Despite the very low incidence of injury progression, neurosurgical management of mild traumatic brain injury (mTBI) at our center has historically consisted of routine repeat head CT imaging at a preordained interval (6–24 hours) with ICU-level monitoring including hourly neurological examinations. This protocol is derived from our management of patients with severe TBI, in whom the risk of serious deterioration is high and immediate recognition may have a profoundly positive influence on outcome. The Centers for Disease Control and Prevention (CDC; www.cdc.gov) estimates that approximately 75% of TBIs are defined as mild (i.e., mTBI). Use of an umbrella TBI protocol for both severe and mildly injured patients very likely results in unnecessary radiation exposure and overuse of hospital resources. Therefore, an opportunity exists to develop an improved mTBI management protocol that reduces patient radiation exposure and resource utilization.

There is a spectrum of sometimes conflicting published recommendations for appropriate clinical and radiographic surveillance of patients with mTBI, including, for example, advocacy of conservative use of repeat head CT scans and other imaging modalities, use of an ICU-level approach, and routine repeat imaging. Use of an umbrella TBI protocol for both severe and mildly injured patients very likely results in unnecessary radiation exposure and overuse of hospital resources. Therefore, an opportunity exists to develop an improved mTBI management protocol that reduces patient radiation exposure and resource utilization.

Objectives

Conventional management of patients with neurotrauma frequently consists of routine, repeat head CT at preordained intervals with ICU-level monitoring, regardless of injury severity. The Brain Injury Guidelines (BIG) are a classification tool for stratifying patients into injury severity and risk-of-progression categories based on presenting clinical and radiographic findings. In the present study, the authors aimed to validate BIG criteria at a single level 1 trauma center.

Methods

Patients were classified according to BIG criteria and evaluated for subsequent radiographic progression or development of neurological decline. A 2-year retrospective cohort review of consecutive patients with neurotrauma (n = 590) was undertaken. The authors then developed a modified BIG algorithm for use at their institution and followed its implementation prospectively over 555 consecutive patients.

Results

In the retrospective analysis, no patient in the BIG 1 category (n = 88, 14.9%) demonstrated progression or neurological decline, and 7.5% of BIG 2 patients (n = 107, 18.1%) demonstrated mild radiographic progression without any decline or need for additional neurosurgical or medical intervention, whereas 15.4% of BIG 3 patients (n = 395, 66.9%) underwent additional neurosurgical procedures. In the prospective analysis, no BIG 1 (n = 105, 18.9%) or BIG 2 (n = 48, 8.6%) patients demonstrated a clinical decline or required any further neurosurgical intervention. By contrast, 12.9% of BIG 3 patients (n = 402, 72%) required immediate neurosurgical intervention, and a further 2.0% required delayed intervention based on clinical and/or radiographic evidence of injury progression.

Conclusions

Application of the BIG criteria in a single large level 1 trauma center reliably sorted patients into appropriate risk categories that accurately guided ongoing management.
for routine reimaging of all patients. This inconsistency stems, in part, from a lack of consensus on the definition of “mild” TBI; patients are generally stratified using only one or a few broad criteria, such as presenting Glasgow Coma Scale (GCS) score or Injury Severity Score. Alone, either of these criteria fail to capture all clinically relevant variables and therefore fail to predict an individual patient’s risk of injury progression. For example, a patient on warfarin with an intracranial hemorrhage (ICH) presenting with a GCS score of 15 carries a significantly higher risk for progression than a similar patient with normal coagulation. It is not surprising, then, that the literature provides highly variable recommendations.

To accurately identify patients at low and high risk for injury progression, in 2014 Joseph et al. at the University of Arizona published Brain Injury Guidelines (BIG) stratifying 3 years of consecutive patients with neurotrauma at a single level 1 trauma center (n = 1232) into 3 categories of ascending severity and risk of progression based on clinical and radiographic findings. The BIG criteria are based largely on hemorrhage type and size, although presenting neurological examination and medical history are also weighted (using variables as determined by consensus opinion). Patients in the lowest risk category, BIG 1 (n = 121), did not develop any radiographic or clinical progression. Patients in the middle risk category, BIG 2 (n = 313), showed radiographic progression in only 2.6% of cases (n = 9) but in no case exhibited clinical decline nor required any change in neurosurgical management. Patients in the severe risk category, BIG 3 (n = 798), demonstrated radiographic progression 21.6% of the time, with 3% of BIG 3 patients requiring neurosurgical intervention based on radiographic findings. The overall reported rate for eventual neurosurgical intervention was 13% (n = 159).

