

BrainScope: Fulfilling the Promise of Emergency Medicine

An Efficient, Patient Centered, and Cost-Effective Device for the Evaluation of Minor Head Injury

When Emergency Clinicians joined the Choosing Wisely Campaign, one of their first recommendations was to avoid low-value Computed Tomography (CT) scans of the head in patients with minor head injury. Since the American College of Emergency Physician's (ACEP) endorsement of the campaign, Emergency Clinicians are quick to identify the goals of choosing wisely; however, low-value CT scans of the head continue to be ordered. Surveys cite an Emergency Clinicians' "concern for serious diagnosis" and "patient or family expectations" for the reason why patients with minor head injury continue to receive a low-value CT head.¹

This paper will explore the complex nature of the Emergency Department (ED) diagnostic work-up of patients with minor head injury, and will focus on a new technology that enables Emergency Clinicians to obtain real-time decision support through a point-of-care brain electrical activity based technology, BrainScope. BrainScope provides objective data on both functional and structural brain injury to the ED Clinician within minutes, helping to inform clinician decisions on the necessity of a CT scan and providing crucial brain functional information to help inform follow-up.

EDs that deploy BrainScope to help guide the evaluation of patients with minor head injury see a reduction in low-value CT scans, reduced radiation exposure to patients, decreased ED length-of-stay, reduced total healthcare costs, and increased ED patient satisfaction. In short, BrainScope helps deliver value-based care to ED patients with minor head injury.

Choosing Wisely Campaign

Reduce cost and improve value



In 2012, the American College of Emergency Physicians (ACEP), like other specialty societies, began a conversation with its members to develop five “Choosing Wisely” recommendations.² Groups that participated in the campaign believed that promoting conversations between clinicians and patients would enable patients to choose care that is: “supported by evidence, not duplicative of other tests or procedures already received, free from harm, and truly necessary.”³

ACEP’s multistep process began with input from its Cost-Effective Task Force (Task Force), who administered a survey to ACEP members asking for strategies to “reduce costs and improve value in Emergency Medicine.” A technical panel then performed an extensive literature review focused on cost related data for the highest rated suggestions. Ultimately, only five strategies were selected for the inaugural Choosing Wisely campaign, and first on the list was the recommendation to avoid Computed Tomography (CT) Scans of the head in patients with minor head injury. In 2014, ACEP unveiled 5 more recommendations to create the 10 current choosing wisely recommendations.⁴ (See appendix for more details)

“ In ACEP’s inaugural Choosing Wisely Campaign, the number one recommendation to reduce cost and improve value in EM, was to avoid CT Scans in minor head injury.

The Task Force determined that the evidence was clear; patients with minor head injury that are low risk for intracranial bleeding or skull fracture by decision rules would benefit from a conversation with their clinician on the utility of a CT head⁵. Given that 3.6% of all ED visits present for head injury, there is significant opportunity to improve the value of care for ED patients.

In fact, nearly 5 million Emergency Department (ED) patients are evaluated for traumatic brain injury (TBI) in United States EDs each year, and 82% of these patients receive head CT scans, yet 91% of them result in no traumatic abnormalities identified.⁶ Head CTs, that expose patients to ionizing radiation and can increase a patients’ lifetime risk of cancer, should not be performed when clinicians can safely risk stratify a patient without the expense of a potentially harmful test.⁵ In 2013, the specialty of Emergency Medicine made a promise to identify CT heads in minor head injury as an opportunity to improve the value-based care in the ED.

Codifying Choosing Wisely

The Centers for Medicare and Medicaid Services (CMS) also saw the value in reducing CT scans for minor head injury and made their reduction one of a small handful of Emergency Medicine Clinical Quality Measures that may be reported as part of the Merit Based Incentive Program (MIPS).⁷ CMS Clinical Quality Measure (CQM) #415 tracks the percentage of ED visits for patients aged 18 years and older who present with minor blunt head trauma who had a clear indication for a head CT for trauma ordered by an Emergency Clinician.

