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Referrals for CT scans in mild TBI patients can be aided by the use of a brain electrical activity biomarker☆

J. Stephen Huff [a], Rosanne Naunheim [b], Samanwoy Ghosh Dastidar [c,*], Jeffrey Bazarian [d], Edward A. Michelson [e]

[a] University of Virginia Health System, Charlottesville, VA, United States
[b] Washington University Barnes Jewish Medical Center, St. Louis, MO, United States
[c] BrainScope Company, Inc., Bethesda, MD, United States
[d] University of Rochester Medical Center, Rochester, NY, United States
[e] Department of Emergency Medicine, Texas Tech Univ. Health Sciences Center, El Paso, TX, United States

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Heightened awareness of the potential short and long-term consequences of mild traumatic brain injury (mTBI or concussion) has resulted in an increase in Emergency Department (ED) visits for traumatic head injury, even as the volume of overall ED visits has remained stable over the same period of time [1]. While the vast majority (~95%) of these head injured patients are mild, >80% receive CT scans of which ~91% are found to be negative [2]. The rising number of negative CT findings, cost, radiation exposure, and ED resource utilization, has led to an increased need for reliable predictors of intracranial injury in the mild head injured population [3].

Several decision rules (such as New Orleans Criteria and Canadian CT Head Trauma Rule) have demonstrated high sensitivity but have extremely poor specificity [4-7] and when strictly applied, are not applicable to significant portions of the population [8,9]. A developing literature attests to the utility of quantitative EEG based biomarkers for prediction of the likelihood of intracranial injuries visible on CT scan in the mild head injured population [10,11].

This retrospective analysis is based on data from an independent validation trial[1] using the BrainScope® One[2] EEG-based structural injury algorithm in mildly presenting head injured patients (N = 719, age 18–85, GCS 13–15, evaluated within 3 days of injury). All subjects provided informed consent. The BrainScope One assessment is based on 5–10 min of eyes closed EEG acquired from frontal and frontotemporal regions and selected clinical risk factors [12,13]. In the validation trial, Hanley and colleagues (2017) reported a binary classification sensitivity of 92% for any finding visible on CT scans, with specificity 2–6 times higher than obtained using the decision rules, NPV of 98%, and an area under the curve of 0.82 [14]. The performance of two decision pathways, measured against an independently adjudicated positive or negative CT finding, is compared in this analysis. The first pathway, representing Clinical Site Practice, follows the clinical judgement of the ED physician at the clinical site for referring patients for a CT scan according to standard of care. The second follows the use of BrainScope One structural injury determination as an input to CT scan referral.

Clinical site practice (Fig. 1) resulted in the referral of 78.4% of the population (564 patients) for a CT scan. In this group, 156 patients were later adjudicated to be CT positive, i.e., "true positives" and 408 patients were later adjudicated to be CT negative, i.e., "false positives". The proportion of false positives within the patients referred for CT scanning, i.e., the "false discovery rate", in this pathway was 72% (=408/564).

On the other hand, use of the BrainScope One assessment (Fig. 2) as input for CT referral would have resulted in a positive structural injury classification for 57.9% of the population (416 patients). This is a 26% reduction (=(564 − 416) / 564) compared to clinical site practice. In this group, 144 were "true positives" and 272 were "false positives" representing a 33.3% reduction (=(408 − 272) / 408) in the number of false positives. In addition, a significantly lower false discovery rate of 65% (= 272/416) was achieved compared to the clinical site practice (one-sided comparison, p = 0.01). The BrainScope One device can contribute to reduced overscanning without compromising the overall clinical performance as evidenced by the reduction in the number of false positives by 33%.

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* Corresponding author at: BrainScope Company, Inc., 4350 East-West Highway, Suite 1050, Bethesda, MD 20814, United States.
E-mail address: sam.dastidar@brainscope.com (S. Ghosh Dastidar).

[1] B-Ahead III validation trial (ClinicalTrials.gov Identifier: NCT02367300) conducted at 11 US Emergency Departments.

[2] BrainScope® One device is registered as the Ahead® 300 (FDA 510(k) clearance, K161068).

