Clinical Policy: Neuroimaging and Decisionmaking in Adult Mild Traumatic Brain Injury in the Acute Setting

INTRODUCTION

There are approximately 1 million emergency department visits annually for traumatic brain injury (TBI) in the United States. The vast majority of these visits are for “mild” injuries that are primarily the result of motor vehicle crashes and falls. The highest incidence of mild TBI (MTBI) is seen in men between the ages of 15 and 24 years and in men and women 75 years of age and older. Three percent to 13% of those patients evaluated in the ED with a Glasgow Coma Scale (GCS) score of 15 will have an acute lesion on head computed tomography (CT). Less than 1% of these patients will have a lesion requiring a neurosurgical intervention. Depending on how disability is defined, up to 15% of patients with MTBI will have compromised function 1 year after their injury. These statistics establish the clinical importance of MTBI to the acute care provider. However, inconsistencies in definitions, inclusion and exclusion criteria, and outcome measures have fueled an ongoing controversy on how best to evaluate and manage the patient with an MTBI.

The question of how best to define an MTBI is of great importance and has been a source of confusion. A small subset of these patients will harbor a life-threatening injury, whereas many will suffer with neurocognitive sequelae for days to months after the injury. In fact, it is difficult to convince a patient disabled from the postconcussive syndrome that their injury was “mild.” Unfortunately, there exists no consensus regarding classification. Terms used have included: “mild,” “minor,” “minimal,” “grade I,” “class I,” and “low risk.” Even the terms “head” and “brain” have been used interchangeably. Head injury and TBI are 2 distinct entities that are often, but not necessarily, related. A “head injury” is best defined as an injury that is clinically evident on physical examination and is recognized by the presence of ecchymoses, lacerations, deformities, or cerebrospinal fluid (CSF) leakage. A “traumatic brain injury” refers specifically to an injury to the brain itself and is not always clinically evident; if unrecognized, it may result in an adverse outcome.

The American Congress of Rehabilitation Medicine delineated inclusion criteria for a diagnosis of MTBI of which at least 1 of the following must be met: (1) any period...
of loss of consciousness (LOC) of less than 30 minutes and GCS score of 13 to 15 after this period of LOC; (2) any loss of memory of the event immediately before or after the accident, with posttraumatic amnesia of less than 24 hours; (3) any alteration in mental state at the time of the accident (eg, feeling dazed, disoriented, or confused). This definition is extremely broad and contributes to the difficulty of interpreting the MTBI literature.

Historically, the system most often used for grading severity of brain injury is the GCS score. The phrase “MTBI” is usually applied to patients with a score of 13 or greater. Some authors have suggested that patients with a GCS score of 13 be excluded from the “mild” category and placed into the “moderate” risk group because of their high incidence of lesions requiring neurosurgical intervention. Lesions requiring neurosurgical intervention may not be the only injuries that require identification. In a prospective study, patients with a GCS score of 13 or greater were grouped according to the presence or absence of head abnormalities. Despite having the same GCS score, those patients with intraparenchymal lesions performed on neuropsychological testing similar to those patients categorized as having moderate TBI by GCS criteria.

Created by Teasdale and Jennett in 1974, the GCS was developed as a standardized clinical scale to facilitate reliable interobserver neurologic assessments of comatose patients with head injury. The original studies applying the GCS score as a tool for assessing outcome required that coma be present for at least 6 hours. The scale was not designed to diagnose patients with mild or even moderate TBI nor was it intended to supplant a neurologic examination. Instead, the GCS was designed to provide an easy-to-use assessment tool for serial evaluations by relatively inexperienced care providers and to facilitate communication between care providers on rotating shifts. This need was especially great because CT scanning was not yet available. Since its introduction, however, the GCS has become quite useful for diagnosing severe and moderate TBI and for prioritizing interventions in these patients. Nevertheless, for MTBI, a single GCS score is of limited prognostic value and is insufficient to determine the degree of parenchymal injury after trauma. On the other hand, serial GCS scores are quite valuable in patients with MTBI. A low GCS score that remains low or a high GCS that decreases predicts a poorer outcome than a high GCS score that remains high or a low GCS score that progressively improves. To illustrate this, in their original paper, Teasdale and Jennett presented a patient who was admitted to the neurosurgical intensive care unit (NICU) with a GCS score of 14. The NICU chart reflected hourly scores of 14 for 3 hours, followed by a decline to 13 and then to 4, at which point the patient was taken to the operating room for evacuation of a subdural hematoma.

From an out-of-hospital and ED perspective, the key to using the GCS in patients with MTBI is in serial determinations. When head CT is not available, serial GCS scores clearly are the best insurance against missing a patient who needs a neurosurgical procedure. The GCS score continues to play this role and to provide important prognostic information. However, the previous discussion should make it clear that the use of a single GCS determination cannot be used solely in diagnosing MTBI. In one of the original multicenter studies validating the scale in the pre-CT era, approximately 13% of patients who became comatose had an initial GCS score of 15. The challenge for the acute care provider lies in identifying the apparently well, neurologically intact patient with a potentially lethal intracranial injury that requires immediate neurosurgical intervention. These patients are the focus of this clinical policy. A second challenge is to identify those patients at risk for post-concussive syndrome to ensure proper discharge planning. These patients are the focus of a separate clinical policy under development by the International Brain Injury Association.

