Healthy Blue

Medical Policy

Subject:	Near-Infrared Spectroscopy Brain Screening for Hematoma Detection		
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Description/Scope

This document addresses the use of near-infrared spectroscopy (NIRS) for the screening and detection of brain hematomas and intracranial bleeding. The InfraScanner® (InfraScan, Inc., Philadelphia, PA) handheld brain scanner unit uses NIRS for the detection of possible development of intracranial hematomas in high-risk individuals, such as those with head trauma.

Position Statement

Investigational and Not Medically Necessary:

Near-infrared spectroscopy scanning for brain hematoma screening (that is, InfraScanner) is considered **investigational and not medically necessary** for all indications.

Rationale

A near-infrared brain hematoma detector (that is, InfraScanner 2000) was cleared for marketing through the U.S. Food and Drug Administration (FDA) 510(k) process in January 2013. According to the 510(k) summary, the device is intended for the detection of traumatic supratentorial hematomas of greater than 3.5 mL in volume that are less than 2.5 cm from the brain surface. In addition, it is intended as an adjunctive device to the clinical evaluation in the acute hospital setting of adults with suspected traumatic supratentorial intracranial hematomas. The device is indicated to assess individuals for head computerized tomography (CT) use but does not serve as a substitute for CT scanning. In July 2020, Model 2500 was cleared for marketing, the indications for use are identical. The InfraScanner Model 2000 and 2500 have the same intended uses and similar indications as the predicate device, the InfraScanner 1000 (InfraScan, Inc., Philadelphia, PA).

Near-infrared (NIR) light can be transmitted through hair, scalp, bone, dura and brain for several centimeters. By knowing how the light is differentially absorbed by hemoglobin through the tissues and by calculating a differential between the right and left sides of the brain, a unilateral hematoma can be detected. Preliminary studies using portable NIRS technology found NIRS as a screening tool for intracranial hemorrhage (ICH) promising, although the studies were limited by small sample sizes (Francis, 2005; Kahraman, 2007; Kessel, 2007).

In 2007, Kessel and colleagues concluded that while infrared spectroscopy allowed early recognition of epidural and subdural hematomas in trauma cases, "further studies are needed to evaluate whether immediate confirmation

or exclusion of epidural and subdural haematomas with portable near-infrared spectroscopy devices improves the decision-making process in the treatment of severely injured people."

In 2010, Robertson and colleauges evaluated the performance of non-invasive NIR-based screening for traumatic intracranial hematomas by comparing the findings of NIR screenings to participant admission CT scans (imaging within 12 hours of blunt or penetrating head injury). The multicenter, observational study enrolled 365 participants; 96 were found to have intracranial hemorrhage with CT imaging. NIR demonstrated a sensitivity of 88% (95% confidence interval [CI], 74.9% to 95.0%) and a specificity of 90.7% (95% CI, 86.4% to 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. Considering all 96 study subjects, the sensitivity was 68.7% (95% CI, 58.3% to 77.6%), and the specificity was 90.7% (95% CI, 86.4% to 93.7%). The authors concluded that:

> The high specificity and high negative predictive value (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 to 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 IR technology in the screening and treatment of traumatic brain injury (TBI).

The Department of Veterans Affairs (VA) published guidelines on the management of concussion or mild traumatic brain injury (mTBI) in 2009 (updated in 2016); these guidelines do not discuss a role for NIR brain hematoma detection using NIRS.

In 2014, Bressan and colleagues reported results from a prospective, observational pilot study assessing the use of the InfraScanner in children with mild head injury. The authors concluded:

> Larger multicenter studies are needed to appropriately assess InfraScanner accuracy for the management of children with minor head injury (MHI) in the emergency department (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.

In 2017, Brogan and colleagues published the results of a systematic review and meta-analysis that evaluated NIRS for detecting traumatic intracranial hematomas. After evaluating 192 studies from 1990-2015, the researchers included 8 in the meta-analysis. NIRS devices included the Infrascanner 1000, CrainScan (India), "smartscan," and a researcher-developed device. In a broad adult population (n=783), the cross-study sensitivity was 78% (95% CI, 72% to 83%), the specificity 90% (95% CI, 87% to 92%), the negative predictive value (NPV) 90% (95% CI, 88% to 93%) and the positive predictive value (PPV) 77% (95% CI, 71% to 82%). The researchers concluded that NIRS

technology for hematoma detection does not meet their requirements for diagnosing and triaging individuals and should not replace CT scans. They stated that "larger and more heterogeneous studies are required that specifically evaluate NIRS performance in detecting intracranial lesions requiring emergency evacuation in the emergency department and prehospital setting."