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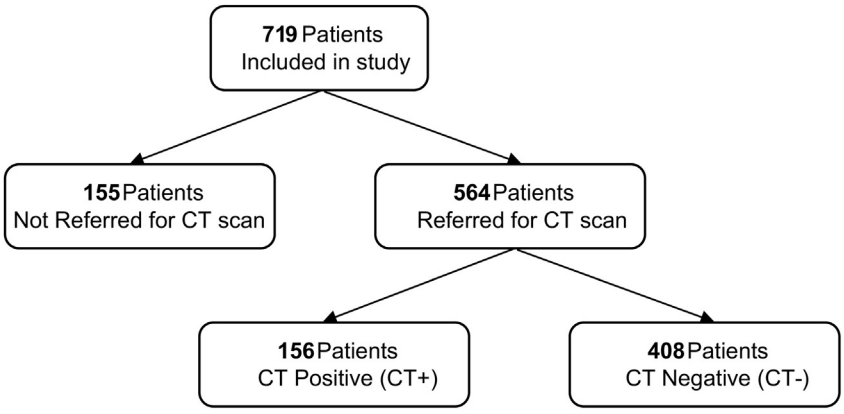

Fig. 1. Population disposition for decision pathway 1. Use of the clinical site practice pathway results in 564 patients referred for CT scanning (age mean 45.2, SD 18.9; 64.4% male). Of these, 156 patients were "true positives" (referred for CT scanning who were later adjudicated to be CT positive) and 408 were "false positives" (referred for CT scanning who were later adjudicated to be CT negative).

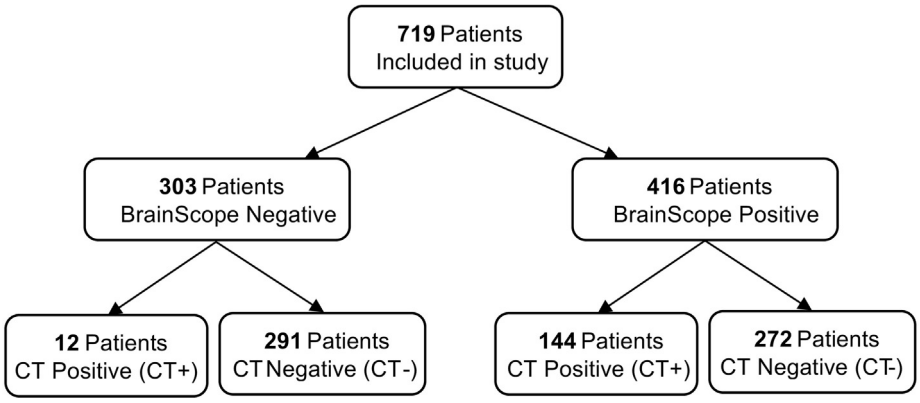

Fig. 2. Population disposition for decision pathway 2. Use of the BrainScope One decision pathway would have resulted in 416 patients referred for CT scanning (age mean 50.2, SD 18.4; 65.4% male). Of these, 144 patients were "true positives" and 272 were "false positives".

The reduced overscanning and false discovery rates do not take into consideration the existence of a small number of false negatives (7.7%). The corresponding false negative number for the clinical site practice pathway cannot be estimated because for these cases, the CT was not ordered. However, it is important to note that none of the false negatives required neurosurgery or returned to the hospital for exacerbation of symptoms or additional neuroimaging, all had GCS = 15, and none had any focal neurological signs.

This retrospective analysis demonstrates that the rapid assessment obtained at the point of care using this easy to use, non-invasive, handheld BrainScope One technology has the potential to significantly contribute to decreasing unnecessary CT scans in the mild head injury population. While not intended to replace a CT scan, the addition of such quantitative, objective information could significantly impact confidence of scanning decisions by the evaluating physician, unnecessary radiation exposure for the patient, as well as cost to the health care system.

Disclosure

Dr. Michelson is on the Medical Advisory Board of BrainScope. Dr. Ghosh Dastidar is an employee of BrainScope. All other authors have nothing to disclose.

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