Definitions

The vast majority of patients classified as having MTBI have a GCS score of 15 when they are in the ED. Consequently, the Task Force members of this clinical policy chose to focus specifically on this group. Large studies demonstrate that the absence of LOC or amne-
sia in patients with blunt head injury are negative predictors of the need for acute intervention after brain injury. After a review of these studies, the Task Force agreed to use LOC or amnesia as a criterion for this clinical policy.\textsuperscript{19,21} Focal neurologic deficits have been associated with an increased incidence of intracranial lesions and thus were used as an inclusion/exclusion criterion by the Task Force.\textsuperscript{17,22} Because MTBI management in the pediatric population has been recently presented in a clinical policy developed by the American Academy of Pediatrics and the American Academy of Family Physicians, this clinical policy specifically addresses MTBI in patients older than 15 years of age.\textsuperscript{23}

Inclusion criteria for application of this clinical policy’s recommendations are:

- Blunt trauma to the head within 24 hours of presentation to the ED
- Any period of posttraumatic LOC or of posttraumatic amnesia
- A GCS score of 15 on initial evaluation in the ED
- Age older than 15 years

Exclusion criteria for application of this clinical policy’s recommendations include:

- Presence of a bleeding disorder
- Penetrating trauma
- Patients with multisystem trauma
- Focal neurologic findings

Evidence-based practice guidelines require that a focused question be asked and that a clear outcome measure be identified. There are many questions to be asked about MTBI management. The task force identified the 3 questions that it thought most important to clinical practice:

- Is there a role for plain film radiographs in the assessment of acute MTBI in the ED?
- Which patients with acute MTBI should have a noncontrast head CT scan in the ED?
- Can a patient with MTBI be safely discharged from the ED if a noncontrast head CT scan shows no evidence of acute injury?

The task force considered several outcome measures in developing this clinical policy, including presence of an acute abnormality on noncontrast CT scan, clinical deterioration, need for neurosurgical intervention, and development of postconcussive syndrome.

- Presence of an acute intracranial abnormality on noncontrast head CT scan was chosen as the outcome measure for all 3 questions.

The limitations of this outcome measure were discussed. There is a paucity of literature that discusses the natural course of acute traumatic intracranial lesions in patients who initially appear intact. The Canadian CT Head Rule suggests that there are inconsequential traumatic lesions, such as smear subdurations less than 4 mm thick, for which detection is not necessary\textsuperscript{20}; however, this is based on survey data and not on prospective studies. Therefore, the Task Force agreed that, although an acute lesion may not predict clinical outcome or development of the postconcussive syndrome, it is the best currently available marker of injury in the acute setting, pending further research.

**METHODOLOGY**

A MEDLINE search of English-language publications was conducted for the period from January 1980 through June 2001 using the medical subject heading (MeSH) search terms mild or minor traumatic brain injury, mild or minor head trauma, acute diagnosis or management, skull radiography, head CT, neuroimaging, and neuroradiography. These terms were searched in all fields of publication (eg, title, abstract, key word).

Age was not used in the search because many articles included both adults and children (age 14 and under) in the study populations. Articles that included children were noted during the critical review by the committee.

The search identified 1,438 articles. Nonsystematic review articles, surveys, editorials, and expert opinion–based articles were excluded. A total of 58 articles were pooled and critically reviewed by the committee. All articles were reviewed by at least 4 committee members, and a composite evidentiary table was constructed.

The group reviewed the methodology of each paper and graded the design using the classification schema used by the American College of Emergency Physicians.
This scheme uses the design and purpose of the study to assign initial design strength as shown in Table 1.

Studies were downgraded 1 or more levels, depending on limitations in the control of bias, assessment of outcome, external validity, and other factors. Essentially, no study’s strength could be higher than its design class, but it could be lower based on the number, severity, and relevance of its limitations. Table 2 illustrates how this combination of design and execution ratings was used to develop a final strength of evidence assessment for an individual study.

An Evidentiary Table was constructed to summarize study design, outcome measure, findings, and limitations. The final “Class of Evidence” assigned to each study was based on the limitations of the study’s methodology and the relevance of end points. Those studies that had sufficient bias to affect validity or end points different from the single target end point chosen by the Task Force were either downgraded to a lower category or discarded if rated as X. Some studies were downgraded to X but left in the evidentiary table because of historical importance or because they contained important background information.

Evidence was combined to support recommendations as follows:

A recommendation—Sufficient Class I evidence in substantial agreement.

B recommendation—Class II evidence in substantial agreement, or Class I studies not in good agreement on size or direction of effect.

C recommendation—Class III evidence, or higher evidence classes not in good agreement.

In general, the strength of a recommendation was not allowed to exceed the strength of the individual pieces of evidence on which it depended. One theoretically possible exception, which is not without some controversy, would be to allow a Class A recommendation to be based on a number of small but well-executed randomized controlled trials (or equivalent Design/Class 1 studies) that had been downrated primarily because of small sample size. In such a case, some might argue for a Class A recommendation, as if there had been a good meta-analysis of those studies.

It should be noted that this evaluation scheme does not consider many of the factors that are important in implementing recommendations. Factors such as cost, practicability, and distributive justice are variables that must be independently weighed by individual health care systems.

CRITICAL QUESTIONS

I. Is there a role for plain film radiographs in the assessment of acute MTBI in the ED?

Skull plain film radiographs continue to be used as the first step in assessing MTBI in many health care

<table>
<thead>
<tr>
<th>Table 1. Literature classification schema.</th>
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<td><strong>Design/Class</strong></td>
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*Objective is to measure therapeutic efficacy comparing 2 or more interventions.
†Objective is to determine the sensitivity and specificity of diagnostic tests.
‡Objective is to predict outcome, including mortality and morbidity.

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<th>Table 2. Approach to downgrading strength of evidence.</th>
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<td>2 levels</td>
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<td>Fatally flawed</td>
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facilities, particularly those where head CT scanning is not readily available. Arienta et al\textsuperscript{19} reported on 7,991 patients; all had plain film radiographs, and 9% demonstrated a fracture. They reported that no patient with a negative radiographic finding developed complications; however, only 592 of the patients had a CT scan, and follow-up was not clearly defined.

