Developing a Decision Instrument to Guide Computed Tomographic Imaging of Blunt Head Injury Patients

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Background: Computed tomographic (CT) head scanning of blunt trauma patients is expensive, delays care, and necessitates radiation exposure, while detecting intracranial injuries in a minority of patients. Clinical characteristics may be able reliably identify patients who do not have intracranial injuries and consequently, do no require imaging.

Methods: Physicians assessed blunt trauma patients undergoing imaging for the presence or absence of specific criteria. Recursive partitioning was used to identify criteria that predict intracranial injuries with high sensitivity.

Results: Intracranial injuries were found in 917 of 13,728 enrolled patients (6.7%). Injuries were rare among patients under age 65 who had no evidence of skull fracture, scalp hematoma, neurologic deficit, abnormal alertness, abnormal behavior, coagulopathy, or persistent vomiting. These characteristics would have identified 901 injury cases (sensitivity 98.3% [CI: 97.2–99.0]), while classifying 1,752 patients (12.8%) as “low risk.”

Conclusions: Clinical characteristics can reliably identify patients who are unlikely to have intracranial injuries and who do not require CT imaging.


Unrecognized intracranial injury can produce permanent brain damage, severe disability, and even death. Reports of “occult” injuries among patients with benign clinical presentations have led many clinicians to obtain imaging on virtually all blunt head trauma patients. Consequently, nearly one million blunt trauma patients undergo head CT imaging annually in the U.S., but fewer than 60,000 (about 6%) prove to have significant intracranial injuries.

Recent work suggests that a clinical decision instrument could be developed to identify reliably blunt head trauma patients who have essentially no risk of significant brain injury. The use of such an instrument could reduce CT imaging and decrease radiographic charges, time in the ED, and radiation exposure among blunt trauma patients.

In an attempt to derive such a decision instrument, we conducted this prospective study of blunt head trauma patients.

PATIENTS AND METHODS

Our methodology (NEXUS-II), a multi-center, prospective, observational study, has been described in detail elsewhere. Briefly, NEXUS-II enrolled all blunt trauma patients for whom head CT scanning was ordered by the managing physician in 21 participating centers. Study participants represent a variety of facilities and were selected to increase the study’s generalizability to the majority of trauma victims evaluated in North American EDs.

Study Subjects

The study population consisted of all acute blunt head trauma victims undergoing CT head imaging at participating centers. Patients with a delayed presentation or without blunt trauma were excluded. Clinicians made imaging decisions based on their clinical judgment and not by study protocol.

Data Collection

Patients were enrolled when a physician ordered CT imaging. To maximize compliance, participating institutions agreed to adopt a rigid protocol, described in detail elsewhere, whereby CT scanning would not be performed until study data had been collected and recorded.

