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Intracranial Pathology (CT+) in Emergency Department Patients With High GCS and High Standard Assessment of Concussion (SAC) Scores

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Objective: To demonstrate that a subpopulation of patients with mild/moderate traumatic brain injury (TBI) had intracranial pathology despite having a Glasgow Coma Scale (GCS) score of 15 and a Standardized Assessment of Concussion (SAC) score of 25 or higher. **Setting:** A network of 11 US emergency departments (ED) enrolling patients in a multisite study of TBI. **Participants:** Men and women between the ages of 18 and 85 years admitted to a participating ED having sustained a closed head injury within the prior 72 hours and a GCS score of 13 to 15 at the time of enrollment. **Design:** Prospective observational study. **Main Measures:** GCS, SAC, computed tomography (CT) positive or negative for intracranial pathology, Marshall scoring of CT scans. **Results:** Of 191 patients with intracranial pathology (CT+) and having a SAC score recorded, 24% (46/191) had a SAC score in the normal range (≥25) as well as a GCS score of 15. All causes of CT+ brain injury were present in both SAC groups. **Conclusion:** A normal GCS score and a SAC score do not exclude the possibility of significant intracranial injury. **Key words:** *assessment*, *brain bleed*, *concussion*, *CT*, *neurocognitive testing*, *TBI*, *traumatic hematoma*

IDENTIFICATION of concussion/mild traumatic brain injury (mTBI) remains a clinical diagnosis with no "gold standard" diagnostic tool. In addition, there are many clinical diagnostic criteria, with the World Health Organization noting 38 different suggested diagnostic criteria in a 2014 report.[1–4] The Standardized Assessment of Concussion (SAC) was developed for acute "sideline" assessment of concussion in the mid to late 1990s.[5] The SAC consists of assessments of orientation to time, day and date, immediate recall, concentration, and delayed recall. The total score achievable is 30, and in many applications, a score of 25 or higher is considered "normal," based upon this score having the maximum sensitivity and specificity.[6] The SAC has been widely used as a sideline screening tool for concussion in many sports.[5,7–13] In 2004, the SAC was included with other assessments to produce the Sports Concussion Assessment Tool (SCAT), currently in its third iteration.[5] The Department of Defense uses a modified version of the SAC called the Military Acute

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Drs O'Neil, Naunheim, and Wright were principal investigators at clinical data acquisition sites. Dr Curley was a consultant to BrainScope Co, Inc, between March and August 2016, and who at the time the study was conducted was the Neurotrauma Research Portfolio Manager for Combat Casualty Care Research Program and Defense Health Program at the US Army Medical Research and Materiel Command.

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Concussion Evaluation (MACE).[8,14] The SAC, the MACE, and the SCAT have been posited as tools for assessing concussions in nonsport settings, but the evidence of their utility has been mixed. In a sample of 62 patients with a diagnosis of mTBI (Glasgow Coma Scale [GCS] score of 15 and a negative computed tomographic [CT] finding), Naunheim and colleagues[15] reported that serial SAC scores correlated with the Conner's Continuous Performance Test, 2nd edition, but was not associated with symptoms. The SAC has begun to be utilized as a screening tool in emergency departments (EDs) in the United States and internationally. Naunheim and colleagues[15] compared the SCAT and the MACE in 49 patients with concussion and 33 patients who were orthopedic controls and found that the SAC portion of the SCAT performed better than the MACE, with modest discriminatory power. Luoto and colleagues[16] studied the SCAT-2 and the MACE in a Finnish ED. Their study concluded that the SAC was useful for identifying cognitive impairment for refining prognosis and assessing recovery in the ED population.[16] Coldren and colleagues found that the MACE lacked sufficient sensitivity and specificity 12 hours or more postinjury in a deployed military population.[17] A recent study by Stone and colleagues[18] assessed the MACE in civilian trauma and concluded that it was a poor screening test in that heterogeneous adult civilian TBI population. However, 3 other studies demonstrated adequate sensitivity extending to 24 hours in civilian ED populations.[7,19,20]