Cooper and Ho\textsuperscript{24} retrospectively studied 207 patients with intracranial lesions on CT scanning who also had plain films, 63% of which were normal. Although this study included only admitted patients, plain films appeared to be neither sensitive nor specific for brain injury. In 1980, Masters\textsuperscript{25} performed a retrospective study on 1,845 patients; 26 (79%) of 33 patients with significant intracranial sequelae had normal skull films. This study was followed 8 years later by a prospective study involving 7,035 patients. Although methodologically flawed, the authors reported that, in the group most similar to the focus of this clinical policy (moderate risk), 3 (6.4%) of 47 patients with a skull fracture had an intracranial lesion, 44 (93.6%) of 47 patients with a fracture had no intracranial lesion, and 7 (70%) of 10 patients with an intracranial lesion had no fracture (95% confidence interval [CI] 35% to 93%). It was concluded that skull film radiographs are rarely helpful in managing MTBI and should not be used to select patients for additional testing.

A meta-analysis published in 2000 examined the association between skull fracture and brain injury.\textsuperscript{4} The authors recognized the difficulty of comparing studies with varying design, and after retrieving 200 studies for review, they identified 20 that fulfilled their inclusion criteria. Their analysis found that the sensitivity of skull fracture in detecting patients with an intracranial lesion ranged from 0.13 to 0.75, with a specificity of 0.91 to 0.995. The authors discussed their concern about both selection bias and verification bias contributing to the high specificity reported by the studies (ie, patients were more likely to receive a CT scan if their GCS score was less than 15 or if they had a positive plain film). Using the combined results for sensitivity, specificity, and prevalence, the authors reported the positive predictive value of a skull fracture for the diagnosis of an intracranial lesion as 0.41 and the negative predictive value as 0.94. These findings suggest that the presence of a skull fracture increases the probability of an intracranial lesion fivefold. However, the meta-analysis concluded that, although a fracture demonstrated on plain film increased the likelihood of an intracranial lesion, its low sensitivity precluded its use to rule out the diagnosis of an intracranial hemorrhage and thus is of limited clinical value in risk stratification for brain injury.

**Recommendation**

**Recommendation B:** Skull film radiographs are not recommended in the evaluation of MTBI. Although the presence of a skull fracture increases the likelihood of an intracranial lesion, its sensitivity is not sufficient to be a useful screening test. Indeed, negative findings on skull films may mislead the clinician.

**II. Which patients with acute MTBI should have a noncontrast head CT scan in the ED?**

Many of the studies on MTBI have focused on identifying lesions in need of neurosurgical intervention.\textsuperscript{20,26} The literature does not clearly state which patients with intracranial lesions deteriorate, nor is it clear about the predictive value of intracranial lesions in predicting the development of postconcussive syndrome. Therefore, the Task Force chose “presence of an acute intracranial lesion” on noncontrast head CT scan as its outcome measure on patients with MTBI.

Livingston et al\textsuperscript{27} evaluated 91 patients who had a GCS score of 15 and reported that 9 (10%) of those had abnormal CT scan findings (95% CI 4.6% to 18%). They were unable to identify any combination of findings that predicted all patients with pathology. Jeret et al\textsuperscript{8} conducted a prospective study on 712 consecutive patients with head trauma who had a GCS score of 15 and a period of LOC or amnesia. There were 67 patients (9.4%; 95% CI 7.3% to 11.8%) with acute traumatic brain lesions; only 2 patients (0.3%) required urgent neurosurgical intervention. They were unable to create a statistical model that could be used to classify 95% of patients into a CT-normal or CT-abnormal group.
Miller et al\textsuperscript{28} prospectively studied 2,143 patients in an attempt to identify risk factors for a neurosurgical lesion. There were 6.4\% (95\% CI 5.4\% to 7.6\%) of the patients with positive CT scan findings, and 0.2\% needed neurosurgery. Nausea, vomiting, severe headache, or depressed skull fracture had a positive predictive value of 100\% for those patients requiring neurosurgical intervention. No patient without a risk factor deteriorated even if CT scan findings were positive.

Borczuk\textsuperscript{29} retrospectively reviewed 1,211 patients with a GCS score of 15 and reported that 75 (5.9\%) had an abnormality on CT scan, and 1 patient (0.08\%) required neurosurgery. Cranial soft tissue injury, focal neurologic deficits, or signs of trauma above the clavicle were found to be predictive of an intracranial lesion.

Dunham et al\textsuperscript{18} retrospectively analyzed a prospectively collected trauma center database and reported on 1,481 patients with a GCS score of 15; 45 (3.0\%) patients had positive CT scan findings, and 2 (0.13\%) required neurosurgical intervention. Positive CT scan findings were correlated with evidence of trauma above the clavicle and age greater than 60 years.

Lee et al\textsuperscript{30} followed up 1,812 patients discharged from the ED after an MTBI and reported that 28 (1.5\%) deteriorated from their injury in the succeeding 2 months. Unfortunately, the majority of the patients in this study did not have an initial CT scan. However, in congruence with the previously cited studies, Lee et al reported that predictors of deterioration included headache, focal neurologic deficit, vomiting, and age greater than 60 years.

Vilke et al\textsuperscript{31} specifically studied the value of a detailed neurologic examination, including a careful mental status assessment, in predicting the presence of an acute intracranial lesion on CT scan. The study’s well-defined methodology was undermined by its small sample size of only 58 patients. Three (5\%) patients were found to have positive CT scan findings, 2 of whom had a normal neurologic examination of whom 1 required a craniotomy. The authors concluded that a decision for CT cannot be based solely on the neurologic examination.

Working with the predictors identified in the aforementioned studies, 2 recent papers have attempted to define criteria for CT scanning in patients with MTBI\textsuperscript{5,20}.

Stiell et al\textsuperscript{20} performed a derivation study by prospectively evaluating 3,121 patients, 2,489 of whom had a GCS score of 15, using a structured assessment tool. Only 2,078 (67\%) of the 3,121 patients had a CT scan; telephone follow-up and a neuropsychiatric test were used as equivalent to negative CT scan findings. Patients had a follow-up interview at 14 days to assess outcome. The primary outcome measure was the need for neurosurgical intervention, and the secondary outcome was a “clinically important brain injury” defined by a survey consensus. “Clinically unimportant lesions” included solitary contusions less than 5 mm in diameter, smear subdurs less than 4 mm thick, isolated pneumocephalus, and closed depressed skull fractures not through the inner table. Because the study sites were the primary neurosurgical centers for the respective cities, the authors concluded that no patient with “clinically unimportant” CT scan findings deteriorated after discharge. The authors concluded that CT in MTBI is indicated only in those patients with 1 of 5 high-risk factors: failure to reach a GCS score of 15 within 2 hours of injury, suspected open skull fracture, sign of basal skull fracture, vomiting more than once, or age greater than 64 years.

