Potential to Reduce Emergency Department Referrals From Urgent Care Centers By Up To 75% for Mildly Presenting Head Injured Patients

Alvaro R. Zeballos, M.D.[i] & Devin Minior, M.D.[ii]
[i] BetterMed Urgent Care, [ii] Banner Urgent Care

Abstract

The standard of care today for assessment of traumatic brain injury (TBI) in the Emergency Department (ED) remains the head CT scan, despite the fact that 91% of those scanned are reported to be negative for structural brain injury. Since approximately 95% of head injured patients present as mild, there are a very large number of unnecessary CT scans performed for the mTBI/concussion population. Urgent Care Centers (UCC) have the potential to significantly impact on initial triage and assessment of mild head injured patients, yet today standard clinical assessment capabilities in UCC result in a large percentage of such patients being referred to the ED for CT imaging, most often found to be negative. The ability to objectively assess these patients at the UCC could greatly improve evaluation and care of the mTBI/concussion population. BrainScope One[iii] is a novel handheld, rapid, easy to use, FDA cleared medical device to aid in the objective assessment of full spectrum of brain injury, including the likelihood of a structural brain injury visible on CT, with high accuracy shown in a prospective independent FDA validation trial. This White Paper evaluates the reduction of unnecessary UCC referrals to the ED for CTs when BrainScope One was integrated into the clinical decision pathway, based on 196 patients whose data was entered data into the BrainScope One Registry by 12 UCC. Significant reductions in ED referrals were realized (as high as 75%) when BrainScope One was used to aid in referral decisions across a wide range (100% to 50%) of prior clinical practice referral rates, supporting the potential to significantly impact on ED diversion and reduction of unnecessary CT scans in the mild brain injury population, benefiting the patient and reducing costs to the healthcare system.

1. Introduction

An estimated 4.8 million people are evaluated annually in the US for traumatic brain injuries (TBI)[1], approximately 95% of whom are found to be "mild" (mTBI/concussion) by current clinical criteria.[2] In addition, these numbers do not reflect millions more injured in recreational and other activities who do not seek treatment. Over 50% of concussed patients have been reported to suffer persistent post-concussive symptomatology.[3] The importance of timely identification of concussive injury has been reported to be an important factor in reducing post-concussive symptoms and the time course of recovery.[4] The ability to effectively identify those with mTBI/concussion is a major public health concern.

The current standard of care for assessment of head injuries in patients seeking care in the Emergency Department (ED) is a head CT scan (>80% of those presenting to the ED receive CT scans), although 91% of these scans are found to be negative.[1] Further, CT scans identify only specific types of brain injury (especially brain bleeds, hematomas), whereas injuries related to brain function, such as that seen in concussion, are not visible on CT, although but can be seen on advanced neuroimaging technologies (e.g., MRI). Further, head injured patients found to be CT negative in the ED are typically discharged without assessment or referrals for the evaluation of concussion. Studies of patterns of healthcare utilization demonstrate that concussed/ functional brain injured patients continue to consume significant healthcare resources related to persistence of symptoms for extensive time periods.

Urgent Care Centers (UCC) are aggressively expanding, already widely outnumbering EDs, and as such offer convenient, rapid, cost effective care, with

[i] Dr. Zeballos is the Medical Director, Chief Growth Officer and Co-Founder of BetterMed Urgent Care
[ii] Dr. Minior is the Chief Medical Officer of Banner Urgent Care Services/Occupational Health
[iii] *BrainScope One* device cleared as the Ahead® 300 device (K161068)

the potential to significantly impact on initial assessment of mild head injured patients. However, standard clinical assessment capabilities at UCC result in a large percentage of such patients being referred to the ED for CT imaging. Recent publications indicate that, in general, most transfers from UCC to EDs result in discharge and were deemed unnecessary.[5] UCC might better serve this population through the incorporation of *BrainScope One* in the triage process. *BrainScope One* is a first of its kind medical device, cleared by the FDA, utilizing electroencephalogram (EEG) technology for the objective assessment of the full spectrum of mTBI, including concussion. *BrainScope One* is a medical device that is handheld, easy to use, and can rapidly assess the likelihood of both structural (brain injury visible on CT) and functional brain injury (such as concussive injury) at the point of care. *BrainScope One* offers an opportunity for dramatic improvement to the current assessment for evaluating mTBI/concussed patients in clinical settings outside the ED, such as UCC, when integrated into the clinical assessment (not intended as a standalone diagnostic). Such integration into UCC environments could result in overall reduction in the cost and time of care, exposure to unnecessary radiation, and contribute to more objective and immediate assessment of concussive injury.

This retrospective study evaluates the potential to reduce UCC referrals to the ED for head CT scans based on the first 196 cases entered (de-identified) into the *BrainScope One* Registry from evaluations performed in the UCC setting.

2. Methods

2.1 Subject Population

The patient population consisted of 196 patients evaluated at 12 UCC groups[iv] and enrolled into the *BrainScope One* Registry (between June, 2017 and April, 2018). The mean age of the population was 27.6 years (range 18.5-45.0), 40% males, with a mean time since injury of 17.6 hours, and a mean Glasgow Coma Scale score (GCS) of 14.9 (range of 13-15). The mechanisms of injury are shown in Table 1.

Table 1: Mechanisms of injury.

Mechanism of Injury	Total	%
Assault	34	17%
Fall Related	62	32%
Motorcycle/Bike Accident	3	1%
Motor Vehicle Accident	43	22%
Sports Related	7	4%
Struck by Vehicle	1	1%
Other	46	23%
Total	196	100%

2.2. Evaluation Pathways for Referrals to ED from UCC

2.2.1 Referrals to ED under standard UCC practice: Since prior clinical site referral patterns for mTBI/concussed patients was not documented at these UCC sites, nor well documented in the literature, diversion was computed for referral patterns to the ED of such mild head injured patients (without BrainScope) across a wide range from 100% to 50%.

