Potential Significant Reduction in Unnecessary CT Scans in Emergency Departments Using an FDA Cleared Medical Device for Brain Injury Assessment

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Abstract

Despite the fact that most CT scans performed on head injured patients are negative, CT remains the "gold standard" for evaluation of head injury in the Emergency Department. This study investigates the utility of the *BrainScope One*[ii] EEG based classification algorithm to aid in the reduction of unnecessary CT scans in the mild head injured population. Evaluations were performed on 64 patients (mean age 43.5, 58% male, 98% GCS=15), enrolled in the *BrainScope One* Registry, who sustained closed head injury and were evaluated in the ED at Washington University (mean time since injury 10.1 hours) and were referred for CT scans by standard clinical site practice pathway. Results were compared with those from *BrainScope One* evaluation. In this population of ED patients, the *BrainScope One* decision pathway would have resulted in a 32.8% reduction in the overall number of CT scans referrals compared to the clinical site practice decision pathway. Importantly, this reduction in CTs was achieved without incurring any false negative cases (100% sensitivity).

1. Introduction

The volume of overall ED visits related to head injuries has risen dramatically throughout the past decade, even during a time when overall admissions to the ED has remained stable [1]. CT remains the standard of care for evaluating traumatic brain injury (TBI) in the ED and while >80% of head injured patients receive CT scans, ~91% of these scans are found to be negative [2]. There is an urgent need for integration of reliable objective predictors of intracranial injury in the mild head injured population to aid in improving referrals for CT scans, supporting better utilization of ED resources and helping to reduce unnecessary head CTs [3].

Attempts to guide head CT referrals are embodied in several decision rules for the prediction of intracranial traumatic findings (such as New Orleans Criteria and Canadian CT Head Trauma Rule) which have been designed to inform CT referral and reduce the use of CT without missing patients at risk for potentially life-threatening injuries. In standard clinical practice these rules are rarely used in isolation as experience has demonstrated that while such rules have high sensitivity, they have extremely poor specificity [4-7], thus leading only to a very small reduction in over-scanning, and further, 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 One* EEG-based Structural Injury Classifier (SIC) algorithm (using a ternary classification output) in mildly presenting head injured patients, Hanley et al. [10] reported a sensitivity of 98.6% for patients with ≥1cc blood visible on CT scans with a specificity 2-4 times higher than that obtained using standard decision rules for CT referral (e.g., NOC, CCHR) applied to the same population. In addition, they reported an NPV of 98.2%. In a retrospective analysis of this multi-site validation trial data, Huff and colleagues (2017) [11] reported that use of the *BrainScope One* EEG based biomarker showed the potential to significantly reduce over scanning in the mild head injured population when compared with standard clinical practice.

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[ii] *BrainScope One* device cleared as the Ahead® 300 device (K161068)

The current study investigates the utility of the BrainScope EEG based algorithm in clinical use in the ED to provide information which could aid in the reduction of unnecessary CT scans in the mild head injured population in a population referred for CT scan by standard site clinical determinations.

2. Methods

2.1 Patient Population

The patient population consisted of 64 patients enrolled into the *BrainScope One* Registry (between June 2017 and April 2018) from the Washington University Medical Center ED. These patients were all referred by standard clinical practice for a head CT, and had a *BrainScope One* evaluation. Patients were between the ages of 18 and 74 years (mean 43.47 years, sd=17.15), 58% male, who presented to an ED within 3 days of sustaining a closed head injury (mean time since injury 10.12 hours, range 1-56, with sd= 11.09), and all but one had a Glasgow Coma Scale (GCS) score of 15 (one patient GCS=14). Table 1 shows the mechanism of injury for the population. It can be seen that 82% of the injuries were caused either by MVAs or falls.

Table 1: Mechanism of Injury

MECHANISM OF INJURY	N	%
Assault	7	11%
Fall Related	24	38%
Motorcycle/Bike Accident	3	5%
Motor Vehicle Accident	28	44%
Struck By Vehicle	1	2%
Other	1	2%

All patients signed informed written consent. Findings of the CT scan as read by a site neuroradiologist and output of the *BrainScope One* SIC were entered into the BrainScope Registry (de-identified) for further analysis and comparisons of findings.

2.2. Evaluation Pathways

Two evaluation triage pathways for CT referrals were compared:

Clinical Site Practice Referral: This pathway followed the clinical judgement of the ED physician for referring patients for a CT scan, according to standard of care. This pathway is considered to represent Clinical Site Practice.

