics was also collected. Results of CT scans were retrospectively collected from the report of the attending neuroradiologist.

Trained NIRS operators were physicians working in the two centres and they were available to recruit patients during weekdays study hours, while on clinical duty. Their training consisted of a 3-h course provided by the distributor of the device. The course included a brief lecture, a demonstration of the device, followed by supervision of practice examinations on normal individuals. The demonstration was videotaped and videos were made available for review by the operators.

The Infrascanner measurements were performed before neuroimaging, in patients undergoing CT scanning. Results of the Infrascanner measurement were collected along with all the other patients' data on a dedicated clinical report form.

Telephone follow-up, between 7 and 90 days after ED visit, as well as monitoring of the electronic PED medical records for return visits, were carried out for the patients who did not undergo a CT scan. This was done in order to exclude initially missed ciTBI.

NIRS device and examination procedures

NIRS technology identifies intracranial haematomas by comparing the optical density (OD) of infrared light absorption between symmetrical regions in the two sides of the head. The extravascular blood of the haematomas absorbs NIR light more than intravascular blood. This is due to the higher concentration of haeme-based proteins, such as haemoglobin, in the haematoma compared with normal brain tissue, where blood is contained within vessels. Under normal circumstances, the brain's absorption is symmetrical. When a haematoma is present on one side of the brain a difference in light absorption is detected and recorded by the NIRS device. The examination includes a set of four pairs of measurements of four regions of the brain (frontal, temporal, parietal and occipital), where the device is placed in sequence on the left and right side over pre-selected locations.

A commercially available handheld NIRS device was used based on the manufacturer's instructions (Infrascanner, Model 1000, InfraScan Inc.). This device includes a sensor and a personal digital assistant (PDA) for data collection and processing. The sensor includes an 808-nm near-infrared diode laser light source and a detector of absorbance, placed 4 cm apart. Both are optically coupled to the patient's head through a disposable sensor cap provided with two light guides and an extra plastic support designed so that it can ensure adequate sensor contact in areas with and without hair and minimize background light interference. Acquired signals from the detector are digitized and transmitted via Bluetooth to the PDA. Absorbance of light is measured and the OD within the various regions is determined. The difference in OD (ΔOD) of the various regions is electronically calculated using the following formula:

$$\Delta \mathrm{OD} = \log_{10} \frac{I_N}{I_H}$$

In this formula, I_N is the intensity of the reflected light on the presumed normal side, and I_H is the intensity reflected light on the presumed abnormal side. Based on previous studies [24], a positive test result was defined by a difference in optical density (ΔOD) >0.2 between two symmetric regions. The detection limits of the device for intracranial haematomas are a volume of blood ≥3.5 mL, within a depth of 2.5 cm of the brain surface.

When a positive scan was obtained during the study, the measurement was repeated to confirm the findings and reduce the chances of a false reading due to trapped hair under the light guides, or inadequate sensor contact with the head. If the repeat scan did not match the original results, a third measurement was performed; the outcome found twice was considered the final result for the study. Negative findings were not repeated, as possible false negative results from impaired coupling of the sensor with the scalp are extremely unlikely.

Statistical analysis

Normally distributed continuous variables are presented as means ± standard deviation. Comparison between continuous variables was carried out using the *t* test. Categorical variables are reported as absolute numbers and percentages. As this was a pilot study no formal sample size calculation was performed. An exploratory calculation of sensitivity, specificity, positive and negative predictive values (PPV and NPV) was performed with their 95 % confidence interval (CI). Statistical analyses were conducted using the statistical program MedCalc 11.1.

Ethics approval

This study was approved by the ethics committees of both Padova and Treviso Hospital and informed written consent was obtained by parents or legal guardians, as well as assent from capable patients.