In a Class I study, Haydel et al\textsuperscript{5} prospectively assessed 1,429 patients with MTBI. The study consisted of an initial phase with 520 patients in whom predictors for intracranial lesions were identified, followed by a validation phase that included 909 patients. The authors reported that 93 (6.5\%) of their patients had an intracranial lesion and that 6 (0.4\%) required neurosurgical intervention. Seven predictors of abnormal CT scan findings were identified: headache (any head pain), vomiting, age greater than 60 years, intoxication, deficit in short-term memory (persistent anterograde amnesia), physical evidence of trauma above the clavicle, and seizure. Absence of all 7 findings had a negative predictive value of 100\% (95\% CI 99\% to 100\%).

Recommendation

Recommendation A: A head CT scan is not indicated in those patients with MTBI who do not have headache,
vomiting, age greater than 60 years, drug or alcohol intoxication, deficits in short-term memory, physical evidence of trauma above the clavicle, or seizure.

III. Can a patient with MTBI be safely discharged from the ED if a noncontrast head CT scan shows no evidence of acute injury?

During the past decade there has been a decline in the hospitalization rate of patients with TBI. This decrease has been attributed to increased reliance on CT scanning to identify patients at risk for life-threatening injuries. The literature does not reflect an increase in morbidity or mortality from this practice; however, up to this point in time, no guidelines exist to help the clinician decide who can be safely sent home. Two issues relevant to this question emerge from the literature. The first issue is that patients who are admitted to the hospital for observation often do not receive the observation for which they were admitted. In 1 study, only 50% of admitted patients had documented serial neurologic examinations ranging in frequency from 1 to 8 hours. In another study, 30% of patients admitted for TBI did not have documented serial neurologic examinations. The second issue is that, although discharge instructions are routinely given to patients with MTBI, they are rarely remembered. Levitt et al found that 23% of patients discharged from the ED with MTBI could not remember any of their discharge instructions. These 2 issues combined suggest that expectant observation might not be the best strategy for managing patients with TBI.

There is literature that clearly identifies a subset of patients with MTBI who deteriorate. The focus of research must be to identify this group. In addition to case reports and small case series, several larger cohort studies exist. Lee et al prospectively followed up 1,812 patients who were discharged from the hospital with a GCS score of 15 at 3, 7, 30, and 60 days. Twenty-eight (1.5%) of these patients deteriorated, 16 (57%) of the 28 within the first 24 hours; 23 (82%) of the 28 who deteriorated required a neurosurgical intervention. Unfortunately, most of the patients did not have initial CT scans. In a Class III retrospective study that is difficult to interpret, Shackford et al reported on 933 patients with normal neurologic examinations and normal head CT findings who were admitted to the hospital for observation. They reported that 11 (1.2%) patients in this group required intubation (ie, deteriorated), although none required neurosurgical intervention. Unfortunately, the authors do not provide the timing of the deterioration or other specific information related to the cases.

Nagy et al prospectively studied 1,170 trauma center patients, all of whom had a CT scan and were admitted for 24 hours of observation. Similar to the studies already described, 39 (3.3%) of the patients had positive CT scan findings, and 4 (0.3%) required neurosurgery. Despite the study design's spectrum bias favoring sicker patients, no patient deteriorated, thus supporting the authors' recommendation to discharge patients who have negative CT scan findings home from the ED.

In the study by Stein and Ross already cited, none of 1,117 patients admitted with a diagnosis of MTBI deteriorated, although the length of observation was not defined. Livingston et al followed up 79 patients with a GCS score of 15 and negative CT scan findings who were discharged from the ED. Although only 57 patients were reached in follow-up at 48 hours, none had deteriorated.

Dunham et al analyzed data from 2,387 trauma center patients; 45 (3.0%) of the 1,481 patients with a GCS score of 15 had positive CT scan findings. No patient with negative CT scan findings deteriorated, and all patients who did deteriorate did so within 4 hours of arrival at the trauma center.

Jeret et al prospectively studied 712 patients, 67 (9.4%) of whom had positive CT scan findings. One patient who initially had normal examination results deteriorated within “several hours” of arriving in the ED, at which point a CT scan disclosed a left temporal contusion; by 6 hours after arrival in the ED, he was lethargic and had a craniotomy.

A recent prospective study by Livingston et al attempted to answer the question of which patients with MTBI could be safely discharged from the ED. Unfortunately, the study's design flaws prevented the formulation of any conclusions regarding those patients addressed in this policy.
**Recommendation**

**Recommendation C:** Patients with MTBI who present 6 hours after sustaining the injury, have a normal clinical examination, and who have a head CT scan that does not demonstrate acute injury can be safely discharged from the ED. Patients can be discharged after a shorter period of observation if they are under the care of a responsible third party.

**Future Directions**

The small number of well-designed studies limits the strength of recommendations that can be made regarding the management of patients with MTBI. Inconsistent definitions and outcome measures contribute to the ongoing controversy of how best to manage these patients. Future research must begin with a collaborative effort in the neuroscience community on how to define MTBI and how to measure its related outcomes.

The true incidence of MTBI is unknown. Epidemiologic studies have focused on those patients managed in trauma centers and admitted; they therefore suffer from selection bias. The vast majority of MTBI epidemiologic studies focus on preexisting data sets that were not originally intended for research purposes, such as *International Classification of Diseases, 9th Revision (ICD-9)* codes.

Many patients sustain MTBI but do not seek medical care and are thus not included in estimates, thereby underestimating the true incidence of MTBI. More thorough and accurate epidemiologic evaluation of MTBI is needed to define the enormity of the problem and to direct both public education and preventative strategies.