Based on their findings, Joseph et al. derived a management algorithm in which patients in the BIG 1 category undergo 6 hours of observation without initial neurosurgical consultation, ICU admission, or repeat head CT imaging. BIG 2 patients are admitted to the hospital for observation without initial neurosurgical consultation or repeat head CT imaging. BIG 3 patients are admitted to an ICU with immediate neurosurgical consultation and interval CT imaging.

The present study was designed to evaluate the accuracy of BIG stratification in a single level 1 trauma center for predicting a risk of neurological deterioration and unplanned neurosurgical intervention, as well as to evaluate resource utilization savings from the implementation of the guidelines to replace an existing umbrella TBI clinical protocol. The initial study component was a retrospective validation of the BIG criteria performed using an independent neurotrauma population. The second component involved implementing modified and streamlined guidelines for prospective validation and evaluation of resource utilization using BIG stratification.

**Methods**

**Retrospective Study**

We performed a 2-year (October 2012–September 2014) retrospective cohort review of consecutive patients with neurotrauma admitted to our institution: a 576-bed, level 1 trauma center covering Oregon and southwest Washington, with additional referrals from Idaho, Montana, Alaska, and northern California. More than one-third of patients come from outside the local metropolitan area. Per institutional policy, all patients with neurotrauma are managed primarily by the trauma service, even in cases of isolated TBI. Similarly, outpatient follow-up is managed solely by the trauma service, unless otherwise specified by the neurosurgical team. Under our prior baseline protocol, patients with any (including trace) ICH noted on CT receive 1) a neurosurgery consult, 2) ICU admission, and 3) a repeat CT in 6 hours as a measure of injury stability. In cases of neurological decline, timing of the repeat scan is accelerated. Patients who exhibit a normal neurological examination with no radiographic progression of injury are transferred to a routine level of nursing care or discharged from the hospital after a 24-hour observation period in the ICU.

Because the institutional workflow generates a neurosurgery consultation for any acute traumatic intracranial imaging abnormality, we are able to capture all patients with a positive head CT (defined by the presence of ICH and/or a skull fracture) following trauma. Patients younger than 14 years of age (evaluated and managed separately by a pediatric trauma service) as well as those with imaging findings and history indicative of a cerebrovascular etiology (i.e., aneurysmal subarachnoid hemorrhage or hypertensive hemorrhage) were excluded. A total of 590 patients were included in the retrospective study, which was approved by the institutional review board with a waiver of authorization under Expedited Category # 5.

Each patient’s electronic medical record was reviewed for the following: demographic data (age, sex); history of coagulopathy (use of antiplatelet agents and/or anticoagulation, as well as thrombocytopoenia/pancytopenia and/or end-stage liver disease); mechanism of injury; presenting GCS score and findings of neurological examination; intoxication (blood alcohol content > 80 mg/dL, or positive urine drug screen); initial head CT findings (ICH type, location, and size); radiographic progression (defined by any increase of ICH on repeat head CT or worsening cerebral edema contributing to mass effect); presence or absence of clinical decline based on serial neurological examination; and need for additional neurosurgical intervention (e.g., ventriculostomy, intracranial pressure [ICP] monitor, and/or craniotomy/cranietomy).

All imaging (head CT) was reviewed by a single investigator for conformity in determining presence, type, and size of hemorrhage. Measurements were performed in millimeters. Epidural hematomas and subdural hematomas were measured by maximum width, whereas intraparenchymal hemorrhage was measured by maximum diameter along the largest axis. Traumatic subarachnoid hemorrhage was classified into 3 categories: “trace” (indicating involvement of only a single sulcus), “localized” (involvement of 2–3 adjacent sulci), or “scattered/diffuse.”

Patients were classified into the appropriate BIG category by using the established criteria. In brief, the BIG classification stratifies patients by severity of injury by accounting for presenting GCS score, antiplatelet/anti-
coagulation status, and radiographic parameters such as hematoma size and location. If patients failed to meet any of the BIG criteria in one group, they were automatically upgraded to the next highest severity level. Primary outcome measures were as follows: 1) interval progression on repeat imaging, 2) patient neurological decline, and 3) occurrence of neurosurgical intervention following repeat head CT.