Since the Choosing Wisely Campaign, avoiding unnecessary head CTs in minor blunt Trauma has become a core tenant of Emergency Medicine, and CMS has tied reimbursement penalties and incentives to their judicious use through the MIPS program. Almost 10 years after identifying CT heads in minor head injury as an opportunity to improve the value-based care in the ED, it appears that the use of CT in minor head injury continues to rise.⁸

Evaluating the Choosing Wisely Promise

After the Choosing Wisely Campaign launched, a series of studies published from 2017-21 evaluated its effects. One of the first published evaluations was a retrospective cohort study at an academic level-1 trauma center. The study included 489 patients with minor head injury and assessed whether ED clinicians appropriately applied the Choosing Wisely criteria. The NEXUS II clinical decision rule, which uses a series of clinical criteria to risk stratify the severity of a patient's head injury, was used as a benchmark.⁹ Clinicians captured the clinical criteria for the decision rule well; however, they still obtained "non-indicated" CTs in 23.1% of patients.⁸

This trend bore-out in further studies, including in 2017-18 when ACEP established its Emergency Quality Network (E-QUAL).¹⁰ This network created the "Avoidable Imaging Initiative" by establishing national benchmarking data for imaging utilization from the voluntary reporting of 305 hospital-based community EDs. The network's goals were to: "disseminate common QI interventions, share best practices to reduce avoidable imaging, and report performance variation and improvement trends."¹¹

During the study period, the overall imaging utilization rate for patients with minor head trauma was 72.6% (IQR 65.6%–81.7%). In comparison to other Choosing Wisely benchmarks, which include CT Head in syncope 50.0% (IQR 38.0%–61.4%) and xrays in non-traumatic low back pain 34.7% (IQR 26.3%–42.6%), the CT utilization for minor head injury was by far the greatest. Despite the Choosing Wisely campaign, ED Clinicians rely on CT scans when evaluating patients with minor head injury.

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Do Clinicians trust the Decision Rules in Minor Head Trauma?

A large survey of Emergency Physicians (EPs) began to unpack the clinician response to the Choosing Wisely campaign. From the results, it appears that as a direct result of the campaign, a "majority (62.7%) were able to identify at least four of five Choosing Wisely recommendations" and most respondents (64.5%) felt more comfortable discussing low-value services with patients." However, the self-reported most prevalent low-value practice that remained was: "computed tomography (CT) brain for minor head injury (29.9%)".

In the case of a CT head, Emergency Physicians cited “concern for serious diagnosis” or “patient or family expectations” for the reason why they did not adhere to clinical guidelines.

Despite familiarity with Choosing Wisely, many Emergency Clinicians report performing low-value services, such as CT in minor head injury.¹ In the case of a CT head, Emergency Physicians cited "concern for serious diagnosis" or "patient or family expectations" for the reason why they did not adhere to clinical guidelines.

In their discussion, the authors state: "some clinicians may have a good understanding of the evidence base, but choose to deviate from guidelines and rely on patient clinical factors or "gestalt," as decision rules are imperfect."¹ When it comes to possible life-threatening diagnosis, like those in head injury, it seems that Emergency Clinicians need an objective test they can trust.

BrainScope

A biomarker for minor head injury



It appears that Emergency Clinicians understand and agree with the sentiment of the Choosing Wisely campaign, but they fear missing a serious diagnosis and want to fulfill the expectations of their patient and the patient's family during their ED visit. BrainScope may be the tool that clinicians can trust to bridge this gap.

BrainScope is a brain electrical activity based biomarker that is easily applied to a patient with minor head injury (FDA cleared for patients with GCS 13-15 within 72 hours of injury) that provides a rapid and objective assessment of mild traumatic brain injury (mTBI). BrainScope demonstrated a 99% sensitivity in identifying the likelihood of the smallest detectable level of intracranial blood (>1 mL) in patients with minor head injury.¹² Through an objective, AI-derived algorithm, BrainScope provides Emergency Clinicians with both the likelihood of having a structural brain injury (a "bleed") and a functional brain index that objectively assesses a patient's probability of brain function impairment after a minor head injury. These objective measures give both clinicians and their patient's objective information related to their head trauma without ionizing radiation.

BrainScope may bridge the disconnect between the Choosing Wisely promise and Emergency Clinicians continuing to order low-value CTs in minor head trauma. BrainScope's value proposition fulfills the promise of Emergency Medicine and helps improve the care of patients with minor head injury in the ED by aiding in reducing low-value head CT utilization and the associated ionizing radiation exposure, reducing ED length of stay, decreasing total healthcare costs, and improving patient satisfaction.