BrainScope One Assessment: The second pathway follows the *BrainScope One* determination in guiding referral for CT scan. The determination, based on the output of the SIC of the *BrainScope One* device, which is a biomarker derived from approximately 2 minutes of artifact-free eyes closed EEG data acquired from a limited frontal montage (including frontal and frontotemporal regions) and selected clinical risk factors often associated with TBI. Details of the derivation of the classifier and its validation described by Hanley and colleagues (2017). [10]

3. Comparison of the two decision pathways relative to reduction in CT referrals

The two decision pathways were compared using the overall reduction in CT scanning had the BrainScope One assessment been integrated into the decision for CT referral. The Clinical Site Pathway results in all patients being referred for CT scans. Adjudication of the CT scans reported 10 CT+ and 54 CT- findings in this group of 64 patients. Therefore, the clinical judgement decision pathway resulted in 54 patients that were referred for CT scanning but were later found to be CT negative.

On the other hand, the application of the second decision pathway using input from the *BrainScope One* assessment resulted in a positive determination for 43 of the patients. The use of this decision pathway as an aid in referral for CT scanning would have resulted in 43 patients being referred for CT scans. This represents a 32.8% (= (64-43)/64) reduction in referral for CT scans compared to the clinical site practice decision pathway.

Table 2: *BrainScope One* results relative to CT reads for 64 patients all referred by standard clinical site practice for CT scans.

		CT RESULT*		
		CT+	**CT-**	**Total**
BSC One OUTPUT	**Positive****	10	33	43
	Negative	0	21	21
	Total	10	54	64

* All patients were referred by site for CT scan
**Assumes Equivocal classifications were treated as BrainScope +

4. Discussion/Conclusion

While early in the clinical use of the *BrainScope One* in the ED, this Registry data demonstrates that the use of the *BrainScope One* medical device can provide important objective additional information to the triage of mild head injured patients, regarding the presence or absence of structural brain injury within three days following injury. If this information was integrated into the decision making process for CT referrals, it could lead to a significant reduction in CT scanning, ~33% in this patient group. Importantly, this decrease was achieved without incurring any false negative cases (100% sensitivity). It is noted that these initial results in the clinical setting are even better than the 26% reduction in the overall CT referral rate reported by Huff et al [11] in the retrospective study of the 720 patients from the FDA validation trial data. The use of such rapidly obtained, objective information can be a significant aid in making confident clinical decisions regarding need for CT scanning, and in helping reduce unnecessary radiation exposure for the patient, as well as reducing cost to the health care system.

References

[1] Marin JR, Weaver MD, Yeaton DM, Mannix RC. Trends in visits for Traumatic Brain Injury to Emergency Departments in the United States. *JAMA* 2014;311(5/14):1917-19.

[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] 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].

[4] Smits M, Dippel DWJ, de Haan GG, Dekker HM, Vos PE, Kool DR, et al. External Validation of the Canadian CT Head Rule and the New Orleans Criteria for CT Scanning in Patients With Minor Head Injury. *JAMA* 2005;294(12):1519-25.

[5] Stiell IG, Wells GA, Vandemheen K, Clement C, Lesiuk H, Laupacis A, et al. The Canadian CT Head Rule for patients with minor head injury. *Lancet* 2001; 357(9266):1391-6.

[6] Haydel MJ, Preston CA, Mills TJ, Luber S, Blaudeau E, DeBlieux PMC. Indications for Computed Tomography in Patients with Minor Head Injury. *NEJM* 2000;343(2):100-5.

[7] Papa L, Stiell IG, Clement CM, Pawlowicz A, Wolfram A, Braga C, et al. Performance of the Canadian CT Head Rule and the New Orleans Criteria for predicting any traumatic intracranial injury on computed tomography in a United States Level I Trauma Center. *Acad Emerg Med* 2012;19(1):2-10.

[8] Stiell IG, Clement CM, Rowe BH, Schull MJ, Brison R, Cass D, et al. Comparison of the Canadian CT Head Rule and the New Orleans Criteria in patients with minor head injury. JAMA 2005;294(12):1511-8.

[9] Smits M, Dippel DW, Steyerberg EW, de Haan GG, Dekker HM, Vos PE, et al. Predicting intracranial traumatic findings on computed tomography in patients with minor head injury: the CHIP prediction rule. *Ann Intern Med* 2007;146(6):397-405.

[10] Hanley D, Prichep L, Bazarian J, Huff J, Naunheim R, Garrett 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):617-627.

[11] Huff JS, Naunheim R, Ghosh Dastidar S, Bazarian J, Michelson EW. Referrals for CT scans in mild TBI patients can be aided by the use of a brain electrical activity biomarker. *Amer J Emerg Med*. 2018;35:1759-1783.