Clinical Utility of an EEG Based Biomarker for the Triage of Head Injured Patients in the ED: INOVA Pilot Study

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Introduction:

Computerized Tomography (CT) scan remains the standard of care for evaluating traumatic brain injury (TBI) in Emergency Departments (EDs). Studies have reported that over 85% of head injured patients receive CT scans in the ED, yet 91% of these scans are found to be negative.[1] Not only does this practice expose these patients unnecessarily to radiation, but it also increases the use of this resource and lengthens throughput times in the ED.[2] In addition, patients found to be CT negative are most often discharged without evaluation or referral for concussion. There is a great need for the integration of reliable objective predictors of intracranial injury in the mild head injured population.[3]

The New Orleans Criteria (NOC) and Canadian CT Head Rule (CCHR) are CT decision rules that aim to aid in selection of mild head injured patients who should be referred for CT scans. In standard clinical practice these rules are inconsistently applied and although have been demonstrated to have high sensitivity,they have extremely poor specificity [5-8].[4-7] As a result, these CT decision rules lead to only a very small reduction in over-scanning. Further complicating clinical decision making, the rules are not applicable to a significant portion of the head injured population.[8-9]

In a multisite independent prospective FDA validation trial using the BrainScope brain activity-based Structural Injury Classifier (SIC) algorithm, Hanley and colleagues[10] found it to be reliable for detecting traumatic brain injury and hematoma in mild head injured patients, with 98.6% sensitivity to detecting the likelihood of ≥1cc blood, with specificity many times higher than that of the standard clinical decision rules, and negative predictive value (NPV) of 98.2%. Integrated in ED triage, Naunheim et al., (2019)[11] reported 100% sensitivity compared to CT scans, with no false negatives. In addition, the BrainScope evaluation provides objective information on brain function impairment, using a Brain Function Index (BFI), computed from the same EEG data sample. Access to the BFI in the ED has been reported to aid in more informed referrals for concussion evaluation in CT negative (CT-) patients.[12]

BrainScope is the only FDA cleared non-invasive medical device that objectively assesses head injured patients for both structural and functional brain injuries. Within one rapid EEG test, BrainScope provides objective data on both brain bleeds and concussions at point of care, using the same EEG recording. The purpose of this pilot study was to determine utilization, staff assessment and patient experience of the BrainScope technology in daily use. The results of the trial were overwhelmingly positive.

Methods:

An evaluation of BrainScope was completed at Inova Fairfax Hospital from April 26th to May 1st, 2021 in the Emergency Department. The

FDA indications for use were followed, including: ages 18-85y, GCS 13-15, within 72 hours of injury. Thirty-nine (39) staff participated in the evaluation assessing a total of 19 patients in the 6-day period. To facilitate the generalization of the findings (not limited to a few clinicians), 16 unique physicians or Physician Assistants had direct patient exposure with 13 ED staff members as operators of BrainScope across the 19 patients.

Patient and provider surveys were used to evaluate the clinical utility of BrainScope integration. In addition, time to complete the BrainScope exam, including total exam time and time to complete the EEG, were recorded to help evaluate the usability in the ED environment.

The specific aims of this pilot were to demonstrate:

- Decreased CT utilization in Mild TBI patient population, reducing unnecessary radiation for patients;
- Decreased LOS for patients that were BrainScope negative for structural injury
- Provider satisfaction with BrainScope utility
- Improved patient experience

Training

Training was conducted over a 5-day period during staff breaks, and included headset application, device operation and EMR print review. Each training took approximately 15 minutes. In addition, providers were briefed on result interpretation and clinical workflow. It is of note that the device also contains self-instructive information readily available to the operator.