The value-proposition of evaluating and treating patients with minor head injury in the ED can align with the promise of the EM community – the clinicians that treat patients with minor head injury now have a brain electrical activity based objective biomarker to help inform their care plans and improve their follow-up recommendations.



“**From the Literature:** *While CT imaging identifies problems that otherwise may be missed by physical examination (e.g., fractures, epidural and subdural bleeds, and subarachnoid hemorrhage), such scans are “positive” for only 6%-8% of patients with mTBI, and <1% of patients with mTBI are found to require neurologic intervention. “There is a need for an alternative, objective triage tool or decision rule that could potentially aid in the safe reduction of the number of CTs ordered. Moreover, when working up a patient with mTBI a normal CT does not rule out the presence of a functional brain injury or concussion.*”

Reduces low value CT scans

When BrainScope conducted its multisite, independent FDA validation study, comparisons were made to results of CT Scan of the head (usual practice) to determine the sensitivity of this non-invasive device in risk stratifying patients for structural brain injuries.¹² In a retrospective analysis of the validation study data, the authors report that integrating BrainScope at triage would have a 26% reduction in the number of CT scans in this ED patient population.¹³

Following FDA clearance, BrainScope was used in clinical practice, starting with convenience sampling of patients in single-centered EDs alongside usual practice in patients aged 18-85 with a GCS of 13-15 within 72 hours of injury. In one such study, all patients received a CT Scan, and were also evaluated with BrainScope. This study predicted a 30.8% reduction in low-value head CT scans had BrainScope been used prospectively in triage for all eligible patients. Further, this reduction in CT scans would have been achieved without any false negatives.¹⁴ In this controlled environment, BrainScope can reduce ED CT scans in minor head injury patients by at least 26-31%. In recent reports outside of the study environment, EDs are experiencing a CT diversion rate of 38-60%.^{15,16}

To make this reduction more concrete and using the published study rate to be conservative, in a 40,000 visit/year ED, there will be approximately 867 patients each year eligible for evaluation with BrainScope (see appendix for assumptions). On average, around 184-220 of these patients will avoid a low-value head CT and its associated radiation.

“**To make this reduction more concrete and using the published study rate to be conservative, in a 40,000 visit/year Emergency Department, there will be approximately 867 patients each year eligible for evaluation with BrainScope. On average, around 184-220 of these patients will avoid an unnecessary head CT and radiation.**”

Reduces radiation exposure

Naturally, if BrainScope can aid in the reduction of the number of unnecessary CT scans ordered for ED patients with mTBI, patients will avoid the associated ionizing radiation. This is the rationale for the CMS Clinical Quality Measure (CQM) #415, which states:

*“Though it is difficult to directly attribute the effects of smaller dosages of radiation, such as that received through computed tomography (CT), the dosage of radiation from CTs has increased in recent years, in part due to the increased speed of image acquisition. Additionally, there is evidence to suggest that the radiation doses from CTs are higher and more variable than generally quoted. Further, as “radiation doses associated with commonly used CT examinations resemble doses received by individuals in whom an increased risk of cancer was documented,” the use of some CT scans is associated with a “nonnegligible” lifetime attributable risk of cancer. As over 1.3 million individuals are treated and released from the ED for mild traumatic brain injury annually, it is critical that CT scans only be utilized when clinically appropriate.”*⁷

In a 40k visit/year ED, BrainScope can help avoid the equivalent of 3,696-4,400 chest X-rays

With the use of BrainScope, Emergency Clinicians can safely avoid the radiation exposure associated with a CT head, while simultaneously obtaining an objective biomarker to assess for a serious diagnosis, such as a brain bleed. In the example of a 40,000 patient visit per year ED, the amount of total radiation that patients will potentially avoid is equivalent to 3,696 -4,407 chest x-rays. BrainScope is an objective biomarker that helps risk stratify patients with minor head injury. In practice, EDs that use BrainScope see a reduction in CT utilization and a corresponding decrease in radiation exposure for their patients.¹⁶

Reduces length of stay

ED performance is based almost entirely on process metrics, such as the time of patient arrival to the ED to the time the patient has a disposition, the "ED length of stay" (LOS).¹⁷ This ED LOS is tracked daily by many ED leaders as a measure of patient flow through the department. A major bottleneck in the ED is the CT scanner; patients wait their turn to obtain a CT, oftentimes adding crucial minutes to hours onto the overall patient visit.