In the ED setting, one of the most important considerations is the ability to discriminate between patients who are safe to be discharged home and those with intracranial hemorrhage (ICH), who are at risk for clinical deterioration, or who need neurosurgical intervention. ICH in patients with a concussion and GCS scores of 13 to 15 are not uncommon. Stiell and colleagues[21] reported that 8.5% of 2707 patients with GCS scores of 13 to 15 and 5.3% of 1822 patients with a GCS score of 15 were found to have "clinically important brain injury," including hemorrhage. Smits and colleagues[22] in a prospective study of 3181 patients found a 9.8% incidence of traumatic ICH. A study of a cohort of patients with mild head injury by Ibañez and colleagues[23] reported an incidence of acute intracranial lesions, including hemorrhage, of 7.5%. More concerning is the report by Thorson and colleagues,[24] who noted 30% of 360 patients with an initial CT positive for ICH went on to sustain progression of the ICH. They also noted that 32% to 59% of those patients who required operative intervention had no neurological decline concurrent with the worsening ICH on repeat CT scans, suggesting that clinical symptoms alone may not be sufficient to assess TBI.

O'Neil and colleagues[25] reported that 38% of patients suspected of having TBI with a CT+ scan in a multisite prospective clinical trial had a GCS score of 15 and a SAC score of 25 or higher. While the SAC is intended to be used as an indicator of concussion and not as a decision tool for CT referral, there is low suspicion that those who have a normal SAC score have sustained a brain injury. The current study evaluates the presence of CT+ findings in those patients with a normal SAC score. This study is a replication and extension of the O'Neil and colleagues[25] study in a large, independent sample of ED patients with a closed head injury.

METHODS

Subjects

The data were collected at 11 EDs across the United States, as part of a multisite study of TBI, which included standard clinical evaluations on intake to the ED and acquisition of an electroencephalogram (EEG). This cohort was extracted from a parent clinical trial.[26] This study was conducted in a convenience sample comprising subjects who sustained a head injury for whom CT scans were found to be positive (CT+) by a blinded independent adjudication panel of neuroimaging specialists and physician experts. Thus, the site determination of referral for CT (with or without the use of imaging guidelines) was not constrained, allowing results to generalize relative to standard clinical practice. Candidates for the study were recruited through a standardized informed consent process after having met the inclusion/exclusion criteria described in the following text (see Table 1).

Inclusion criteria

Candidates for the study included males and females between the ages of 18 to 85 years (the entire age range) who were admitted to the ED within the prior 72 hours and who sustained a closed head injury (ie, skull was intact). Subjects had a GCS score of 13 to 15 at the time of enrollment and were found to have a brain injury visible on the CT scan (CT+).

Exclusion criteria

Exclusion criteria included forehead, scalp, or skull abnormalities that might prevent proper application of the electrode set on the forehead. This was necessary due to the parent study requiring EEG acquisition. Subjects were excluded if they had a history of dementia, a known neurological or seizure disorder, a history of brain surgery, an evidence of acute psychosis, substance dependence, or a history of transient ischemic attack

TABLE 1 *Demographics/characteristics of participants*[a]

Feature	Value
Participants, *n*	191
Age, mean (SD) (range), y	52.9 (18.0-85.6) (20.4)
Sex, male/female, %	69.5/30.5
Time of injury to CT, mean (SD), h	15.1 (13.2)
SAC score, mean (SD) (range)	20.8 (5.2) (2-29)
Time of injury to SAC evaluation, mean (SD), h	24.5 (17.9)
CT+/SAC score ≥25 GCS, mean (range)	15.0 (all 15)
CT+/SAC score ≥25, *n* (%) all had GCS score = 15	46 (24)
CT+/SAC score ≥25, mean (SD)	26.4 (1.3)
CT+/SAC score <25, *n* (%)	145 (75.9)
CT+/SAC score <25 GCS, mean (range)	14.9 (13-15)
CT+/SAC score <25, mean (SD)	19.0 (4.7)

Abbreviations: CT, computed tomography; GSC: Glasgow Coma Scale; SAC: Standardized Assessment of Concussion.
[a]More than 1 finding may be attributed to each patient.

or stroke within the last year or if they were currently receiving dialysis, had an active fever defined as greater than 100°F or 37.7°C, or had sustained an open head injury. In addition, subjects were excluded if they were receiving advanced airway management (ie, mechanical ventilation) and/or sedative medications (eg, benzodiazepine, anesthetic, *N*-methyl-D-aspartic acid receptor antagonist, or opioid agonist), pregnant, or prisoners. It is noted that the exclusion criteria applied for the most part to the EEG data acquisition, which is not presented herein. Written informed consent was obtained from all subjects, or by legally authorized representative, and was approved by the respective local institutional review boards. The Conley test[27] was utilized to ensure the ability of the patient suspected of having TBI to understand the consent process in cases where the patient provided consent.