Given that the BIG criteria were developed based on the institutional consensus opinion of Joseph et al.’s group, we developed a modified BIG (mBIG) algorithm (Table 1) in an attempt to streamline implementation at our institution. In the original BIG algorithm proposed by Joseph et al., variables such as “loss of consciousness” and “intoxication” did not influence stratification and were deemed unnecessary to the successful implementation of our protocol. Given that nondisplaced skull fractures are routinely managed conservatively at our institution, we allowed these to be de-escalated to BIG 1 provided they met all other criteria. Although the original study did not address the classification of patients with nonpharmacological coagulopathies (e.g., cirrhosis, thrombocytopenia, etc.), we considered these patients to have received anticoagulation therapy, and they were automatically upgraded to the BIG 3 category in the modified algorithm. The original algorithm specifies that any “abnormal” neurological examination be stratified to BIG 3—we clarified this in our protocol by substituting GCS score, which allows patients with nonlocalizing confusion (e.g., E4V4M6) or lethargy (e.g., E3V5M6) to be stratified to BIG 1, and those with more significant neurological findings to be upgraded.

**Prospective Study**

After completing the retrospective review, we implemented the mBIG criteria (Table 1) beginning in June 2016 and collected prospective data in order to validate these criteria. The standard institutional neurotrauma workflow remained the same, with all positive head CT imaging in patients with trauma generating a neurosurgical consultation, but with modified consultation recommendations and subsequent management: BIG 3 category patients were admitted to the ICU and received a repeat head CT after a 6-hour interval, BIG 2 category patients were admitted to the ICU for 24 hours of close observation without imaging, and BIG 3 category patients were observed for 23 hours on a regular nursing ward or in the emergency department. All patients received a repeat head CT for any clinical neurological change regardless of BIG category, and all patients continued to be followed and examined by the neurosurgery service for the duration of their protocol-guided observation or, if a neurological decline had occurred, until they became clinically stable.

We identified and included 555 consecutive patients in the prospective study. The altered patient care protocol based on the mBIG clinical and imaging stratification was implemented by the institutional trauma program as a quality improvement initiative. Prospective data collection for the purposes of this study was again approved by the institutional review board with a waiver of patient consent. Patient medical records and imaging were reviewed by the on-call neurosurgeon at the time of consultation and re-

<table>
<thead>
<tr>
<th>Table 1: Institutional modified Brain Injury Guidelines</th>
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<tbody>
<tr>
<td><strong>Institutional modified Brain Injury Guidelines 1</strong></td>
</tr>
<tr>
<td><strong>Glasgow Coma Scale</strong></td>
</tr>
<tr>
<td>≤12</td>
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<tr>
<td><strong>Institutional modified Brain Injury Guidelines 2</strong></td>
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<tr>
<td><strong>Glasgow Coma Scale</strong></td>
</tr>
<tr>
<td>14–15</td>
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<tr>
<td><strong>Institutional modified Brain Injury Guidelines 3</strong></td>
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<tr>
<td><strong>Glasgow Coma Scale</strong></td>
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<td>≤12</td>
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reviewed by 2 investigators to identify protocol failures. We recorded patient demographics (age, sex), history of coagulopathy (use of antiplatelets or anticoagulation, as well as thrombocytopenia/pancytopenia and/or end-stage liver disease), mechanism of injury, presenting GCS score and initial BIG stratification. We noted any initial neurosurgical interventions indicated by these findings (e.g., ventriculostomy, ICP monitor, and/or craniotomy/craniectomy). We then followed patients for radiographic progression (defined by any increase of ICH on repeat head CT or worsening cerebral edema contributing to mass effect), presence or absence of clinical decline based on serial neurological examination, and/or occurrence of additional neurosurgical intervention. We recorded all deaths during the initial hospitalization.

**Results**

**Retrospective Analysis**

A total of 590 patients were identified and included in the retrospective study. A summary of patient demographics is presented in Table 2; 67.9% were male, and the mean age overall was 54.6 ± 22.3 years (mean ± SD). Coagulation was compromised in 28.4% of reviewed patients; warfarin, aspirin, or clopidogrel use were the most common causes. The most common causes of injury were ground-level falls (30.3%) and motor vehicle collisions (20.7%). Less frequent causes included pedestrian–auto collisions, falling down stairs, and being “found down” with clinical signs of trauma.