When analyzing the time course for the ED work-up of mild traumatic brain injury, Michelson et al. developed a theoretical model to demonstrate that approximately "one-half of the time associated with the current typical ED evaluation work-up of suspected mild traumatic brain injury (mTBI) is the result of the decision to order and the time and resources necessary to complete and obtain an interpretation of a head CT."¹⁸ The authors go on to state that the steps of ordering, waiting, transporting, obtaining, and reviewing a head CT adds approximately 151 minutes to the total ED LOS. Therefore, the authors suggest, "elimination of the head CT and all related steps . . . would result in an estimated time savings of 151 minutes, as a substantial proportion of the time required to assess suspected mTBI was attributable to steps following the decision to order a CT."¹⁸

When integrating BrainScope into the triage of minor head injured patients, ED leaders can expect to decrease the ED LOS in patients with minor head injury by approximately 151 minutes when avoiding a CT head. Thus, in a 40,000 visit/year ED, the cumulative time savings in the ED LOS would translate into the capacity to see approximately 178-213 more patients per year. If each of these visits are billed at the national average for an E&M Level Three visit, the institution should expect additional revenue of \$42,100 - \$50,400 in facility fees alone.

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Reduces total healthcare cost

A recent analysis of the economic impact of BrainScope on the Healthcare System was conducted, where Bentokover et al. developed the BrainScope Economic Analyzer Model (BEAM).¹⁹ This model looks at the economic impact of BrainScope on costs to payers as well as patients and predicts the broader economic impact of the device on the healthcare system. The model assumes a moderate penetrance of BrainScope into the healthcare system, including its use in Urgent Care Centers, where ED referrals for minor head injuries decreased with the use of BrainScope.²⁰

The model also includes the demonstrated reduction in CT scans to form an actuarial model to "specifically analyze the associated costs related to the initial triage of mTBI patients."¹⁹ Fees related to Emergency Medical Services, ED Physician, ED facilities, CT facility and technical components, and patient observation times were inputted into the model using 2016 data from the IBM MarketScan database. The model predicts a total healthcare costs savings of \$622 per patient. This cost savings is realized by payers and patients, adding further incentives for hospitals and their outpatient systems to integrate BrainScope into their clinical workflow.

The authors go on to conclude that the broader effects associated with using BrainScope include: "decreased ED overcrowding by diverting patients and reducing ED referrals; reduced radiation exposure by avoiding unnecessary CT Scans; increased care access points by integrating devices in various patient care settings including rural settings where CT may not be available; decreased processing time for non-critical patients by lowering the number of touchpoints during triage, thereby freeing capacity for higher acuity patients; early intervention through objective functional injury data; reduced patient wait times, increasing productivity and improving patient satisfaction; and provision of objective data to aid clinicians in making a more informed and confident decisions to hold patients for observation" could not be captured in the actuarial model.¹⁹ Implementing BrainScope does not just benefit internal ED operations, its effects are felt by reducing overall healthcare costs as well, fulfilling a major tenant of modern healthcare improvement.²¹

Improves patient satisfaction

Initial pilot studies with BrainScope not only demonstrate a realized reduction in low-value head CT scans, but also show a strong signal for improving patient satisfaction.¹⁶ Thus, BrainScope may address the self-reported concern for why clinicians order low-value heads CTs in minor head injury – fulfilling “patient or family expectations.”¹ In a recently reported evaluation of BrainScope in Inova Fairfax Hospital, the only level-one trauma center in Northern Virginia, USA, BrainScope was deployed in the ED.