An improved elucidation of the pathophysiologic characteristics of MTBI is critical for the research and development of therapeutic measures. Pharmacologic therapy used to prevent or reduce neuronal injury after MTBI remains a formidable yet crucial goal. More conclusive evidence is needed to help identify in a timely manner the small but important number of patients who develop intracranial hematomas despite initially normal CT scan findings and normal neurologic examination results. Only a multicenter, prospective study with long-term patient follow-up, implementing the specific guidelines as outlined in this document, will identify the subset of patients at risk and validate the recommendations presented in this document.

Patients with a GCS score of 15 and normal head CT scan findings are at risk for the development of cognitive, psychosocial, and neurobehavioral abnormalities related to MTBI. This postconcussive syndrome may adversely affect the patient's personal, financial, and social life. Thus, future research must address mechanisms for identifying patients at risk and interventions that may minimize or prevent disability.

It is possible that the resolution of head CT scanning limits the diagnosis of clinically significant neuronal lesions that may be responsible for the postconcussive syndrome. The role of magnetic resonance imaging and other neuroimaging modalities in the acute evaluation of MTBI is yet to be determined. The implication on the management and follow-up of the nonoperative lesions found on CT scanning or other neuroimaging studies is also an area in need of elucidation.

This project was funded by an International Brain Injury Association (IBIA) grant and the Irving I. and Felicia F. Rubin family brain injury research grant.

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CLINICAL POLICY: ADULT MILD TRAUMATIC BRAIN INJURY

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The developers thank Rhonda Whitson, RHIA, for her assistance in preparing the document for publication.

REFERENCES


OTHER BACKGROUND REFERENCES


Holmes JF, Baier ME, Derlet RW. Failure of the Miller criteria to predict significant intracranial injury in patients with a Glasgow Coma scale score of 14 after minor head trauma. Acad Emerg Med. 1993;1:788-792.


## Evidentiary Table

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<thead>
<tr>
<th>Article, yr</th>
<th>Design</th>
<th>Patients</th>
<th>Outcome Measure</th>
<th>Findings</th>
<th>Limitations</th>
<th>Class of Evidence</th>
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<tr>
<td>Arienta, 1997</td>
<td>Retrospective</td>
<td>10,000 patients, 4 categories; α group: no LOC; β group: LOC/PTA, or vomiting, or subgaleal hematoma</td>
<td>Deterioration</td>
<td>No patient in the α group deteriorated; all 799 patients in the β group had skull radiographs performed, 73 (9%) had a fracture; 592 of 799 patients in the β group had CT scans performed, 21 (3.5%) results were positive; no patient with negative radiographic findings developed complications</td>
<td>Groups not well defined to allow for conclusions; follow-up not clearly defined</td>
<td>III</td>
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<tr>
<td>Ashkenazi, 1990</td>
<td>Case series</td>
<td>6 patients; GCS score of 14–4; 2 patients had no LOC</td>
<td>Repeat CT scan showing epidural</td>
<td>All patients had a GCS score of &lt;15</td>
<td>III/NA</td>
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<td>Bell, 1971</td>
<td>Prospective questionnaire</td>
<td>1,500 patients; all ages/ types of injury</td>
<td>Fracture on radiograph</td>
<td>High-yield criteria were not sensitive for fracture</td>
<td>No CT correlation; no GCS</td>
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<td>Borczuk, 1994</td>
<td>Retrospective</td>
<td>1,448 patients; GCS score 13–15; 1,211 patients had GCS score of 15</td>
<td>Abnormal CT; neurosurgery</td>
<td>119 (8.2%) patients with CT abnormalities; 72 (5.9%) had GCS score of 15; 11 (0.72%) required neurosurgery; 1 (0.08%) had GCS score of 15; cranial soft tissue injury focal neurologic deficit/signs of basilar skull fracture/age &gt;60 identified all patients with neurosurgical lesion; 91.6% sensitivity for identifying any injury</td>
<td>Retrospective; no long-term outcome</td>
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<td>Brown, 1978</td>
<td>Case series</td>
<td>3 patients; GCS score &lt;13</td>
<td>Neurosurgery</td>
<td>Initial CT scan findings were normal or near normal; repeat CT scans with significant pathology</td>
<td>Methodology</td>
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<td>Chambers, 1996</td>
<td>Prospective, follow-up study</td>
<td>129 mild to moderate blunt trauma without suspicion of head injury</td>
<td>PCS symptoms at 1 month; telephone interview using the PCS checklist tool</td>
<td>41 (32%) patients reported 2 or more symptoms combined with PCS</td>
<td>No CT scan; symptoms may be caused by stress and not by MTBI; no formal neuropsychologic testing performed</td>
<td>X</td>
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<td>Cook, 1994</td>
<td>Prospective cohort</td>
<td>107 consecutive patients adult, alcohol (ETOH) &gt;80</td>
<td>Abnormal CT scan findings; 8-point neurologic scoring examination used that included remembering 3 words after 1 minute and spelling name backwards; repeat examination in 1 hour</td>
<td>9 (8.4%) of 107 patients had abnormal CT scan findings; 2 (1.9%) of 107 patients needed neurosurgery; 7 patients had clinical signs of basilar skull fracture but normal CT findings; 1 patient deteriorated from a GCS score of 12 to a GCS score of 7; no set of clinical predictors identified patients with positive CT scan findings; 1 patient discharged with “normal” CT returned 6 weeks later with bilateral subdural hematoma; 1 neurosurgical lesion was missed on initial CT scan reading</td>
<td>5 of 9 patients had a GCS score of 15; ETOH levels and patient alertness were not provided; good study protocol using neurologic examination and repeat examination; emphasizes need for repeat examination and clinical judgment; 1-hour observation is of limited value</td>
<td>II/NA</td>
</tr>
<tr>
<td>Cooper, 1983</td>
<td>Retrospective chart review</td>
<td>207 patients with known intracranial lesions; inclusion: CT and plain films</td>
<td>Presence of fracture on plain film</td>
<td>16 (7.7%) had Grady coma scale score of 15; 1 patient sent home returned with extradural hematoma; 76 (38.7%) patients had fractures; presence of fracture did not predict outcome; sensitivity of skull film radiographs found to be low</td>
<td>Retrospective; patients without abnormal CT scan findings were not included, and only admitted patients were studied (selection bias, but spectrum bias favorable)</td>
<td>III</td>
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### Evidentiary Table (continued)