**BIG criteria stratification** was as follows: 88 (14.9%) patients in BIG 1, 107 (18.1%) patients in BIG 2, and 395 (66.9%) patients in BIG 3 (Table 3). This proportion of patients falling into the BIG 3 category is similar to that observed at the University of Arizona. Of the patients in this group, one hundred fifty-five BIG 3 category patients (39.2%) demonstrated radiographic progression, of whom 61 underwent procedural intervention due to new findings. In patients whose classification was changed to BIG 1 under the institutional modifications, 5 (4.5%) had radiographic progression without neurological decline (2 from the BIG 3 and 3 from the BIG 2 category).

**Prospective Analysis**

A total of 555 patients were included in the prospective study from June 2016 through August 2017. Of the prospective cohort, 64.3% were male, and the mean age was 56.7 ± 22.3 years (mean ± SD). Coagulation was compromised in 31.6% of patients with aspirin as the most common cause, followed by warfarin and clopidogrel. Ground-level falls represented the most common mechanism of injury (33.4%), with other common causes including motor vehicle and motorcycle collisions, falls down stairs or from a height, pedestrian–auto collisions, and being “found down” with clinical signs of trauma.

Each patient was stratified to an institutional mBIG category at the time of initial neurosurgical consultation. Overall, 105 patients (18.9%) met BIG 1 criteria, 48 patients (8.6%) met BIG 2, and the remaining 402 patients (72.4%) met BIG 3 criteria. Thus, a slightly higher proportion of patients was stratified into BIG 3 than in the retrospective analysis or the University of Arizona study.

No BIG 1 category patient demonstrated clinical neurological decline during the observation period. Due to protocol failures, 12 patients in the BIG 1 category (11%) received repeat head imaging, none of which demonstrated radiographic progression. Among BIG 2 category patients, none experienced a clinical neurological decline during the observation period. Thirteen patients in the BIG 2 category were reimaged (12 due to protocol failures, 1 requested by another service for facial fracture evaluation), of whom 4 demonstrated radiographic progression without clinical correlate or intervention. Fifty-two BIG 3 category patients (12.9%) underwent neurosurgical intervention based on the findings of their admission CT, including ICP monitor or external ventricular drain placement, craniotomy, and/or decompressive craniectomy. One hundred five additional BIG 3 category patients demonstrated radiographic progression on repeat head CT (30% of patients without immediate intervention, 26.1% of all BIG 3 category patients). Twenty-one patients with radiographic progression also experienced an accompanying neurological decline (6% of patients without immediate intervention, 5.2% of all BIG 3 category patients). Eight of these with radiographic progression underwent additional surgi-
TABLE 3. Institutional patients stratified by BIG criteria

<table>
<thead>
<tr>
<th>Criterion</th>
<th>BIG 1, n = 88</th>
<th>mBIG 1, n = 110</th>
<th>BIG 2, n = 107</th>
<th>BIG 3, n = 395</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT progression (no., %)</td>
<td>0 (4.5)</td>
<td>5 (7.5)</td>
<td>8 (7.5)</td>
<td>155 (39.2)</td>
</tr>
<tr>
<td>Neurological decline</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Procedural intervention (no., %)</td>
<td>0 (15.4)</td>
<td>0 (15.4)</td>
<td>0 (15.4)</td>
<td>61 (15.4)</td>
</tr>
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</table>

Discussion

With the development of any guidelines, external validation provides evidence in favor of application to a broader set of patients. We applied the original BIG criteria to an independent single-center neurotrauma population at an institution with a different set of baseline characteristics (age, mechanisms of injury, proportion of patients on anticoagulation, etc.) from patients in the original Arizona study. Despite the natural variances between the two patient populations, the proportion of BIG 3 category patients was very similar in the two studies. In the prospective study, the institutional mBIG criteria slightly enlarged the proportion of patients assigned to BIG 3. This could be attributable to historical bias, with the physicians tasked with implementing the prospective protocol being more inclined to over-stratify patients. Nevertheless, no patients in the institutional mBIG 1 or 2 categories experienced a clinical neurological decline or underwent further neurosurgical intervention. Using the institutional criteria, the approximately one-quarter of patients in the lower-severity categories again showed very low risk for progression and no observed risk for additional surgical or aggressive medical intervention.