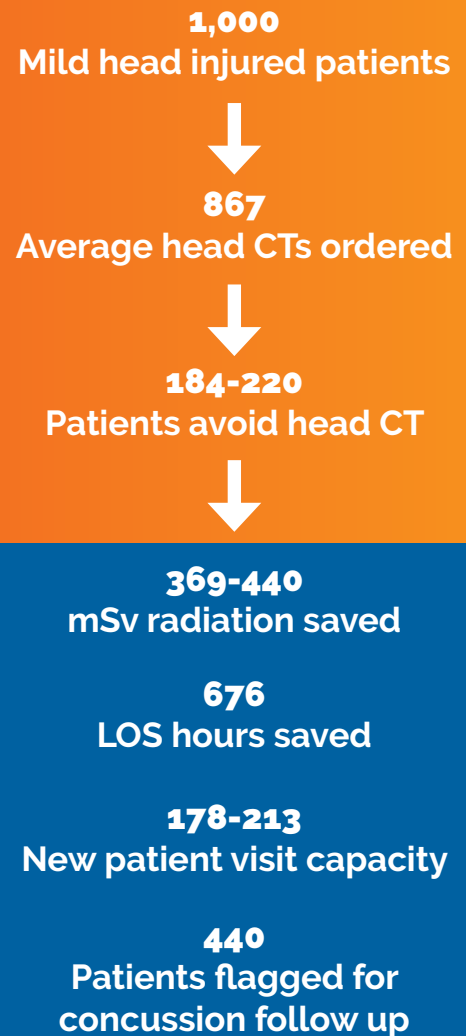
During this pilot, both patients and clinicians were surveyed. The author reports similar decreases in CT Scan utilization to previous studies, and also comments on the benefit of the “Brain Function Index” feature, which physicians reported “enabled discussions” with their patients regarding concussion. However, and possibly related to these conversation generating features, the most striking aspect of this 19-patient report was the signal of patient satisfaction – a positive patient experience was reported 100% of the time.¹⁶

While this cohort is small and the metrics reported were not via a validated patient satisfaction survey tool, there is a body of literature that supports these signals regarding the clinical benefits of BrainScope. In 2018, Michelson et al. hypothesized that “reducing the time from presentation to diagnosis by limiting CT or other recognized inefficiencies . . . could contribute to increased levels of patient satisfaction.”¹⁸ In fact, studies do show a correlation between decreasing ED LOS and improvements in publicly reported quality-of-care measures, including patient satisfaction. Chang et al. report that each additional hour of ED LOS was associated with 0.7% decrease (95% confidence interval = 0.4 to 1.0; $p < 0.01$) in proportion of patients giving a top satisfaction rating (score of 9 or 10 on a 10-point scale) of patients who would “definitely recommend” the ED.²²

Thus, by decreasing the ED LOS, more patients will become net-promoters. Further studies show similar correlations of likelihood-to-recommend scores to median LOS among discharged patients, which shows a precipitous drop in satisfaction scores after a median LOS approaches 4 hours.²³ Therefore, the predicted 151 minutes that a CT scan adds to the ED LOS for a patient with mTBI, becomes even more important to ED clinical leaders.¹⁸ In a 40,000 visit/year ED, there are 185-220 patient visits/year where this time savings and potentially improved satisfaction score may be realized.

While more research is indicated and underway, the clinician reports out of Inova Fairfax seem to indicate that the expectations of patients “getting a test” in the ED is fulfilled with BrainScope. In fact, much like the well-documented physician fear of needing an objective test in addition to a clinical decision rule to assess for the likelihood of a “serious diagnosis” in mTBI, BrainScope seems to also fulfill the “patient or family expectations” of the ED care-experience. Furthermore, the conversations that BrainScope enables echo the call for promoting conversations between clinicians and patients that the Choosing Wisely campaign originally envisioned.