Data Collected

Upon enrollment, clinicians collected limited demographic information (date and time of evaluation, age, sex, and race), documented the presence or absence of each candidate variable (Table 1), and assessed each patient’s Glasgow Coma Scale (GCS) score. Candidate variables were drawn from among those previously found to be reliably assessable in the clinical environment.
Table 1 Physician Instructions, Guidelines and Medical Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal behavior</td>
<td>An inappropriate action displayed by the victim. It includes such things as excessive agitation, inconsolability, refusal to cooperate, lack of affective response to questions or events, and violent activity.</td>
</tr>
<tr>
<td>Abnormal level of alertness</td>
<td>Is evidenced by a variety of findings, including but not limited to a Glasgow coma score of 14 or less; delayed or inappropriate response to external stimuli; excessive somnolence; disorientation to person, place, time or events; inability to remember three objects at five minutes; perseverating speech; and other findings.</td>
</tr>
<tr>
<td>Significant skull fracture</td>
<td>Includes, but is not limited to, any signs of basilar skull fracture (peri-orbital or peri-auricular ecchymoses, hemotympanum, and drainage of clear fluid from the ears or nose). Signs of depressed or diastatic skull fracture (a palpable step-off of the skull, a stellate laceration from a point source, or any injury produced by an object striking a localized region of the skull [such as a baseball bat, club, pool cue, golf-ball, baseball, pipe, etc.]).</td>
</tr>
<tr>
<td>High-risk vomiting</td>
<td>Is evidenced by recurrent, projectile or forceful emesis (either observed or by history) after trauma, or vomiting associated with altered sensorium.</td>
</tr>
<tr>
<td>Evidence of intoxication</td>
<td>Includes: a) a history of intoxication or recent intoxicating ingestion is provided by a patient or observer; b) test of bodily secretions (blood, urine, saliva, breath, etc) is positive for drugs or alcohol; c) patient has physical evidence suggesting intoxication (odor of alcohol, slurred speech, ataxia, dysmetria or other cerebellar findings), or behavior consistent with intoxication and unexplained by medical or psychiatric illness.</td>
</tr>
<tr>
<td>A motor deficit</td>
<td>Is a finding of abnormal weakness in any one or more of the four extremities, as determined by systematic testing of muscle strength in all four limbs.</td>
</tr>
<tr>
<td>Gait abnormality</td>
<td>Is the inability to walk normally due to inadequate strength, loss of balance or ataxia; it is determined by systematic testing of gait, including tandem and heel-toe walking, and Romberg testing.</td>
</tr>
<tr>
<td>Cerebellar abnormality</td>
<td>Is manifested by ataxia, dysmetria, dysdiadokinesis, or other impairment of cerebellar function; it is determined by systematic testing of cerebellar function, including tests of ataxia, and finger-nose-finger, heel-to-shin, and rapid alternating movement testing.</td>
</tr>
<tr>
<td>Cranial nerve abnormality</td>
<td>Is an abnormality of cranial nerves II-XII; it is determined by systematic testing of each of these cranial nerves. The ability to read and write is determined by asking the patient to read the physician's name from an identifying badge, or a written piece of paper, and subsequent ability to write that same name.</td>
</tr>
<tr>
<td>Age 65 years or more</td>
<td>Is determined by available clinical history.</td>
</tr>
<tr>
<td>Neurologic deficit</td>
<td>Was considered to be present if a patient exhibited an abnormal Glasgow Coma Scale score, motor deficit, gait abnormality, abnormal cerebellar function, or cranial nerve abnormality (patients were deemed to have a “neurologic deficit” if any constituent variables were abnormal, and were considered “normal” only if all constituent variables were normal).</td>
</tr>
</tbody>
</table>

A composite variable, “neurologic deficit,” was constructed by combining the elements of the Glasgow Coma Scale score with the presence or absence of motor deficit, gait abnormality, abnormal cerebellar function, and cranial nerve abnormality. Patients were considered to have a ‘neurologic deficit’ if any of constituent variables were abnormal, and were considered “normal” only if all constituent variables were normal.
necessary. CT scans were interpreted by clinical radiologists at each site. Copies of all final radiographic readings were collected and abstracted to determine the presence or absence of intracranial injuries. The diagnosis of intracranial injury was based solely on final radiologic interpretations of all imaging studies, including subsequent inpatient studies. Investigators determined final injury classification while blinded to information about clinical variables (and thus to the patient’s classification by possible decision instruments).

The definition of significant intracranial injury was based on outcomes documented in previous clinical work, and consists of any injury that may require neurosurgical intervention (craniotomy, intracranial pressure monitoring, mechanical ventilation), or lead to rapid deterioration or significant long-term neurologic impairment.

**Intracranial Injuries Considered Significant:**
- Mass effect or sulcal effacement
- Signs of herniation
- Basal cistern compression or midline shift
- Substantial epidural or subdural hematomas (greater than 1.0 cm in width, or causing mass effect)
- Substantial cerebral contusion (more than 1.0 cm in diameter, or more than one site)
- Extensive subarachnoid hemorrhage
- Hemorrhage in the posterior fossa
- Intraventricular hemorrhage
- Bilateral hemorrhage of any type
- Depressed or diastatic skull fracture
- Pneumocephalus
- Diffuse cerebral edema
- Diffuse axonal injury

**Data Analysis**

Data from clinical evaluations were merged with head CT scan results to form the final derivation data set. Cases lacking radiographic reports were deleted from the final data analysis.