In 2017, Peters and colleagues conducted a small feasibility study that compared the NIRS InfraScanner 2000 to CT scans in 25 individuals. Subjects were evaluated for TBI with the InfraScanner device before or during emergency helicopter transport to the hospital. Physicians were unable to complete a full scan for 10 individuals due to inaccessibility. Compared to the CT scan, the InfraScanner had three false positives and one false negative. The sensitivity was 93.3% and the specificity was 78.6%. Limitations of the study included a small sample size, potential selection bias, and lack of long-term follow-up. The authors concluded that further research is needed.

In 2017, Xu and colleagues compared CT scan results with the NIRS InfraScanner 2000 for the detection of traumatic hematomas occurring within 12 hours of a blunt or penetrating head injury in a single-center observational study. A total of 85 subjects were categorized as either having intracranial hemorrhage (n=45), having a Glascow Coma Scale (GCS) score of 15 (indicating no intracranial hemorrhage; n=20), or healthy volunteers (n=20). Results included a specificity of 92.5% (95% CI, 78.5% to 98%), a sensitivity of 95.6% (95% CI, 83.6% to 99.2%), an NPV of 94.9% (95% CI, 81.4% to 99.1%), and a PPV of 93.5% (95% CI, 81.1% to 98.3%). Limitations of the study included methodological design; the healthy volunteers received magnetic resonance imaging (MRI) scans instead of CT scans. The authors noted concerns that the InfraScanner could miss bilateral hematomas, deep bleeds, and small contusions. Certain characteristics can create false positives such as scalp injuries, high-neck clothes, thick and dark hair, and scalp displacement. Additionally, it is not certain how different skin colors affect results. The researchers concluded that the InfraScanner has potential as a portable device, but future studies are needed.

In 2017, Schober and colleagues conducted an observational pilot study on the use of the InfraScanner 2000 as a first-time-right monitor in a helicopter emergency medical service setting. The researchers performed InfraScanner measurements on 17 healthy adult volunteers who were healthcare employees and had no history of neurologic disease. In the field, the researchers found the device to be portable, lightweight, and feasible for use. However, the first measurement with the device confirmed no intracranial hematomas in only 5/17 subjects. The study is limited by a small sample size and the lack of comparison to CT or MRI scans. The researchers concluded the device is not suitable, at this time, as a first-time-right monitor due to false positives. They recommended further studies.

In 2018, Liang and colleagues (2018) compared the InfraScanner 2000 to CT scans in a military hospital setting for individuals with suspected TBI in a single-center observational study. Inclusion criteria included individuals of any age who were undergoing a CT scan within 12 hours of a blunt or penetrating head injury. InfraScanner readings were taken within 30 minutes of the CT scan. A total of 127 individuals were screened for participation; however, per protocol the population was 102 after 25 individuals were excluded. Exclusion criteria included individuals with large scalp lacerations or blood on the scalp over the scan area (n=3), not meeting inclusion criteria (n=2), and lack of hospital staff following the scanning protocol (n=20). Of the 102 individuals, 24 were confirmed by CT scan to have a hematoma that was within the detection range of the InfraScanner 2000 (epidural, subdural, and intracerebral hematomas, volume > 3.5 mL and distance < 2.5 cm from brain surface). The results included the

following: specificity 93.6 (95% CI, 85 to 97.6), sensitivity 100 (95% CI, 82.8 to 100), NPV 100 (95% CI, 93.8 to 100), and PPV 82.8 (95% CI, 63.5 to 93.5). The researchers observed that subgaleal hematomas contributed to 5 false positive InfraScanner readings. In addition, the researchers noted that the size, type, and location of hematomas could not be as precisely determined with the InfraScanner as with CT scans. The researchers concluded that the InfraScanner 2000 could supplement clinical information and may be useful when CT scans are not available.