Impact of reducing low value head CTs in a 40,000 visit/year ED



The importance of follow up

One of the tenets of EM is the importance of follow-up after an ED visit. It appears that at most 68% of ED patients that are diagnosed with Traumatic Brain Injury (TBI) are referred to a physician or clinic for follow-up, and approximately 44% of patients with mTBI, actually see a clinician within three months for follow-up.^{6,28} A 2022 study involving 2,697 participants across 18 level-one trauma center EDs on the outcomes of patients with "mild traumatic brain injury without acute intracranial traumatic injury," suggests that even in patients with a GCS score of 15 and a negative head CT scan, most participants reported an incomplete recovery during their two-week and 6-month follow-up visits. The authors conclude that "emergency department clinicians should recommend 2-week follow-up visits" for mTBI patients discharged from the ED "to identify those with incomplete recovery and to facilitate their rehabilitation."²⁴

The recent experience with BrainScope at Inova Fairfax indicates that the BrainScope Function Index (BFI) can help identify those patients that will likely benefit most from a follow-up appointment, as the BFI is a quantitative marker of brain function impairment that scales with severity.^{16,25} In the Inova Fairfax ED experience, the author reports that "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."¹⁶ The authors conclude that not only does the BFI 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."¹⁶ The objective nature of BrainScope technology allows clinicians to safely avoid unnecessary head CTs while also giving clinicians a BFI score that can trigger a conversation with patients about the importance of follow-up.

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Therefore, in a 40,000 visit/yr ED, if the trend in the Inova Fairfax ED experience represents a common experience, approximately 440 patients with a low BFI index will be flagged for appropriate follow-up. These BFI findings may improve pre-discharge ED counselling and may improve follow-up recommendation adherence. They may also enable ED clinicians to clear patients for work or sports much faster and with more confidence should the BFI indicate a normal brain function index.

Conclusion

In 2013, with the roll-out of the Choosing Wisely campaign, EM made reducing low-value CT scans in patients with minor head injury a top priority. Subsequent studies showed that EM clinicians know the evidence behind CT-scan decision rules and are familiar with the Choosing Wisely campaign, but remain concerned that relying solely on clinical decision rules when evaluating patients with minor head injury may facilitate missing a serious diagnosis or not fulfilling a patient or their family's expectations. Almost a decade later, despite Choosing Wisely, EM clinicians continue to order low-value CT scans that expose their patients to unnecessary radiation.

BrainScope, a novel point-of-care brain electrical activity based technology, can be rapidly deployed in the ED as an objective decision support tool to alert clinicians to the likelihood of both structural and functional brain injuries, which aid clinicians to avoid low-value CT scans and their associated radiation. In addition, use of BrainScope can decrease ED LOS associated with a CT scan, reduce total healthcare costs for payers and patients, improve ED patient satisfaction, and provide a brain function assessment to objectively discuss a patient's prognosis and arrange appropriate follow-up. In short, BrainScope improves value; it enables EM clinicians to fulfill the promise of modern Emergency Medicine.

Appendix

The Choosing Wisely Campaign and ACEP

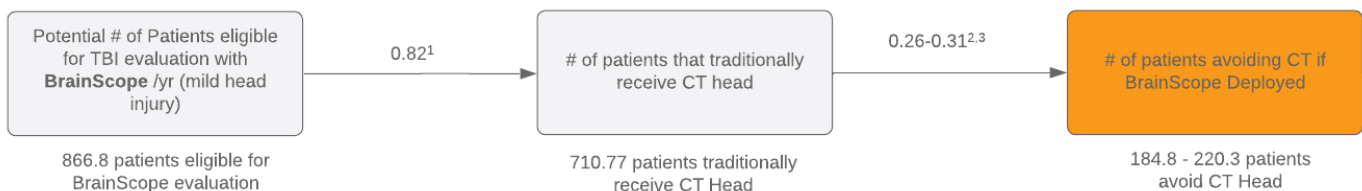
The American College of Emergency Physicians (ACEP) was deliberate in its participation with the Choosing Wisely Campaign, which was founded by the American Board of Internal Medicine Foundation (ABIM). Multiple specialty groups (over 80) signed on to the campaign to "promote conversations among physicians and patients about using appropriate tests and treatments and avoiding care when harm may outweigh benefits" prior to ACEP's ongoing deliberate internal discussion to join.²⁶

ACEP's multistep process began with input from its Cost-Effective Task Force, who administered a survey to ACEP's 30,000+ members asking for strategies to "reduce costs and improve value in Emergency Medicine." From over 200 suggestions, the group used a modified Delphi technique to begin to rank these suggestions. A technical panel then performed an extensive literature review focused on cost related data for the highest rated suggestions. Ultimately, only five strategies were selected for the inaugural Choosing Wisely campaign, and first on the list was the recommendation to avoid Computed Tomography (CT) Scans of the head in patients with minor head injury. In 2014, ACEP announced 5 more strategies to bring their total recommendations up to ten.^{2, 3, 4}