**Formulation of the Optimal Decision Instrument**

We used $\chi^2$ recursive partitioning to evaluate the importance of individual criteria, and to identify combinations of criteria that could be used to form tentative decision instruments that predicted intracranial injuries with high sensitivity and excluded intracranial injuries with high negative predictive value. We calculated the specificity of each tentative instrument, and defined the instrument exhibiting the highest specificity as the “optimal” decision instrument. By design, this optimal instrument has very high sensitivity and NPV, and the highest possible specificity. We employed exact methods to determine the confidence intervals associated with each operator characteristic (sensitivity, NPV and specificity). Operator characteristics were calculated for the performance of the instrument among all blunt head injury victims, while separate calculations were made to determine the performance among patients with “minor” head injury (defined as a cases presenting with GCS scores of 15).

**Assessing Potential for Bias**

Because we enrolled only patients who underwent CT imaging and did not verify injury status among un-imaged patients, our methodology is vulnerable to “verification” bias. To assess the potential for verification bias, we conducted three-month follow-up interviews with all blunt trauma patients presenting to our core facility who did not undergo CT imaging. Each patient (or a surrogate family member) was asked whether they had eventually undergone radiographic imaging, been diagnosed with intracranial injuries, or ultimately required neurosurgical intervention.

**Patient Consent**

NEXUS-II was an observational study that did not mandate or direct any aspect of patient care and posed no risk to patients. The study protocols, methodology and request for waiver of informed consent were reviewed and approved by the Federal Office for the Protection from Research Risks, as well as by the institutional review board at each site. Waivers of informed consent were granted to each participating institution.

**Results**

In total, we enrolled 13,728 patients in the study, including 917 patients diagnosed with clinically important intracranial injuries. This latter group included 330 patients who presented with minor head injuries. The median age of the blunt head trauma population was 37 years (inter-quartile range [IQR]: 23 – 52); the median age of those with clinically important intracranial injuries was 40 (IQR: 22 – 62) and the median age for minor head injury victims with intracranial injuries was 41 (IQR: 24 – 58).

The ethnic distribution of the overall population included 6,912 Whites (50%), 2,418 Blacks (18%), 1,985 Hispanics (15%), 330 Asians (2%), 99 Middle Easterners (1%), 157 Native Americans (1%), and 1,827 others (13%). There were 8,988 males (66%) and 4,718 females (34%); gender was not recorded in 22 patients (0.2%).

The 917 patients with clinically important intracranial injuries included 528 Whites (58%), 118 Blacks (13%), 114 Hispanics (12%), 29 Asians (3%), 3 Middle Easterners (0.3%), 5 Native Americans (0.5%), and 120 others (13%). This population included 656 males (72%), 260 females (28%), and 1 individual of unknown gender (0.1%).

Table 2 presents the prevalence of the individual criteria in patients with and without intracranial injuries. Among all patients, loss of consciousness, noted in 48%, was the most frequently observed criterion, while only a small proportion of subjects presented with evidence of significant skull fracture (4%). Among patients with intracranial injuries, neurologic deficit was the most frequently observed criterion (noted in 65% of such patients), while seizure and coagu-
Intracranial injuries were much more likely to present with evidence of significant skull fracture (21% versus 3%). Recursive partitioning identified eight criteria that were independently and highly associated with intracranial injuries. These include: 1) evidence of significant skull fracture, 2) scalp hematoma, 3) neurologic deficit, 4) altered level of alertness, 5) abnormal behavior, 6) coagulopathy, 7) persistent vomiting, and 8) age 65 years or more. The remaining variables failed to show a significant association with intracranial injuries under any partitioning scheme.