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<tr>
<td>Dacey, 1986</td>
<td>Prospective</td>
<td>610 consecutive patients; all ages; GCS score of 13–15 in the ED and history of LOC or neurologic deficit; all patients were admitted; 583 (95.6%) patients received plain radiographs; only patients who deteriorated received a CT scan</td>
<td>Neurosurgical complication</td>
<td>533 (87.3%) patients had a GCS score of 15; 583 patients received plain radiographs; 66 (11.3%) had positive findings; 18 (3.0%) patients required neurosurgery (8 (45%) with GCS score of 15); presence of skull fracture increased chances of neurosurgical intervention 20-fold; conversely, 1 in 5 patients with hematoma had normal findings on radiograph; concluded that skull film radiographs predicted all patients requiring neurosurgery, but not all patients had a CT scan performed</td>
<td>CT scan not obtained at admission; therefore, study does not help with stratifications. Only 68 patients had a CT scan performed; 9 of 12 surgical patients had right lesions that may have delayed recognition (language).</td>
<td>III/NA</td>
</tr>
<tr>
<td>de Lacey, 1980</td>
<td>Retrospective; consecutive</td>
<td>Films and notes of 130 patients during 1975</td>
<td>Skull fracture</td>
<td>4 (3.1%) patients had skull fracture; 99 (76%) patients had additional radiographs performed</td>
<td>Small number of patients; no follow-up; no CT scans</td>
<td>X</td>
</tr>
<tr>
<td>Dunham, 1996</td>
<td>Retrospective analysis of a prospective database</td>
<td>2,587 consecutive patients age &gt;13 years with head injury, LOC, or PTA; 2,252 direct transports used for analysis</td>
<td>Positive CT scan findings</td>
<td>163 (7.2%) of 2,252 direct transports with positive CT scan findings; 1,481 patients with GCS score of 15 and amnesia; 45 (3.0%) with positive CT scan findings; 54 (12.4%) of 435 patients with GCS score of 14 had positive CT scan findings; 29 (25.0%) of 116 patients with GCS score of 13 had positive CT scan findings; 15 (10.0%) of 150 patients aged &gt;60 y with GCS score of 15 had positive CT scan findings; positive CT scan findings were independently related to cranial soft tissue injury, age, and GCS score; 35 (42.1%) of 83 patients with skull fracture had positive CT scan findings; no patient required a craniotomy for hematoma when the CT scan performed on day of injury revealed negative findings; all patients who deteriorated within 4 h of arrival</td>
<td>Trauma center admissions (selection bias toward the more severe); no standard protocol; 196 (8.7%) of 2,252 patients did not have a CT scan performed; unknown follow-up; skull fracture data related to fractures seen on CT scan were not on plain radiographs</td>
<td>III</td>
</tr>
<tr>
<td>Feuerman, 1988</td>
<td>Retrospective</td>
<td>373 patients</td>
<td>Positive CT scan findings or deterioration</td>
<td>236 patients with GCS score of 15</td>
<td>Not all patients had a CT scan performed; no follow-up</td>
<td>X</td>
</tr>
<tr>
<td>Garra, 1999</td>
<td>Retrospective chart review</td>
<td>65 patients taking warfarin with head injury but without LOC</td>
<td>Abnormal CT scan findings or clinical deterioration</td>
<td>39 patients (60%) had a CT scan performed; the rest had telephone follow-up; 38 patients (58%) had prothrombin time recorded; no complications</td>
<td>Retrospective; not all patients received tests</td>
<td>X</td>
</tr>
<tr>
<td>Gomez, 1996</td>
<td>Retrospective</td>
<td>2,484 patients with consecutive GCS score of 13–15; age &gt;15 y</td>
<td>Abnormal CT scan findings</td>
<td>Advanced age, GCS score of 13–14, presence of skull fracture and focal signs increased incidence of abnormal CT scan findings; coagulation disorders did not increase abnormal CT scan findings; LOC in only 26% of patients with GCS score of 15</td>
<td>Only 7.5% of patients had CT scan performed; only 72% had skull radiographs performed; no protocol</td>
<td>X</td>
</tr>
<tr>
<td>Harad, 1992</td>
<td>Retrospective</td>
<td>251 patients with GCS score of 15</td>
<td>Abnormal CT scan findings</td>
<td>43 (17.1%) patients with GCS score of 15 had positive CT scan findings; 5 (1.9%) patients with GCS score of 15 required neurosurgery for epidural or subdural hematoma</td>
<td>No defined criteria for obtaining a CT scan in patients with GCS score &gt;12; possible selection bias because there is a higher incidence of positive CT scan findings than reported in other studies</td>
<td>III</td>
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<tr>
<td>Haydel, 2000</td>
<td>Prospective</td>
<td>Phase 1: 520 patients aged &gt;2 y; Phase 2: 909 patients, validation; Inclusion: GCS score of 15 and LOC or amnesia</td>
<td>Abnormal CT scan findings</td>
<td>93 (6.5%) of 1,429 patients with positive CT findings; 6 (0.4%) patients had neurosurgical lesions; 7 predictors of abnormal CT scan findings: headache, vomiting, age &gt;60 y, drug or ETOH intoxication, deficits in short-term memory, physical evidence of trauma above the clavicle, and seizure; absence of all 7 had 100% negative predictive value</td>
<td>No follow-up after discharge</td>
<td>I</td>
</tr>
<tr>
<td>Hofman, 2000</td>
<td>Meta-analysis; 20 studies</td>
<td>Papers from 1960–1988</td>
<td>Skull fracture and intracranial hemorrhage</td>
<td>13 studies with documented intracranial hemorrhage; 322 patients (44%) with skull fracture; skull fracture increases the predictive value of an intracranial hemorrhage but is not sensitive enough to be an effective screening tool</td>
<td>Studies are heterogeneous</td>
<td>II</td>
</tr>
<tr>
<td>Holmes, 1997</td>
<td>Prospective, consecutive patients</td>
<td>264 patients; age &gt;17 y; GCS score of 14; validate Miller criteria for high risk of positive CT scan findings: headache, nausea, vomiting, or signs of depressed skull fracture</td>
<td>Abnormal CT scan findings</td>