Model Assumptions

Calculating BrainScope Eligible Patients & CT Reduction

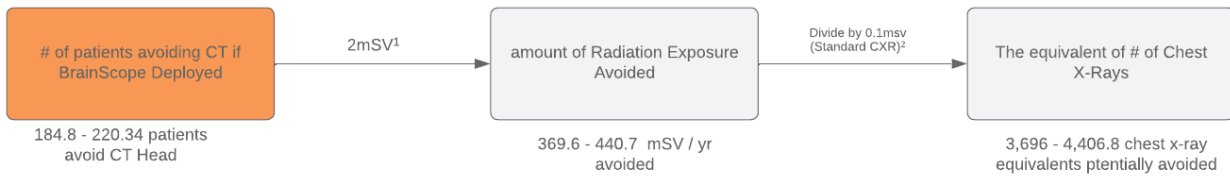
From population-based data from the National Hospital Ambulatory Medical Care Survey (NHAMCS) we know approximately 3.6% of ED visits are for Traumatic Brain Injury (TBI) each year.⁶ 94.5% of these patients are classified as "minor" head injury with a GCS of 13-15 upon presentation.¹⁸ Of these patients, 70% are between the ages of 20-75, which is the reported cohort closest to BrainScope's approved age range of 18-84.⁶ While BrainScope can detect structural abnormalities in patients on anticoagulation, there are many reported clinical algorithms in EM that state a CT Head for patients on blood thinners with minor head trauma is indicated. For now, we will assume that the 9.1% of the ED head injured population that is on blood thinners will not be eligible for BrainScope.²⁷ Therefore, with just the annual ED volume, we can assume from population-based studies, how many patients are BrainScope eligible. In this paper we will use an ED annual volume of 40,000 patients to give concrete examples of the BrainScope value proposition.



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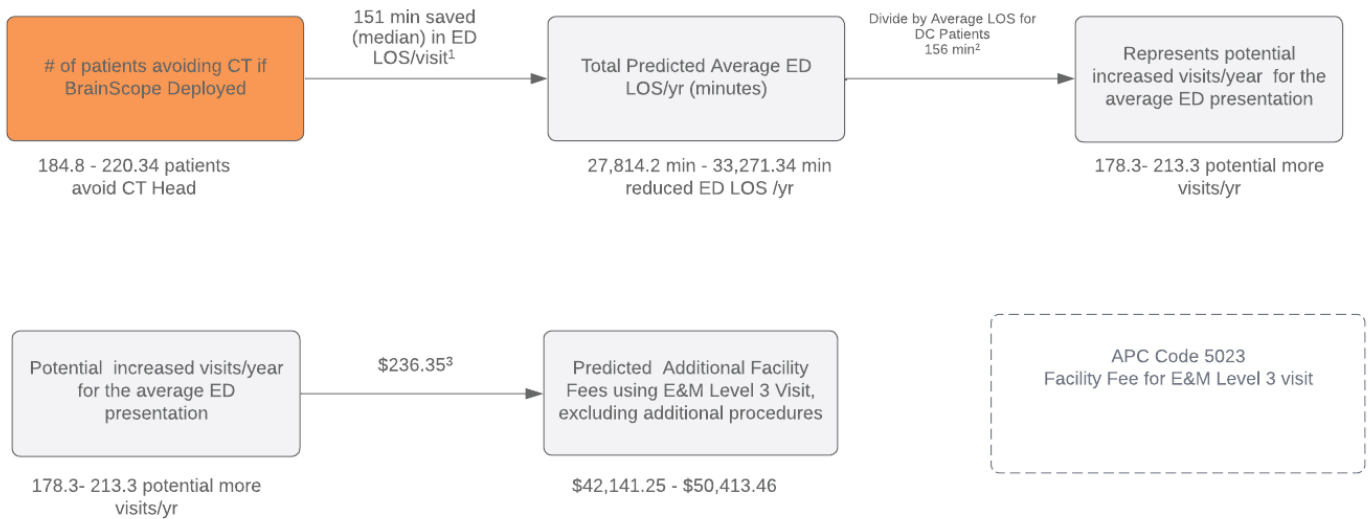
Radiation reduction