BrainScope data acquisition and output

Five to ten minutes of eyes closed EEG was acquired on the BrainScope handheld system using a disposable electrode headset with sensors on frontal and frontotemporal scalp locations. Selected clinical risk factors often associated with TBI are also queried on the device. The EEG signals are processed using a real-time suite of algorithms for artifact detection which identify for removal of any physiologic and non-physiologic contamination (e.g., including lateral and horizontal eye movement, muscle activity (EMG)), assuring quality of EEG data. Both the SIC and BFI algorithms are computed using 1 to 2 minutes of artifact-free data. The output of the device for SIC indicates “Positive” (likely CT +), “Negative” (likely CT-) or “Equivocal” (requires additional observation). Also provided is the BFI percentile (0-100).

Figure 1 shows the BrainScope EEG acquisition unit and peripherals, and Figure 2 shows the headset affixed to a patient’s forehead and the operator holding the handheld device.

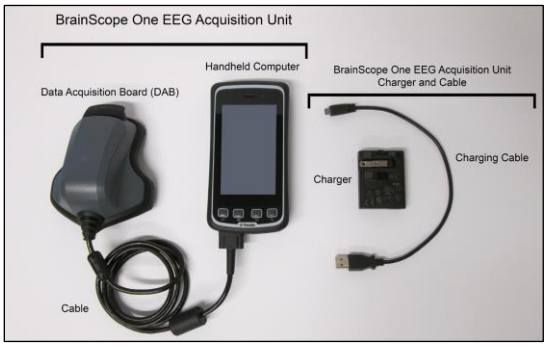

Figure 1: BrainScope data acquisition unit, handheld and charging peripherals.

Figure 2: Patient with headset being tested with electrodes affixed to forehead locations.

Evaluation Results:

SIC/BFI Results and Impressions:

Utilizing BrainScope's structural injury classifier (SIC), 10 patients were found to be negative, 6 patients were found to be positive, and no equivocal results were obtained. Of the 10 SIC negative cases, 6 of the 10 were indicated to have been considered for CT referral prior to integration of the BrainScope results, thus, integration of the SIC- finding resulted in a 60% reduction of CT referral. In the remaining 4 SIC- cases, the decision not to scan was confirmed. Thus, the addition of the SIC results to clinical judgment resulted in none of the SIC- cases receiving CT scans, avoiding unnecessary radiation and resulting in a shorter length of stay.

Of particular note, is one case in which the initial clinical assessment ruled out referral for head CT, however, the patient was suspected of having a concussion. A BrainScope exam was ordered by the provider to assess the likelihood of concussion, using the Brain Function Index (BFI). Using the same EEG recording, the exam provides information on both likelihood of structural (bleed) and functional brain injury. In this case, the SIC was found to be positive for likelihood of acute injury. Subsequently, a head CT was ordered, and the patient was found to have a small bleed that would have otherwise been missed.

Utilizing the BFI to assess patients for concussion, of the 16 patients tested, 1 had a BFI percentile between 2.5-10 (6.25%), 7 between 10-50 (43.75%) and 8 above 50 (50%). Using the clinical guideline of referring patients with a BFI below the 50th percentile for appropriate concussion care, 50% of the patients would have been referred for concussion care and follow-up who previously may not have received such a referral. Not only does this objective data allow us to appropriately assess when patients need concussion care follow-up, it also enabled the providers to have a better discussion with the patient regarding their conditions.

These results reinforce the clinical utility of BrainScope to not only reduce unnecessary CT's but also as a reliable tool for clinicians to proactively catch injuries that may not have been sent for CT. BrainScope has demonstrated to be a very effective aide in decision making for appropriate use of imaging for closed head injuries.

User Evaluations:

Responses to the evaluation questions verified the benefits and ease of use of BrainScope and the use of rapid bedside EEG to assess mTBI in the ED. Provider feedback was overwhelmingly positive and indicated that having both the BrainScope SIC and BFI was helpful in making appropriate decisions for CT scan, and in addition enabled discussions with their patients regarding concussion. Often, prior to using BrainScope, patients left unsatisfied with their assessment of concussion.