A decision instrument based on these eight criteria correctly identified 901 of the 917 patients with clinically important intracranial injuries (sensitivity 98.3% [CI: 97.2–99.0]), while classifying 1,752 patients as “low risk” (negative predictive value [NPV] 99.1% [CI: 98.5–99.5]). Specificity was 13.7% [CI: 13.1–14.3]. Table 3 describes the patients and injuries that would have been missed by this combination of criteria. Most of these “false negative” patients had relatively minor injuries, and while most were admitted for observation, only one required immediate neurosurgical intervention (ICP monitoring).

Among patients with minor head injury, the decision instrument correctly identified 314 of 330 with clinically important intracranial injuries, while correctly classifying 1,752 as “low risk” (sensitivity 95.2% [CI: 92.2–97.2], NPV 99.1% [CI: 98.5–99.5], and specificity 17.3% [CI: 16.5–18.0]).

Several other decision instruments were constructed, which had slightly less useful test characteristics (Table 4). In each case, these alternate combinations of clinical variables could not achieve equivalent sensitivity without further sacrificing specificity.

We identified 2,397 patients who had sustained blunt head trauma, but did not undergo emergent head imaging, including 1,266 patients (52.8%) who agreed to participate in the long-term outcome study. CT scanning was ultimately performed in 27 of these patients (2.1%), magnetic resonance imaging in 29 (2.3%), and skull radiography in 14 (1.1%). No significant intracranial injuries were found in any of these patients. There were no cases of missed intracranial injuries among the follow-up cohort, no subsequent hospitalizations or neurosurgical interventions to treat intracranial injuries, and no deaths due to intracranial injuries.

**DISCUSSION**

Decision instruments are frequently used to screen patients for radiographic imaging. An ideal instrument recommends imaging for all patients who have a significant injury (high sensitivity), guarantees that injury is absent in patients not selected for imaging (high NPV), and limits imaging among patients who do not have injury (high specificity). To be clinically useful, however, such an instrument must also

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**Table 2** Prevalence of Individual Criteria among Blunt Head Injury Patients

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Age (yrs)</th>
<th>Race/Sex</th>
<th>Injuries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seizure</td>
<td>4%</td>
<td>White/male</td>
<td>Small subdural hematoma in the middle cranial fossa. Small amount of subarachnoid blood.</td>
</tr>
<tr>
<td>Loss of consciousness</td>
<td>48%</td>
<td>White/male</td>
<td>Hemorrhage in the left frontal base, probably a combination of epidural and parenchymal hemorrhages. Siver of subdural hemorrhage in the left anterior convexity.</td>
</tr>
<tr>
<td>Prolonged loss of consciousness</td>
<td>8%</td>
<td>Other/female</td>
<td>High left medial parietal convexity parafalcine focus of contusion.</td>
</tr>
<tr>
<td>Severe headache</td>
<td>17%</td>
<td>48</td>
<td>White/male</td>
</tr>
<tr>
<td>Coagulopathy</td>
<td>4%</td>
<td>Black/male</td>
<td>Diffuse edematous changes within the cerebral hemispheres bilaterally slightly greater on the left than the right.</td>
</tr>
<tr>
<td>Abnormal behavior</td>
<td>22%</td>
<td>White/female</td>
<td>Subdural/subarachnoid hemorrhage with dilated lateral and third ventricles and sulcal effacement.</td>
</tr>
<tr>
<td>Abnormal level of alertness</td>
<td>28%</td>
<td>White/male</td>
<td>Occipital skull fracture with small right occipital collection that is epidural or subdural blood.</td>
</tr>
<tr>
<td>Significant skull fracture</td>
<td>4%</td>
<td>White/white</td>
<td>Comminuted left temporal bone fracture with subjacent air.</td>
</tr>
<tr>
<td>Persistent vomiting</td>
<td>6%</td>
<td>White/male</td>
<td>Comminuted, depressed fracture, frontal bone, with subjacent right frontal lobe contusion and pneumocephalus.</td>
</tr>
<tr>
<td>Evidence of intoxication</td>
<td>24%</td>
<td>White/male</td>
<td>Frontal sinus fracture with air and probable blood near the anterior left falx, just posterior to the frontal bone.</td>
</tr>
<tr>
<td>Inability to read/write</td>
<td>6%</td>
<td>White/male</td>
<td>Small focus of hemorrhage in the right frontal lobe deep white matter</td>
</tr>
<tr>
<td>Scalp hematoma</td>
<td>33%</td>
<td>White/male</td>
<td>Right subdural hematoma.</td>
</tr>
<tr>
<td>Extreme age</td>
<td>14%</td>
<td>22</td>
<td>White/male</td>
</tr>
<tr>
<td>Neurological deficit</td>
<td>28%</td>
<td>19</td>
<td>White/male</td>
</tr>
<tr>
<td>Number 4</td>
<td>957</td>
<td>8</td>
<td>Black/male</td>
</tr>
<tr>
<td>Number 4</td>
<td>957</td>
<td>7</td>
<td>Other/female</td>
</tr>
</tbody>
</table>
offer some advantage over clinical judgment in selecting patients for imaging.