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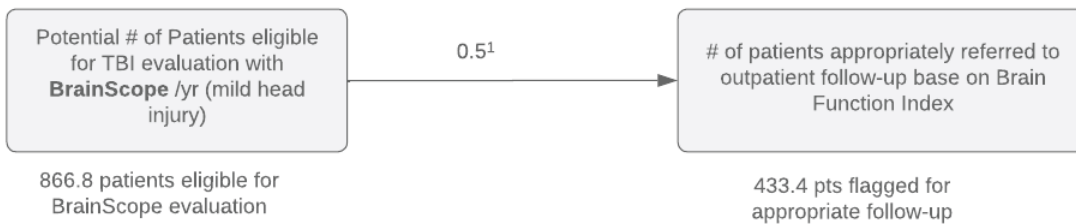
Length of stay reduction



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Patients flagged for follow up care



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BrainScope Technology Overview

Data acquisition unit connects headset to device

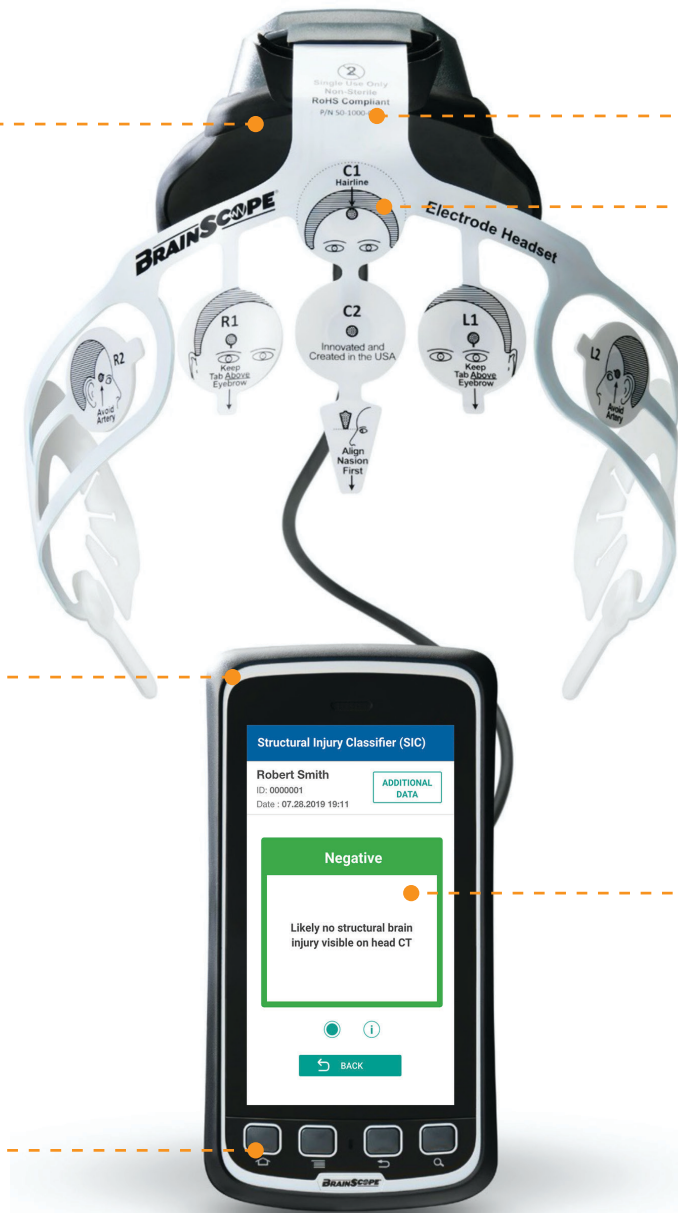
Disposable headset

Placement instructions on every headset

No connectivity required

On-screen support and real-time feedback assures rapid test time

Ruggedized handheld device can be used with gloved hands



8 FDA CLEARANCES / 33 PEER-REVIEWED PUBLICATIONS /
12 YEARS R&D / 14,000+ SUBJECT EVALUATIONS

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