Clinical assessments

The Sports Concussion Assessment Tool–3rd Revision (SCAT-3) was administered on all enrolled patients within 72 hours of injury. The SCAT-3 incorporates the SAC,[6,8] which measures immediate recall, orientation, delayed recall, and concentration. A SAC with a low score indicates potential deficits in cognitive performance (scores range from 0 to 30). The *SAC Manual for Administration, Scoring and Interpretation (2000)* was used as a guideline and is based on a large population of healthy controls and athletes with concussion. The manual indicates that a cut point score of 25 yields maximum levels of sensitivity and specificity.[6] The GCS, a clinical assessment tool widely used to assess severity of brain injury in the acute setting, was utilized to rate patients on a score range of 3 to 15, where a score of 15 indicates normal function for the limited performance measures assessed. The SCAT-3 was only used for study purposes. No clinical decisions were made on the basis of the SCAT-3 score.

Marshall scoring of CT scans

CT scans were obtained at the discretion of the treating physician and were read by an independent adjudication panel of experts, who also rated the CT abnormalities using a Marshall score. The Marshall scoring system is used to rate the severity of a CT abnormality and is used to describe the combination of the volume of blood detected on the CT scan as well as the amount of any midline shift.[25,28] Scores range from I to IV, where a low score implies either no observable pathology (score of I, CT− finding) or a small focus of pathology is detected (score of II, CT+ finding). A score of III or IV suggests significant intracranial lesions that will likely require critical care and possibly neurosurgical intervention. The Marshall scale was utilized in this study by an independent neuroimage reading center blinded to any other findings.

Data analysis

After the total scores were calculated, subjects were divided into 2 groups, based upon whether their SAC scores of 25 or higher or less than 25. Additional details of the CT+ findings are also reported. A *t* test was used to evaluate the significance of the differences between the 2 groups. In specific cases, where the assumption of normal distribution could have been violated, the nonparametric Wilcoxon rank-sum test was performed in addition to the *t* test.

RESULTS

Subjects included 197 patients with a head injury who were adjudicated as CT+ based on blinded central neuroradiologist interpretation of CT DICOM images. These patients were the subset of the 691 patients with head injuries in the parent study who were found to be CT+. Image interpretation followed a rigorous and quantitative procedure involving sequential use of independent imaging specialists and physician specialist readers with image-based adjudication of discrepant readings and fully adjudicated unanimity for final determinations as CT+ truth.

Of the 197 patient images identified as CT+, 191 patients had SAC scores recorded; the remaining 6 subjects were therefore eliminated from further study. Positive CT scan findings included ICH and/or subdural hematoma (SDH) and/or epidural hematoma (EDH; $n = 73$; 38.2%), intraventricular hemorrhage (IVH) or IVH in combination with ICH and/or SDH and/or EDH ($n = 7$; 3.7%), subarachnoid hemorrhage (SAH; $n = 35$; 18.3%), SAH in combination with ICH and/or SDH and/or EDH ($n = 68$; 35.6%), IVH or IVH in combination with ICH and/or SDH and/or EDH and SAH ($n = 8$; 4.2% of population).

Note that contusions were captured in the intracerebral hemorrhage category. All major types of intracranial injury commonly associated with TBI and visible on CT scans (eg, SDH, EDH, SAH) were present in both SAC groups, and no significant predilections for certain causes were seen between SAC groups.

Sixty-nine percent of participants in the full sample were male, and the mean age of the sample was 52.9 years (range = 18.0-85.6 years, SD = 20.4 years). A significant age difference was observed between those with a SAC score of less than 25 (mean age = 55.9 years) and those with a SAC score of 25 or higher (mean age = 43.4 years; 2-sided t test, 2 sample with unequal variance, $t = 3.87$, $P = .0002$). The mean GCS score for the sample was 14.9. All patients in the group with a SAC score of 25 or higher had a GCS score of 15, and the mean GCS score for those with a SAC score of less than 25 was 14.9.

SAC score

The average SAC score in this sample was 20.77 (SD = 5.24; range, 2-29). Twenty-four percent (46/191) had SAC scores categorized as normal, 25 or higher points (mean = 26.39; SD = 1.34). In total, 75.9% (145/191) of patients had a SAC score of less than 25 (mean = 18.99; SD = 4.73). There was a negative correlation between the SAC score and age (slope = −1.11, $r = -0.28$, $P < .0001$).