The decision instrument developed in this study includes eight criteria, and may at first glance appear somewhat cumbersome. However, it has excellent construct validity, and suggests that intracranial injuries are rare in patients under age 65 who do not exhibit signs of significant trauma to the calvarium (as manifested by evidence of skull fracture or scalp hematoma), neurologic dysfunction (including focal neurologic deficits, altered level of alertness, or abnormal behavior), persistent vomiting, or coagulopathy. A decision instrument based on these criteria would have identified nearly all of the patients with intracranial injuries in this study, and would have produced a modest decrease in CT imaging. We were unable to identify any other set of variables that performed as well or better.

Our findings also suggest that clinicians are already adept at identifying patients who require CT head imaging, and it appears that any decision instrument is likely to provide only marginal benefit over current clinical practice. Instruments exhibiting higher sensitivity inevitably suffer from poorer specificity and are less efficient at limiting imaging, while instruments that could significantly reduce imaging do so at the cost of unacceptable rates of missed injury.

Many previous efforts to develop screening tools for traumatic brain injury have had difficulty attaining the sensitivity required for clinical application. In contrast, instruments recently developed by Haydel and Stiell exhibit adequate sensitivity, but suffer in other ways that limit their utility. First, both instruments apply only to patients who have sustained loss of consciousness (while Stiell also enrolled patients with amnesia and disorientation, these criteria were subsequently found to exclude patients from low-risk classification), and neither provides guidance for patients who have not lost consciousness. Second, these instruments used surrogate markers, rather than validated clinical measures, to determine patient outcomes, limiting the clinical relevance of the final rule. Furthermore, the rule developed by Haydel mandates imaging for all patients with evidence of trauma above the clavicles, including those with small contusions, abrasions, lacerations and minor facial injuries.

While this criterion helps to ensure adequate sensitivity, it requires imaging for many patients who would otherwise be cleared on the basis of clinical judgment, and is likely to result in increased imaging at many centers.

Clinical decision instruments are unlikely to be used if they are complex or cumbersome. The rule proposed by Stiell is very complex, and it also requires close observation of head trauma patients for two hours before they can be judged low-risk. Such a period of observation is likely to prove difficult in busy trauma centers; in addition, it might lead to harm for that patient who fails to improve during this period, and is found on subsequent CT to have a lesion requiring neurosurgery. Consequently, we suspect many clinicians would abandon this rule in favor of clinical judgment, or worse, rote imaging.

Several factors must be considered in assessing the benefits of a decision instrument over clinical judgment. Reduced imaging decreases radiographic charges, ED waiting times, and exposure to potentially dangerous ionizing radiation. Decision instruments may also offer other less quantifiable benefits, including the ability to standardize care and inform medicolegal practice. However, the use of a decision instrument is not without cost. If the instrument in this study is validated, it would be expected to miss approximately 1.7% of cases with “clinically important” intracranial injuries. Virtually all such missed injuries, however, are relatively minor and should not result in serious immediate consequence. Few of these patients require hospitalization or neurosurgical intervention, but all require careful instructions regarding signs and symptoms that could indicate the need for additional evaluation. Such “head injury precautions” should be expected to further reduce the possibility of a serious adverse outcome among patients considered to be “low-risk,” in whom an initial CT scan would not be done. Follow-up for such patients is important even in the absence of this concern, because post-traumatic sequelae occur in many head injury patients, so the “safety net” of careful follow-up does not represent an additional requirement mandated by use of this instrument.