Results from the Provider Evaluation form were overwhelmingly positive and indicated a positive patient experience 100% of the time, in line with the "patient first" focus for Inova. The results indicated further that patients were happy to have the test performed, had a shorter visit and glad to receive information related to concussion. In addition, it was indicated that 6 of the 10 SIC negative patients, would have been sent for CT based on clinical information alone. Of these 10 patients, none were sent for CT when clinical judgement was aided by the information provided from the SIC result. As providers continue to use BrainScope and get comfortable with its use assessing

concussion, they indicated the expectancy to see continued and increased physician satisfaction aiding in discussions with the patient regarding their concussion.

Usability in the ED environment and Time to Perform BrainScope Evaluation:

Of the 19 patients BrainScope was ordered on, 16 were successfully completed. The 3 that were unable to be completed were for the following reasons:

1. Extremely intoxicated patient declined test after starting and was discontinued
2. Patient was overly anxious and defecated, test was discontinued
3. Insufficient data due to muscle artifact, patient declined to continue

Performance of BrainScope evaluation includes: entry of patient data, placement of BrainScope headset, collection of the EEG, and removal of the headset, and presentation of the results. With an average collection time of 16 minutes to complete the entire BrainScope evaluation (range 8 minutes to 36 minutes), this demonstrates ease of use and ability of staff to effectively utilize BrainScope in a normal clinical setting. Within the BrainScope evaluation, the average time to collect the EEG was 6.05 minutes (SD = 2.69, range 3-10 minutes). To date, 96 RN's, EMT's and PAs at INOVA were trained on how to use BrainScope.

Conclusions:

Within one rapid EEG test at the point of care, BrainScope provides objective data on both brain bleeds and concussions to assist healthcare providers in evaluating head injured patients. This study was successful in determining utilization, staff assessment, and patient experience of the BrainScope technology in daily use. The results of the trial were overwhelmingly positive and demonstrated the following:

- Improved patient experience meeting Inova's "patient first" initiative:
  - *100% patient satisfaction with BrainScope*
- Improved CT utilization in the Mild TBI patient population:
  - *60% reduction in Head CT.*
  - *Decreased radiation exposure.*
  - *1 patient was sent for CT after BrainScope SIC+ that was found CT positive that may not have otherwise been sent.*
- Decreased LOS for patients that were BrainScope negative for structural injury.
  - *An average of 16-minute testing times had a significant impact on length of stay for patients that were BrainScope negative.*

This pilot study was focused on the immediate use and implementation of BrainScope in the ED environment for the triage of head injured patients. The results from this study reinforce the clinical utility of the BrainScope technology to be a reliable tool for clinicians to proactively catch injuries that may not have been sent for CT and to reduce unnecessary CT's, thus reducing LOS. BrainScope has demonstrated to be a very effective aide in decision making for appropriate use of imaging for closed head injuries.

Next Steps - *Implementation:*

The reduction of 60% of head CTs in mTBI patients in conjunction with 100% patient satisfaction over 6 days, propelled the immediate integration of BrainScope into Inova's triage pathway. The utilization further expanded to include the offsite freestanding emergency departments, one of which does not have a CT scanner available. BrainScope allows for a much needed solution in reduction of patient transfer for imaging, while providing patients the confidence of objective

assessment of both concussion and likelihood of brain bleed.

BrainScope training has been incorporated into the yearly skills fair and on-board training programs for all new nurses with the incorporation of emergency technician staff planned for soon after. On a forward looking basis, a set of considerations for broad implementation and fully adopted use are being reviewed by both the Technology Assessment Committee (TAC) and Technology Value Acquisition Committee (TVAC). These considerations, in addition to LOS and head CT utilization, are scheduled for six months from the initial adoption of BrainScope. A final review is scheduled after twelve months, when permanent adoption is anticipated. During the pilot, BrainScope has proven to be easily adopted in the clinical workflow of a level one trauma center while maintaining patient data security without any adverse or threatening implications for current CT use or revenue. The demonstrated effects of BrainScope utilization has generated great excitement with respect to both the current and future possible uses of the BrainScope technology.

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