American Journal of Emergency Medicine xxx (xxxx) xxx

Contents lists available at ScienceDirect

American Journal of Emergency Medicine

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

Reduction in unnecessary CT scans head-injury in the emergency department using an FDA cleared device

Keywords:
Traumatic brain injury
Concussion
Electrophysiological biomarker
CT
Imaging
Overscanning

Emergency Department (ED) visits for mild Traumatic Head Injury (mTBI) have greatly increased due to more awareness of potential consequences of such injuries [1]. While the vast majority (>80%) of mTBI patients who go to the ED receive a head CT scan, >90% of them are found to be negative [2]. This practice unnecessarily exposes these patients to radiation, increases the use of ED resources, and lengthens throughput times [3]. The integration of reliable, objective predictors of intracranial injury for making important initial assessment decisions [4] can impact significantly on this practice.

Hanley and colleagues (2017) [5] described the results from a multisite independent prospective FDA validation study using the EEG based biomarker output of the BrainScope One Structural Injury Classifier (SIC). Sensitivity was reported to be 99% for detecting hematoma's with ≥1 cc, in head injured patients with GCS 13–15, evaluated within 72 h of injury (see Hanley et al., for details and full performance metrics).

The current observational study investigates the clinical utility in the ED of integrating the EEG based SIC biomarker in initial assessment of mTBI patients, providing information to aid in the reduction of unnecessary CT scan referrals compared with standard site clinical determinations. A convenience sample of ninety-one (91) patients were evaluated between 6/2017–8/2018 at Barnes-Jewish Hospital Washington University Medical Center ED. Patients were 18–76 years of age (mean 44.64, sd = 17.6), 57% male, presenting to the ED within 3 days of sustaining a closed head injury (mean time since injury 10.8 h, range 1–62, with sd = 12), and all but one had a Glasgow Coma Scale (GCS) score of 15 (one patient GCS = 14). Eighty-two percent (82%) of the injuries were caused either by motor vehicle collisions (MVCs) or falls.

All patients received a CT scan which was read by the site neuroradiologist and evaluated for related traumatic injury. Patients also received an EEG evaluation (5–10 min acquired using the BrainScope One handheld device), with a disposable headset which places electrodes on the frontal and frontotemporal forehead regions [6].Physician assistants, nurses and technicians administered the EEG evaluation.

Two potential initial evaluation pathways were compared for CT referrals:

a. *Clinical Site Practice Referral:* Relying on clinical judgement of the ED physician according to site standard of care.
b. *EEG Based Classification Algorithm Assessment*: Relying on the ternary output of the SIC (positive, negative, equivocal) to inform CT referral decision. The SIC is an electrophysiological based biomarker derived from selected EEG features and a small set of clinical associated symptoms, using machine learning and advanced classification algorithms to identify those features which optimally characterize the pattern of changes in brain function that occur with head injury. Of the 91 patients referred to CT, 13 were read as positive and 78 as negative. These 91 CT referrals made using the clinical judgement decision pathway resulted in 78 patients who were found to be CT negative. Using the second pathway with input from the EEG based classification algorithm assessment (SIC) resulted 63 of the patients to be positive for CT referral. Thus, the use of the *EEG Based Algorithm* decision pathway to aid in referral for CT scanning would have resulted in 63 patients being referred for CT scans instead of 91 referrals made following standard clinical site practice. This represents a reduction of 28 fewer head CTscans, a 30.8% (= (91–63)/91) reduction.

While still early in the clinical use of this EEG based biomarker, this data demonstrates that the BrainScope One medical device can provide objective information to aid in the initial assessment of mTBI patients in the ED. Integrating this data into the decision-making process for CT referrals would have lead to a significant reduction of ~31% in CT scanning. Importantly, this decrease in CT use and its associated radiation was achieved without incurring any false negative cases (100% sensitivity). This study replicated results previously published by Huff and colleagues (2017) [7] who reported potential reduction in unnecessary CT scans (26%) in a retrospective study of the data collected in the BrainScope FDA validation study [5], extending it to clinical use and reporting a higher potential reduction of CTs. It is noted that in the current study all patients received a CT scan by standard site guidelines, thus limiting information about BrainScope One in assessing those patients who are not referred for CT, future studies should include such a population, with potential to aid in confidence of decision not to scan such patients.

It is of note that one patient in the sample was originally read as CT positive with a SIC negative finding. Upon review, this positive CT result was for an old infarct and showed no acute intracranial injury (as correctly indicated by the negative EEG biomarker result). This clearly demonstrates the efficacy of the algorithm at detecting only acute associated intracranial pathology, independent of an old injury visible on the CT.

The integration of such a rapidly obtained, objective biomarker from the BrainScope One device in the initial assessment of mTBI patients shows promise to aid in reduction of unnecessary radiation exposure and to speed up throughput times for these patients, thus, reducing overall cost to the health system.

Sources of support

Washington University School of Medicine Division of Emergency Medicine was reimbursed by BrainScope at a fair market value

https://doi.org/10.1016/j.ajem.2019.04.037
0735-6757/

commensurate with their time and effort in entering the de-identified patient data into the Registry.

References

[1] Marin JR, Weaver MD, Yeaton DM, et al. Trends in visits for traumatic brain injury to emergency departments in the United States. JAMA 2014;311(5/14):1917–9.
[2] Korley F, Kelen G, Jones C, Diaz-Arrastia R. Emergency Department evaluation of traumatic brain injury in the US, 2009-2010. J Head Trauma Rehabil 2016;31(6):379–87.
[3] Michelson EA, Huff JS, Loparo M, et al. Emergency department time course for mild traumatic brain injury workup. West J Emerg Med 2018;19(4):635–40.
[4] ACEP. ACEP Announces Lists of Tests as Part of Choosing Wisely Campaigns, https://www.acep.org/Clinical—Practice-Management/ACEP-Announces-List-of-Tests-As-Part-of-Choosing-Wisely-Campaign; 2013 [accessed 24.04.17].
[5] Hanley D, Prichep L, Bazarian J, et al. Emergency Department triage of traumatic head injury aided by using a brain electrical activity marker: a multisite prospective observational validation trial. Acad Emerg Med 2017;24(5):617–27.
[6] Prichep L, Jaquin A, Filipenko J, Dastidar SG, Zabele S, Vodencarevic A, et al. Classification of traumatic brain injury severity using informed data reduction in a series of binary classifier algorithms. IEEE Trans Neural Syst Rehabil Eng 2012;20(6):806–22.
[7] Huff JS, Naunheim R, Ghosh Dastidar S, et al. Referrals for CT scans in mild TBI patients can be aided by the use of a brain electrical activity biomarker. Am J Emerg Med 2018;35:1759–83.

Rosanne Naunheim*
Monique Konstantinovic Koscso
Robert Poirier
Department of Emergency Medicine, Washington University Barnes Jewish Medical Center, St. Louis, MO, United States of America
*Corresponding author at: 1 Barnes Jewish Hospital Plz, Saint Louis, MO 63110, United States of America.
E-mail address: naunheir@wustl.edu.

12 March 2019
Available online xxxx