Results

Population characteristics

A total of 1,083 children were assessed for MHI in both centres during the study period. Of these, 844 were ineligible because they had either trivial injuries or they belonged to the very-low-risk group. Of the 349 children meeting the criteria for MHI at intermediate or high risk, 175 presented outside the recruitment hours. Of those presenting during the recruitment hours 37 were excluded as the injury had occurred more than 12 h prior to the ED visit. One patient was excluded because neuroimaging was performed at another centre before arrival and one had a large scalp laceration overlying the sites of the Infrascanner measurement. Of the 135 eligible patients, 115 were approached for participation in the study. Five patients refused to participate, and a total of 110 patients were finally enrolled (Fig. 2).

Feasibility

Of the 110 children enrolled in the study, 103 (94 %) had a complete successful Infrascanner examination. Demographics and clinical characteristics of these subjects are presented in Table 1. Forty-six children were younger than 2 years of age, 57 (55.3 %) were male and 42 (40.8 %) sustained a frontal impact to the head. Thirteen patients belonged to the high-risk PECARN group.

Infants were preferentially assessed either when asleep or when breast/bottle feeding. Older children were able to

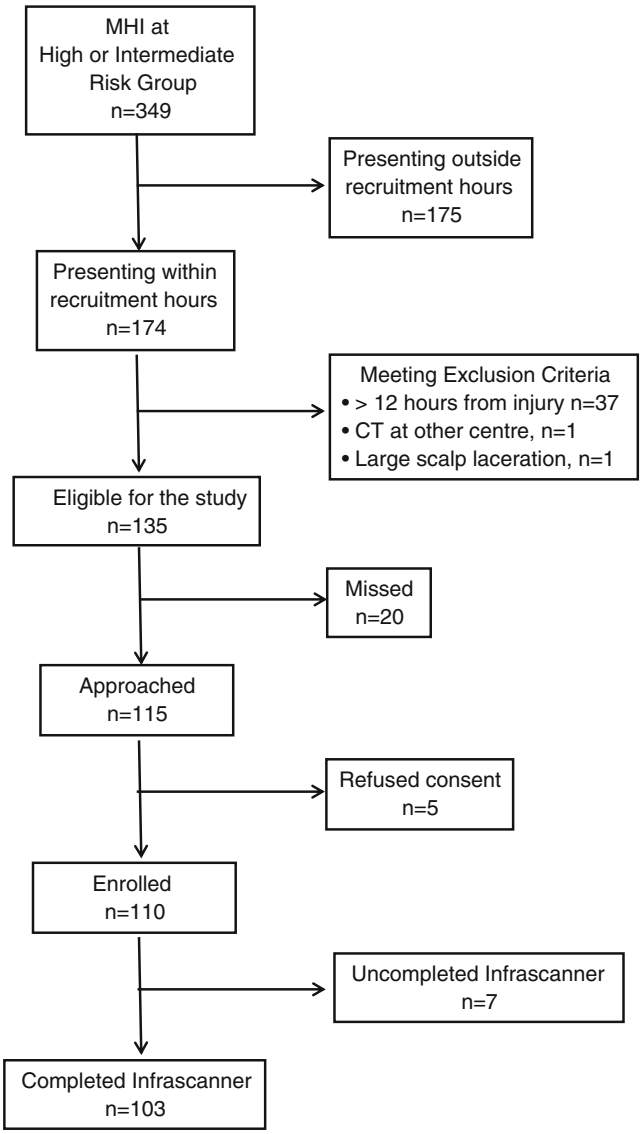

Fig. 2 Flow-chart of enrolled patients

tolerate the performance of measurements after simple explanation and instructions. We were unable to complete the examination in seven children. Of these, one had thick hair that impaired proper coupling of the sensor with the patient's head and six were uncooperative. These six were less than 2 years old, leading to a success rate of 88.5 % in children younger than 2 years of age. Overall the mean time to complete the examination was 4.4±2.9 min. The completion time was longer in children younger than 2 years compared with the older group (5.5±3.1 min and 3.5±2.2 min, respectively, $p=0.018$).

Potential usefulness in reducing CT scans

Eight patients had a positive Infrascanner measurement in one or more locations. Of these only one underwent a CT scan that showed a parietal extradural haemorrhage corresponding to the site of the positive measurement. None of the seven patients with positive Infrascanner examination, who did not undergo a CT scan, had a missed ciTBI, as ascertained by telephone follow-up (Fig. 3). Of these patients, four had large scalp haematomas overlying the sites of measurement.