Initiating the institutional BIG project with a retrospective analysis of previous patients, without changing care protocols, allowed validation within the local trauma system and refinement of the original BIG criteria based on institutional data. In addition, the preliminary institution-based data gave confidence to both general and neurological surgeons in the trauma system for a second-phase intervention in which patient management was directly altered based on the admission modified institutional BIG criteria classification of each patient. Another modification chosen to fit institutional culture was to continue routine neurosurgical consultation for all patients, including those categorized to BIG 1 and 2, while managing their care in lower-intensity settings and/or without routine reimaging.

BIG criteria identify patients with injuries that are both of low severity and at low risk for progression. The criteria are biased toward safety-oriented management; any single parameter observed leads to upgrade to a higher risk category. In the BIG 1 and 2 categories, clinical parameters are important markers of injury severity; only patients with a presenting GCS score of 14 or 15 are eligible for BIG 1 classification. BIG is also relatively simple and easy to introduce and use accurately. We observed a misclassification rate of only 1.6% in the prospective analysis of BIG as a new clinical tool in the institutional trauma system. The majority of protocol failures resulted in unnecessary repeat imaging and there were no misclassification-related patient harms. We expect that as providers in our institution become more familiar with the BIG criteria this very small error rate will decrease further.

BIG criteria do not serve as the sole determinant of trauma patient management, being trumped, for example, by considerations related to polytrauma. BIG was designed only for isolated, acute cranial neurotrauma. Nor is BIG eloquent as to indications for outpatient follow-up or postdischarge imaging.

We were able to observe meaningful resource savings after implementation of the BIG protocol. Using institutional mBIG criteria in the prospective portion of this study, we avoided 30% of repeat head CT imaging and 15% of ICU admissions in a large population of patients with isolated cranial neurotrauma. Additional efficiencies accrued from critical care and radiology professional services savings and reduced transport needs. In a hospital with a very high average census such as our institution, considerable benefit occurred by freeing ICU beds for other injured patients, helping to avoid system delays or diversions. Trauma ICU nurses informally but repeatedly reported work satisfaction by avoiding off-unit travel for their least severely injured patients.

Average hospital charges were $99,098 per admission in the retrospective cohort versus $68,104 in the prospective cohort, equivalent to a 31.3% reduction in overall cost of care per patient. This reduction is probably confounded by comorbidities and other costs of care, which may be dissimilar in the two groups, but does suggest a substantial potential cost savings.

Finally, a substantial subset of patients was exposed to less diagnostic radiation. The lifetime attributable risk of...
cancer for a single head CT is 0.23 cases per 1000 patients as reported in a large series. Our prospective study prevented 148 head CT scans over 13 months; at an annualized rate, we could expect our BIG implementation to prevent 1 case of radiation-induced cancer over a 31-year period.

Analysis of the data in this study was limited by its retrospective nature, particularly because maximal care was provided to all patients in that cohort, perhaps masking potential criteria failure. This consideration was a principal driver of continuing on to study the prospective cohort. There remains, however, the possibility of unconscious bias toward maximizing the care of neurotrauma patients even after they are reasonably stratified into the BIG 1 or BIG 2 categories, given a strong institutional history and culture of treating every patient with a level of care closer to that required by BIG 3.

Conclusions

The BIG criteria neurotrauma initiative at our institution successfully reduced the incidence of repeat head CT imaging and ICU admission for patients with isolated cranial neurotrauma without resulting in any protocol-related delay in treatment or neurological morbidity. Previously published BIG criteria were tested using retrospective institutional data and modified to fit both these data and institutional care priorities. Subsequent prospective implementation and evaluation of the institutional mBIG criteria revealed significant care system improvements and a greater than 98% protocol adherence. Recursive study and implementation of care protocol improvements in neurotrauma offers the possibility of both improved care and resource savings in trauma systems that are challenged to deliver the best care possible to high volumes of injured patients.

Acknowledgments

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References


Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions

Conception and design: Cetas, Pang. Acquisition of data: Ross, Pang. Analysis and interpretation of data: Cetas, Ross, Pang, Raslan. Drafting the article: all authors. Critically revising the article: Cetas, Ross, Raslan, Selden. Reviewed submitted version of manuscript: Cetas, Ross, Raslan, Selden. Approved the final version of the manuscript on behalf of all authors: Cetas.

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