<td>35 (13%) patients had abnormal CT scan findings; 4 (1.5%) had neurosurgery; positive predictive value: 0.2; negative predictive value: 0.9; 18 (20%) of 90 patients at high risk had positive CT scan findings; 17 (10%) of 174 patients at low risk had positive CT scan findings</td>
<td>Small number of patients; ETOH included; 5 of 17 patients with abnormal CT scan findings and low risk were lost after discharge from ED; 2 low-risk patients needed craniotomy; both were intoxicated</td>
<td>II/NA</td>
</tr>
<tr>
<td>Jeret, 1993</td>
<td>Prospective consecutive patients</td>
<td>712 patients; GCS score of 15; age &gt;17 y; examination performed by neurologist</td>
<td>Abnormal CT scan findings</td>
<td>67 (9.4%) patients had abnormal CT scan findings; 2 (0.2%) required neurosurgery; neurologic examination, digit span, and object recall did not predict abnormal CT scan findings; no combination of physical or subjective findings predicted all patients with positive CT scan findings; 1 deterioration in serial examination in 49-year-old assault victim; no ETOH; completely normal initial neurologic examination</td>
<td>No follow-up; lack of validation</td>
<td>II</td>
</tr>
<tr>
<td>Lee, 1995</td>
<td>Prospective</td>
<td>1,812 patients with a GCS score of 15 and blow to head or LOC or PTA; patients had CT performed only if they had symptoms; follow-up at 3, 7, 30, and 60 d</td>
<td>Deterioration after discharge</td>
<td>28 (1.5%) patients deteriorated; 16 (57%) of these in &lt;24 h; 5 (18%) of these between days 2–7; 28 (1.3%) patients required neurosurgery; age &gt;60 y, vomiting, and headache increased the risk of deterioration</td>
<td>Patients without LOC included but not clear whether they were in the group that deteriorated; most patients did not have a CT scan performed; strength is that follow-up was obtained</td>
<td>III</td>
</tr>
<tr>
<td>Livingston, 1991</td>
<td>Prospective</td>
<td>Assess safe discharge in patients with normal CT scan findings and normal neurologic examination; GCS score of 14–15; no focal neurologic findings</td>
<td>Deterioration after discharge</td>
<td>111 patients; 15 (14%) had abnormal CT scan findings; 5 patients with normal CT scan findings admitted because of lethargy; of patients with normal neurologic examination and normal CT scan findings who were discharged, 79 had GCS score of 15 and 11 had GCS score of 14; 66 (59%) patients were positive for ETOH</td>
<td>Small number of patients; 57 (63%) patients contacted by telephone in 48-h follow-up; none had deterioration</td>
<td>III</td>
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<tr>
<td>Livingston, Retrospective 1991</td>
<td>138 patients with a GCS score of 14–15 were admitted; 83 admitted for isolated head injury; LOC or suspected LOC in 110 (80%) patients; GCS score of 15 in 103 patients</td>
<td>Deterioration after initial period of being lucid</td>
<td>75 patients had CT scan performed; 13 (17%) had abnormal findings; no patient with normal CT scan findings developed a neurosurgical complication; 1 patient needing neurosurgery had negative skull radiograph findings; 1 patient (0.7%) required neurosurgery</td>
<td>Not all patients received CT scans; 2 patients who returned to ED had not had initial CT scan performed</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>Livingston, Prospective, GCS score of 14–15, LOC or amnesia;standardized physical and neurologic examination; CT scan and admission; outcome measured at 20 h and at discharge; helical CT scan used</td>
<td>GCS score of 14–15, LOC or amnesia;standardized physical and neurologic examination; CT scan and admission; outcome measured at 20 h and at discharge; helical CT scan used</td>
<td>Clinical deterioration, need for neurosurgery, death</td>
<td>Of 2,152 patients, 1,788 had negative CT scan findings, 217 had positive CT scan findings, and 119 had equivocal findings; 1 patient had negative CT scan findings, deteriorated, and required neurosurgery (patient had multiple facial fractures); negative predictive value of CT was 99.7%; 33 patients with negative CT scan findings had an intervention (ie, combative, seizure, additional injuries [not well defined])</td>
<td>GCS score of 14 and 15 not reported separately; timing from injury to CT scan not recorded; group of patients who deteriorated not well described, although it appears that clinical course was predicted early on (eg, GCS score of 14); confusing data analysis; negative predictive value is the wrong test for reporting findings with a low incidence</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Lobato, Retrospective 1991</td>
<td>211 patients with head injury who talked at some time before deterioration</td>
<td>Deterioration after initial period of being lucid</td>
<td>Of 211 patients, 75 (36%) were fully oriented during the lucid interval with verbal score of 5; 65 (31%) were confused with GCS verbal score of 4; deterioration occurred within 24 h in 140 (71%) of 197 cases; 170 (81%) of 211 patients who deteriorated had a mass lesion on CT scan</td>
<td>Initial clinical status not presented, only noted that there was a lucid interval; GCS score was not presented, although verbal score was; timing of CT scan not presented</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Madden, 2-phase prospective observational study 1995</td>
<td>Phase I: 540 patients; for 51 patients, a variable data collection form was used; all patients had CT scans performed; Phase II: 273 patients</td>
<td>Phase I: univariate analysis led to 10 criteria protocol—LOC, combative, decreasing LOC, facial injury, penetrating skull injury, depressed skull fracture, pupillary inequality, signs of basal skull fracture, and GCS score &lt;15; 23% of patients with GCS score of 14 had positive CT scan findings; 8% of patients with a GCS score of 15 had positive CT scan findings; no patient without criteria had a neurosurgical lesion, but 2 had positive acute intracranial lesions</td>