Since our study enrolled only individuals who underwent imaging, this instrument would almost certainly exhibit higher specificity when applied to the population of all blunt head trauma patients. This is because clinicians are more likely to omit imaging among patients who do not exhibit worrisome clinical findings, such as our criteria. At the same time, our study included only individuals who underwent imaging, and thus the instrument may offer lower sensitivity when applied to the population of all blunt head trauma patients. In addition, the instrument may offer lower specificity when applied to the population of all blunt head trauma patients, as it is unlikely that the instrument would have been used in a manner consistent with the criteria it was developed to use. Consequently, the instrument may offer lower specificity when applied to the population of all blunt head trauma patients, as it is unlikely that the instrument would have been used in a manner consistent with the criteria it was developed to use.

### Table 4: Operator Characteristics of Alternate Decision Rules Formed By Adding Additional Elements to the Optimal Combination of Criteria

<table>
<thead>
<tr>
<th>Additional Element(s)</th>
<th>Sensitivity</th>
<th>NPV</th>
<th>Specificity</th>
<th>PPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seizure</td>
<td>98.5 (97.5–99.2)</td>
<td>99.1 (98.5–99.5)</td>
<td>12.3 (11.8–12.9)</td>
<td>7.5 (7.0–8.0)</td>
</tr>
<tr>
<td>Loss of consciousness</td>
<td>99.3 (98.6–99.8)</td>
<td>99.0 (97.8–99.6)</td>
<td>4.5 (4.2–4.9)</td>
<td>6.9 (6.5–7.4)</td>
</tr>
<tr>
<td>Prolonged unconsciousness</td>
<td>98.9 (98.0–99.5)</td>
<td>99.2 (98.5–99.6)</td>
<td>9.4 (8.9–9.9)</td>
<td>7.2 (6.8–7.7)</td>
</tr>
<tr>
<td>Headache</td>
<td>98.8 (98.0–99.5)</td>
<td>99.2 (98.5–99.6)</td>
<td>10.2 (9.7–10.8)</td>
<td>7.3 (6.9–7.8)</td>
</tr>
<tr>
<td>Seizure, loss of consciousness, headache</td>
<td>99.8 (99.2–100)</td>
<td>99.4 (97.9–99.9)</td>
<td>2.7 (2.4–3.0)</td>
<td>6.8 (6.4–7.3)</td>
</tr>
<tr>
<td>Seizure, prolonged unconsciousness, headache</td>
<td>99.6 (98.9–99.9)</td>
<td>99.5 (98.7–99.9)</td>
<td>6.2 (5.8–6.6)</td>
<td>7.1 (6.6–7.5)</td>
</tr>
</tbody>
</table>
time, because there were no missed injuries among un-imaged patients, the sensitivity of our decision instrument, if applied to the entire blunt head trauma population, is likely to be no worse than reported here.

It is important to recognize that our decision instrument is intended to identify patients who are unlikely to have significant injuries revealed by CT imaging. While most of these patients can probably be safely discharged following their evaluation, it is beyond the scope of this study to determine their ultimate management. Physicians will need to use clinical judgment in deciding subsequent care.

Our study has some important limitations. Although recursive partitioning is very efficient in identifying criteria to produce an optimal rule among a derivation cohort, this does not guarantee equivalent performance among a second cohort. Thus while the sheer size of our study is reassuring, and provides the best information to guide imaging decisions to date, our results should be validated in an independent cohort. In addition, the criteria used in this instrument are relatively subjective. Nevertheless, they can be consistently assessed by different observers, and appear to identify reliably patients with intracranial injuries, as suggested by the current study. Finally, we were unable to derive any instrument with adequately high sensitivity for important intracranial injuries that also exhibited specificity dramatically better than current clinical practice.

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