The Infrascanner results were negative for intracranial haematomas in 95 (92.2 %) children. Of these 17 underwent a CT scan. All 17 CTs were negative for intracranial injury. The remaining 78 patients did not undergo CT scanning. Review of return visits and telephone follow-up ascertained that ciTBI were not missed in any of these children (Fig. 3).

NIRS technology correctly identified 17/17 (100 %) patients without intracranial haemorrhages, as ascertained by CT

Table 1 Demographics and clinical characteristics of study subjects ($n=103$)

	No.	Percent
Age<2 years	46	45
Gender (M)	57	55.3
Site of impact		
Frontal	42	40.8
Temporal	5	4.9
Parietal	11	10.7
Occipital	27	26.2
Unknown	18	17.5
Severe mechanism of injury	69	67
Loss of consciousness	7	6.8
Amnesia (>2 years of age)	6	5.8
Vomiting (>2 years of age)	12	11.7
Headaches (>2 years of age)	13	12.6
Not acting normally per parent (<2 years of age)	12	11.7
Large scalp haematoma (<2 years of age)	8	7.8
Signs of basal or skull fracture	1	1
Altered mental status	9	8.7
GCS 14	9	8.7
Risk group		
Intermediate	90	87.4
High	13	12.6
Hair colour		
Light	53	51.5
Dark	39	37.9
Black	11	10.7
Skin colour		
White	95	92.2
Dark	4	3.9
Black	4	3.9
Hair thickness		
Thin	30	29.1
Normal	65	63.1
Thick	8	7.8

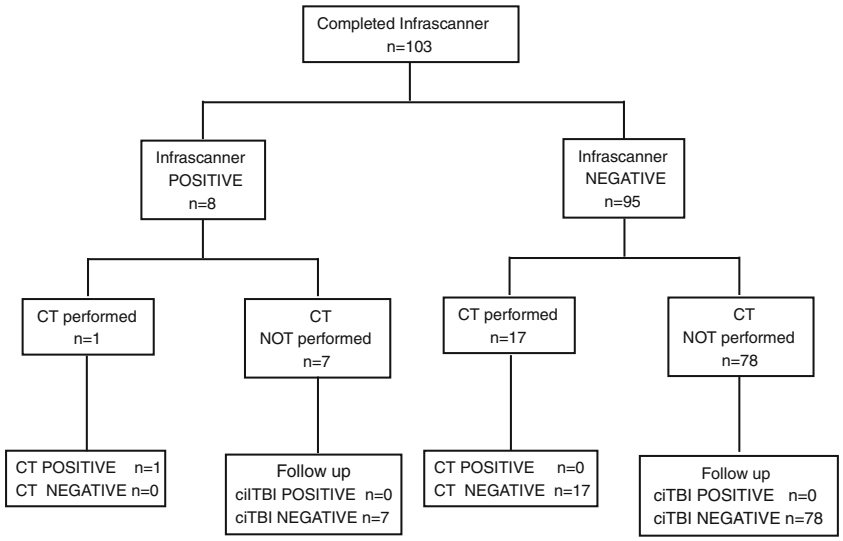

Fig. 3 Results of Infrascanner examination, CT scan performance and follow up. *ciTBI* clinically significant traumatic brain injury

scan. The remaining 78, who did not have CT turned out to be ciTBI negative (100 %).

The sensitivity, specificity, PPV and NPV for prediction of intracranial haemorrhages identified on CT scan were 100 % (95 % CI, 20.7–100), 100 % (95 % CI, 81.6–100), 100 % (95 % CI, 20.7–100) and 100 % (95 % CI, 81.6–100), respectively.

The sensitivity, specificity, PPV and NPV for prediction of ciTBI identified by either CT or follow-up were 100 % (95 % CI, 20.7–100), 93.1 % (95 % CI, 86.5–96.6), 12.5 % (95 % CI, 2.2–47.1) and 100 % (95 % CI, 96.1–100), respectively.