The mean time between injury and SAC evaluation was 24.5 hours (SD = 17.85). No significant differences were found between the time of injury and SAC evaluation between the 2 groups (SAC ≥25 and SAC <25; Wilcoxon rank-sum test $P = .0998$). In total, 56.5% of subjects were scanned within 12 hours of injury and the mean time from injury to the CT scan was 15.1 hours (SD = 13.17). No significant difference was found in time from injury to the CT scan between the 2 groups (SAC ≥25 and SAC <25; Wilcoxon rank-sum test $P = .0993$).

CT+ scans and SAC scores

Sixty-five percent of subjects had Marshall scores of II (the lowest level of the Marshall system for CT+ scans). Twenty-eight percent of subjects had Marshall scores of III, and 7% of subjects had Marshall scores of greater than III ($n = 13$; 6.8%). The CT+ results for those subjects with SAC scores of 25 or higher included 25 SDHs, 18 SAHs, and 2 EDHs. This demonstrates that the CT abnormalities found in this group of patients were potentially life-threatening injuries.

DISCUSSION

Although the SAC was originally validated in young football athletes, it has been utilized in other sports as well as in EDs and military field settings. [5,7–11,16,18] In the present study, the SAC was used as part of a structured assessment of patients at enrollment. It is noted that the SAC score was not evaluated herein as an indicator of need for the CT scan, but rather as a metric to reflect the likelihood of suspicion of mTBI or concussion, as was done in earlier work by O'Neill and colleagues.[25]

In an earlier report, O'Neil and colleagues[25] reported that 37.9% (25/66) of CT+ patients with a mild head injury to have a SAC score of 25 or higher and a GCS score of 15. In both the O'Neil and colleagues and the present study, the populations studied were cohorts embedded in the larger parent studies. The only differences in inclusion criteria of the parent study were a greater GCS range in O'Neil and colleagues' study and the broadening of the time for performing the SAC assessment from 24 to 72 hours. As such, some differences were observed between the 2 studies, including differences in mean ages (46.7 and 52.9 years), difference in mean time from injury to CT (6.5 vs 15.1 hours), and time to SAC assessment (13.8 vs 24.5 hours). However, importantly, the data of this study replicated those of the prior work, independently supporting caution in interpreting a normal SAC score as an indication of no TBI, with a high percentage of CT+ patients with a mild head injury having a SAC score in the normal range.

Most of the patients in this study had CT scan abnormalities with a Marshall score in the lower range (II); however, there were 18 instances of SAH, 25 of SDH, and 2 of EDH. Although it is not the intention of the SAC score to identify the likelihood of CT+ injuries, these findings demonstrate that normal SAC scores are not an indication of the absence of brain injury. Since most prior SAC validation studies in student athletes did not incorporate CT imaging, it is unknown if ICHs were missed. This raises a major concern regarding the sensitivity of these screening tools on the sideline or initial assessment of the patient with a suspected concussion. The false-negative findings of these concussion screening tools could place certain populations at increased risk of secondary injury upon their return to activity or sports without having a more detailed assessment by a qualified healthcare provider.

One of the weaknesses and limitations of this study is that the time between injury, CT scan, and SAC evaluations was not controlled. Patients may have also been impaired by alcohol or drugs but were not consented until they were no longer obtunded. Effects of alcohol and drugs would be anticipated to lower the SAC and GCS scores, which in the case of the population of interest, which had a GCS score of 15 and a SAC score of 25 or higher, were not relevant. Another potential limitation relates to the fact that the parent study relied on each individual site to determine the referral for CT. Although the rationale for using standard of care as the sole criterion was to increase the generalizability of the findings, the use of a consistent protocol including use of CT decision rules might have added to the interpretability of these results.

In recent years, concerns regarding the overuse of CT scans, their long-term effects on health, and their cost have been a significant issue.[29–31] Reports from advanced neuroimaging studies reveal brain injury (eg, diffuse axonal injury) that is not visible on the CT scan, suggesting that the problem related to reliance on current assessment methods can be even more prevalent that reported in this study.

The results of this report replicating those of the O'Neil and colleagues study, combined with the rapidly advancing knowledge in the field, suggest that reliance on existing assessment methods in the prehospital and ED settings can and does lead to missed diagnoses.[25] It is incumbent upon us to develop more thorough and objective means of assessment of potential TBIs rapidly and at the point of care.

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