This range represents an assumption of referral patterns in which 100% of mTBI/concussed patients were referred to the ED, to more modest referral rates of 90%, 80%, 70%, 60% and 50%. In this way, the relationship between impact of adding the *BrainScope One* assessment to aid in triage decisions for referrals to the ED could be estimated across the range of potential standard referral patterns.

2.2.2 Referrals aided with *BrainScope One* assessment: Referrals to the ED for CT scans were determined with consideration of 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 easy to use electrode headset placed on the forehead of the patient, and selected clinical risk factors often associated with TBI. Details of the derivation of the algorithm and its validation are described by Hanley and colleagues (2017).[6] *BrainScope One* outputs include three categories, "positive" (likely brain injury present, consider further evaluation including advanced neuroimaging or CT scan), "negative" (likely no brain injury visible on head CT), and "equivocal" (consider

[iv] UCC include: Banner Health, BetterMed Urgent Care, Central Jersey Urgent Care, ClearChoice Urgent Care, HealthCare Express, Marque Medical, Moore Life Urgent Care, Pentucket Express Care, StatCare Urgent Medical Care, StatMed Urgent Care, Urgent Team Urgent Care

further observation and evaluation). In this UCC population 71% were found to be *BrainScope One* negative, 21% positive, and 8% equivocal.

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

Referrals for CT scans with and without integration of *BrainScope One* assessments were compared. Since there is not a clinical standard for the rate of referrals to EDs for UCC, comparisons were made for a range of potential clinical practice for such referrals for mild head injured patients, from 100%, to as low as 50% of such patients. While current referral rates to the ED from UCC may vary by site and provider, rates tend to be at the upper end of this range.

Percent reduction was computed comparing the actual number of referrals to the ED made with the aid of *BrainScope One* assessment, to those that would have been made without *BrainScope One* for the full range of prior clinical ED referral rates. Table 2 shows the percentage overall reduction in CT scanning when *BrainScope One* assessment was integrated into the decision for CT referral. Significant reductions in ED referrals (only 49 patients of the 196 were referred) were seen across the range of assumed referral patterns, ranging from 75% (when assumed that 100% would have been referred previously), to 50% (when assumed only 50% would have been referred).

This study focused on the age group 18-45 as approximately 75% of the Registry cases were in this age range and performing unnecessary head CT scans in this age range is of high concern. However, it is of note that if one extends the age range to the full range indicated for use with *BrainScope One* (18-85years), high diversion rates were also demonstrated (with the range being 64%-28%) despite the additional risk factors of the older population. The full age range will be studied further as more Registry cases are gathered.

Discussion/Conclusion

Based on this study of the first 196 UCC patients entered in the *BrainScope One* Registry, data demonstrates that use of the *BrainScope One* medical device can aid in significantly reducing UCC referrals to the ED for a CT scan. The divergence rate was shown to be as high as 75%, if one assumes that under standard clinical practice all of these patients would have been referred to the ED. Since the prior rates of ED referrals are not well documented and can vary based on clinical site practice guidelines for each UCC, reduction in referrals to the ED were also computed for a range of prior referral rates between 100% and 50%, although rates are most likely at the higher end of this range currently. Throughout the range significant diversion was demonstrated, with the lowest rate (still a significant reduction), 50%, when it was assumed that only 50% of the patients would have been referred without use of *BrainScope One*.

The integration of *BrainScope One*, a rapid, objective assessment of mTBI/concussion, can aid in significant diversion from ED referrals by UCC. This can help relieve ED overcrowding and patient wait times, eliminate unnecessary CT scans and radiation exposure for the patient, and reduce costs incurred by the patient and insurers, resulting in an overall benefit to the patient and the healthcare system.

Table 2: Percent reduction in ED referrals for CT scans when *BrainScope One* is used as part of the initial assessment, compared to a range of clinical referral rates under standard clinical practice.

% ED/CT Referral From UCC Under Standard Practice (without use of *BrainScope One*)	**% Reduction in ED/CT Referral From UCCs Integrating *BrainScope One***
100%	75%
90%	72%
80%	69%
70%	64%
60%	58%
50%	50%

Acknowledgement

The data presented represents the efforts of all the UCC that participate in the *BrainScope One* Registry and whose data is included in this report.

Reference List

[1] 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.

[2] Fakhran S, Delic J, Alhilali L. Evolution of MRI of brain injury in concussion patients. *Future Neurol* 2014; 9: 517-520.

[3] McMahon P, Hricik A, Yue JK, Puccio AM, Inoue T, Lingsma HF, Beers SR, Gordon WA, Valadka AB, Manley GT, Okonkwo DO; TRACK-TBI Investigators. Symptomatology and functional outcome in mild Traumatic Brain Injury: Results from the prospective TRACK-TBI study. *J Neurotrauma*. 2014;31:26-33.

[4] Guskiewicz K, McCrea M, Marshall SW, Cantu RC, Randolph C, Barr W, Onate JA, Kelly JP. Cumulative Effect Associated with Recurrent Concussion in Collegiate Football Players: The NCAA Concussion Study. *JAMA.* 2003; 290(19): 2549-2955.

[5] Zitek T, Tanone T, Amos A, Fama R, Ali AS. Most transfers from Urgent Care Centers to Emergency Departments are discharge and many are unnecessary. *J Emerg Med.* 2018;on-line ahead of print.

[6] 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.

BrainScope One is intended for patients 18-85 years of age presenting within 72 hours of mild head injury. BrainScope One is not a stand-alone diagnostic nor a replacement for CT scan. Please refer to: www.brainscope.com/products for complete indications.