According to this exploratory analysis, if the result of the NIRS examination had been used for clinical decision making, this would have led to a net avoidance of ten CT unnecessary scans (as seven unnecessary scans would have been performed based on the positive Infrascanner results). The CT scan rate would have reduced by 58.8 %, from 17.5 % (18/103) to 7.7 % (8/103).

Discussion

Our results show that Infrascanner examination is feasible in children with MHI in the ED, even in the younger group of children aged less than 2 years of age, with a success rate above 90 % overall and nearly 90 % in younger children. Study operators obtained these very good results after only a limited required training of 3 h. The relatively short time to completion, 4.4±2.9 min, makes this examination a potentially easy to use tool in the ED setting. Our study showed a longer time to completion in children younger than 2 years, 5.5±3.1 min; this is to be expected because of their lack of cooperation and need of repeat measurement. However, even in this age group the average time to completion did not interfere with the high-pace ED clinical activity. This study is the first to assess times to completion in children with MHI in the setting of an ED. A recent study including 28 children admitted to a paediatric intensive care unit, who received a CT scan as part of their routine clinical care, showed a NIRS completion rate of 79 %, and a completion time up to 15 min [25]. The different population included in this study (more severely injured patients, as well as patients with conditions other than trauma) likely explains the difference in the results. The other studies including both adults and children [3, 23, 24] did not report specific data on completion rate or time to completion for children. Studies mainly conducted in adults report a time for NIRS examination completion of 2 to 3 min [12, 14, 15] or less than 10 min [23].

Our study population included a large proportion of children younger than 2 years of age (45 %) that may represent a more challenging group in clinical practice, especially for adult emergency physicians who may have to take care of children in community hospitals.

A small proportion of the study subjects, approximately 10 %, had thick, darkly coloured hair or dark-black skin. These factors may affect performance of an optical method such as NIRS [12, 26]. Improvement in the technology and device design over time likely account for the good results of our study. We were unable to complete the examination in only one child, who had thick hair that impaired proper coupling of the sensor with the patient's head.

In the study population, a CT scan was performed in 18 (17.5 %) children. Only one had an intracranial haemorrhage that was correctly identified by the Infrascanner measurement. Of the 95 (92 %) patients who had a negative Infrascanner result, 17 had a negative CT scan and 78 had no missed ciTBI, as ascertained by follow-up.

According to our exploratory analysis Infrascanner might be a useful tool in further optimizing the selection of CT scan in children with MHI and is worth additional investigation in

future larger multicentre studies. The very high specificity and NPV found for both intracranial haemorrhages and ciTBI means that a negative result on the Infrascanner examination seems highly predictive of the lack of intracranial haemorrhage and ciTBI in children with MHI. As for sensitivity and PPV, our exploratory analysis failed to provide sufficient data for their proper calculation, as shown by the broad confidence intervals. However, if NIRS examination had been used for clinical decision making, it would have led to a net CT scan reduction of nearly 60 %. If these results were confirmed by future larger studies, this would have important implications for clinical practice in terms of reduction of children's lifetime risk of cancer due to radiation, as well as in important savings for the healthcare system, especially in settings with higher CT scan rates.

Previous studies assessing NIRS accuracy for traumatic intracranial haemorrhages in different populations have reported a good sensitivity and a specificity mostly greater than 85 and 75 %, respectively, with a wide range of PPV (18 to 100 %) and good to very good NPV (80–98 %) [3, 9, 13, 15, 24, 25]. The only studies providing separate data on children have found a specificity ranging from 64 to 80 % and a NPV ranging from 80 to 98 % [3, 25]. However, the inclusion of different populations [3, 25], as well as the little details provided on the clinical characteristics of paediatric patients in the study by Coksun and colleagues [3] limit the applicability of these results to the population of children with MHI assessed in the ED.

In children with PECARN MHI the great majority do not have intracranial injuries, with a prevalence of ciTBI ranging from 1 to 5 % according to the risk group [14]. The influence of the large prevalence of disease-free subjects on NPV values likely accounts for the optimal results we obtained in our convenience sample.