In a single-center study, Kontojannis and colleagues (2019) evaluated the InfraScanner 2000 for the detection of intracranial hematomas in the emergency department. They included all individuals admitted between 2015 and 2016 with potential brain injury who were ≥ 16 years old and who did not have lacerations or conditions that prevented NIRS usage. NIRS examination was completed after the primary survey and was used to assess frontal, parietal, and temporal regions (occipital areas were not examined due to supine positioning after trauma). After the individuals were stabilized, CT imaging was performed. A total of 218 individuals were recruited, but 13 were excluded because of missing Infrascanner results. For the 205 individuals with NIRS results, there was a match in 125 individuals between NIRS and CT results (61%). The NIRS device was found to have a sensitivity of 75%, specificity of 50.43%, negative predictive value of 72.84%, and positive predictive value of 52.23%. Although NIRS can potentially support clinical assessment, the researchers noted that the results of the study "would not support clinical decision-making based on near infrared result alone."

Although NIR-based technology has been used to screen for brain hematoma at the site of injury, there have been limited published clinical studies and the clinical utility is unproven. Further well-designed studies of portable NIR brain imaging are needed to evaluate the effectiveness of this technology in improving the diagnosis of intracranial bleeds and in improving individual outcomes.

Background/Overview

According to the Centers for Disease Control and Prevention (CDC), in 2013 there were nearly 2.8 million Americans who suffered TBI, resulting in more than 50,000 deaths. According to the CDC, a TBI "is caused by a bump, blow or jolt to the head or a penetrating head injury that disrupts the normal function of the brain." These injuries are principally the result of motor vehicle accidents, violence, sports injuries, and falls. Individuals who have suffered a TBI often experience residual impairments affecting motor control, communication skills, social behavior and cognition. These deficits may result in a variety of alterations in the individual, including but not limited to changes in memory, language, attention and concentration, visual processing, reasoning, and problem-solving, as well as emotional and behavioral control.

The InfraScanner brain imaging system is a portable device created to detect and evaluate traumatic supratentorial hematomas. The technology compares regional differences in absorbance of NIR light. The application of NIRS to hematoma evaluation is based on the principle that intracranial hemoglobin concentration will differ where a hematoma is present, compared to hemoglobin concentrations in normal intracranial regions.

Definitions

Hematoma: Localized swelling filled with blood, resulting from a ruptured blood vessel.

Traumatic brain injury: Occurs when an external mechanical force causes brain dysfunction, often associated with a diminished or altered state of consciousness, and potentially leads to permanent or temporary impairment of cognitive, physical, and psychosocial functions. TBI usually results from a violent blow or jolt to the head or body, but can also be caused by an object penetrating the skull.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

93998	Unlisted noninvasive vascular diagnostic study [when specified as NIR imaging of the brain for hematoma screening]

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

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13. Xu L, Tao X, Liu W, et al. Portable near-infrared rapid detection of intracranial hemorrhage in Chinese population. J Clin Neurosci. 2017; 40:136-146.

Government Agency, Medical Society, and Other Authoritative Publications:

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2. Centers for Disease Control and Prevention (CDC). Injury prevention & control: traumatic brain injury. Updated March 27, 2015. Available at: https://www.cdc.gov/traumaticbraininjury/pdf/tbi_clinicians_factsheet-a.pdf. Accessed on October 10, 2020.
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4. Department of Veteran Affairs Department of Defense. VA/DoD clinical practice guideline for management of concussion/mild traumatic brain injury. Washington (DC): Department of Veteran Affairs, Department of Defense; 2016. Available at: https://www.healthquality.va.gov/guidelines/Rehab/mtbi/mTBICPGFullCPG50821816.pdf. Accessed on October 10, 2020.
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InfraScanner 2000
InfraScanner 2500
Near-Infrared Spectroscopy
Traumatic Brain Injury

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Revised	11/05/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Removed model number from the Position Statement. Updated Description, Rationale, Background/Overview, and References sections.
Reviewed	11/07/2019	MPTAC review. Rationale and References sections updated.
Reviewed	01/24/2019	MPTAC review. Rationale, Background, and References sections updated.
Reviewed	02/27/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Rationale and References sections updated.
Reviewed	02/02/2017	MPTAC review.
Reviewed	02/04/2016	MPTAC review. Updated Description and References section. Removed ICD-9 codes from Coding section.
New	02/05/2015	MPTAC review. Initial document development.