Despite the advantages of portable NIRS technology and the potential role in the management with children with MHI, this technology is not designed to substitute CT scan and its intrinsic limitations should be noted.

First of all the detection limits of the device for intracranial haematomas are a volume of blood ≥3.5 mL, within a depth of 2.5 cm of the brain surface. This does not allow for reliably screening for deep haematomas or contusions, or very small superficial bleeding.

Second, bilateral haematomas cannot be reliably identified by near-infrared technology, as the technique relies on comparison of light absorption between the two hemispheres.

Third, the utility of NIRS in detecting subacute or chronic haematomas is limited, since this technology is based on the absorption characteristics of acute bleeding and haemoglobin breakdown products that develop in the following hours do not have the same absorption characteristics. This was the reason why in our study the Infrascanner examination had to be performed within 12 h of the head injury, according to the instructions of the manufacturer, for optimal sensitivity.

Fourth, scalp haematomas are confounding factors for near-infrared technology measurements. Blood contained within a scalp haematoma can alter the difference in optical density and cause a false-positive result. Despite symmetrical measurements can be performed at the edges of the haematoma, this limit questions the applicability of near-infrared technology to the challenging group of children younger than 2 years of age with large isolated scalp haematomas.

Furthermore, thick hair may affect examination performance, while cervical collars may limit the ability to perform the measurements in the occipital pair of locations.

However, NIRS technology in children with MHI is not meant to be used in isolation, but incorporated into clinical decision rules, as a screening tool to further guide clinical management.

Our study is limited by the small sample size. This limit is intrinsic to the study design, being designed as a pilot study based on the resources available, to inform on possible opportunities for larger multicentre studies.

Furthermore, a CT scan was not performed in all patients. However, follow-up was carried out in all patients who did not receive a CT scan, in order to exclude initially missed ciTBI. ciTBI is a more clinically relevant outcome, compared to CT findings alone, and it was previously used in the PECARN study [14].

The results of our study suggest that Infrascanner examination is feasible in the ED even for children younger than 2 years of age and is worth of further investigation as a potential tool to reduce CT scan rate in children with MHI when used in conjunction with a clinical prediction rule. This tool might help decision making in symptomatic children who sustained a MHI up to 12 h from presentation, who neither have large scalp haematomas or lacerations affecting the measurement nor obvious signs of injuries that require CT scan investigation independently of the presence of an intracranial haemorrhage (such as obviously depressed skull fracture or signs of base of skull fracture). Larger multicentre studies are needed to appropriately assess the Infrascanner accuracy for the management of children with MHI in the ED, as data on false negative results should be carefully analysed in order to minimize the risk of missing ciTBI while optimizing the selection of patients who need a CT scan. In addition, it would be interesting to assess the possible impact of negative NIRS results on the duration of observation in the ED or in the ED-based observation unit, following a MHI.

Conclusions

Infrascanner seems an easy-to-use tool for children presenting to the ED following a MHI, given the high completion rate and short time to completion. Our preliminary results suggest

that Infrascanner is worthy of further investigation as a potential tool to decrease the CT scan rate in children with MHI.

Acknowledgments The authors thank Chiara Stefani, MD, and Giovanni Dei Tos, Medical Student for their contribution in patients' enrolment and data collection. The authors thank Davide Pilotto and Gilberto Bottaro, from SEDA S.p.A., for training the study operators and for the assistance provided with the study device.

Conflict of interest statements The authors have no conflicts of interest to disclose. The authors have not received any financial support, salary or other personal benefits by SEDA S.p.A. for the present study and do not hold stock in the company. The Infrascanner devices and necessary equipment were provided free-of-charge by the distributor, SEDA S.p.A, for the purpose of this study.

Contributorship SB conceived the idea of the study, searched the literature, interpreted the final results and drafted the manuscript. MD, FM, DD and FM substantially contributed to the study design, data collection and drafting of the manuscript. IPS substantially contributed by reviewing the literature, interpreting final results and critically reviewing the manuscript. LDD substantially contributed to the conception and design of the study, supervised study conduct, contributed to interpretation of final results and critically reviewed the manuscript.

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