<td>Phase I: univariate analysis led to 10 criteria protocol—LOC, combative, decreasing LOC, facial injury, penetrating skull injury, depressed skull fracture, pupillary inequality, signs of basal skull fracture, and GCS score &lt;15; 23% of patients with GCS score of 14 had positive CT scan findings; 8% of patients with a GCS score of 15 had positive CT scan findings; no patient without criteria had a neurosurgical lesion, but 2 had positive acute intracranial lesions</td>
<td>Inclusion criteria were broad but not defined</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>Masters, Retrospective 1980</td>
<td>1,845 patients</td>
<td>Skull fracture</td>
<td>79 patients with skull fractures; 33 patients with significant intracranial sequelae; 7 with fractures; 218 had CT scans performed; 32% had no fractures but had positive CT scan findings; 27% had fractures and negative CT scan findings</td>
<td>Recorded only sequelae, not presence of lesion; patients not stratified by GCS score</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>Masters, Prospective 1987</td>
<td>7,035 patients; follow-up performed on 3,658 (52%) patients</td>
<td>Deterioration</td>
<td>Management strategy developed based on review of the literature; 5,254 low-risk patients; 2,459 (47%) did not have radiographs; none had CT scans performed; 12 had simple linear fractures; none deteriorated; advertisement looking for cases not managed correctly following the proposed strategy</td>
<td>3,377 (48%) of patients had no follow-up; GCS score not reported; does not address CT findings; focuses on limited value of plain radiographs</td>
<td>X</td>
<td></td>
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<tr>
<td>Mikhail, 1992</td>
<td>Prospective</td>
<td>Convenience sample; 112 patients with GCS score &gt;12, 17 (15%) were lost to follow-up</td>
<td>Deterioration</td>
<td>35 patients had CT scans performed; 8 had positive findings; 3 needed neurosurgery; all patients with positive CT scan findings had GCS score of 15; 4 patients had no LOC, of whom 3 went to surgery and 1 died; headache and age &gt;40 y associated with positive CT scan findings; LOC does not predict intracranial injury</td>
<td>Limited follow-up; not clearly presented why only some patients received CT scans; conclude that CT scans should be obtained in patients with clinical evidence of basilar skull fracture or neurologic focal findings; not clearly presented how these conclusions were derived</td>
<td>III</td>
</tr>
<tr>
<td>Miller, 1996</td>
<td>Prospective</td>
<td>1,382 patients of all ages; LOC or amnesia present</td>
<td>Positive CT scan findings; neurosurgery</td>
<td>Entry GCS score of 15 with &quot;normal mental status&quot;; 84 (6.1%) patients had positive CT scan findings; 3 (0.2%) required surgery; in patients with no complaints, 24 (3.0%) of 789 had positive CT scan findings; none required neurosurgery; do not recommend CT based only on LOC or amnesia</td>
<td>Does not define normal mental status or document performing neurologic examination; unknown follow-up</td>
<td>II</td>
</tr>
<tr>
<td>Miller, 1997</td>
<td>Prospective</td>
<td>2,143 consecutive patients; GCS score of 15 with history of LOC; ETOH included; injury must be &lt;24 h before presentation to ED; all had CT scans performed within 8 h; severe headache distinguished from mild to moderate; compared predictive value of severe headache, nausea, vomiting, and depressed skull fracture to patients with no complaints; all patients monitored for at least 3 h in ED</td>
<td>Abnormal CT scan findings</td>
<td>1,302 (61%) patients with no risk factors vs 841 (39%) with risk factors; 138 (6.4%) had positive CT scan findings; 48 (4%) with no risk factors vs 90 (11%) with risk factors; use of predictors had a sensitivity of 65%; positive predictive value of someone needing neurosurgery 100%; 5 patients (0.2%) required neurosurgery; all had risk factors; 41 patients with no risk factors but acute intracranial lesion on CT scan were hospitalized for an average of 2 days; none deteriorated; an additional 7 patients had skull fracture only; recommendation to use predictors to stratify need for CT scan</td>
<td>Methodology was well described; no follow-up in patients without lesion; discussion states that patients with lesions were admitted but not stated in methodology; argues that CT scan findings do not predict PCS</td>
<td>II</td>
</tr>
<tr>
<td>Miller, 1990</td>
<td>Retrospective</td>
<td>183 patients &gt;10 y who were able to open eyes, were oriented to person, place, and time, and obeyed commands when first seen who deteriorated</td>
<td>Deterioration</td>
<td>1,080 patients with neurosurgical lesions; 183 (17%) with GCS score of 15 at presentation; times available in 138 patients: 97 (70%) patients were seen within 6 h; 116 (84%) within 24 h; 71 (39%) had &quot;no record&quot; of LOC, amnesia, headache, or vomiting being present or absent; 78 (43%) had focal deficit or signs of basilar skull fracture</td>
<td>Retrospective without knowledge of initial evaluations; no use of data collection instrument</td>
<td>X</td>
</tr>
<tr>
<td>Mills, 1986</td>
<td>Prospective</td>
<td>407 patients with mixed etiologies including both medical and surgical emergencies; 103 (25%) had head trauma</td>
<td>Abnormal head CT scan findings</td>
<td>31 patients with head trauma had abnormal head CT scan findings</td>
<td>All patients were included, not just trauma victims; GCS not reported for any patients</td>
<td>X</td>
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<tr>
<td>Mohanty, 1991</td>
<td>Retrospective</td>
<td>348 patients aged &gt;17 y with a GCS score &gt;12 who remained neurologically stable for 20 min after arrival, with no evidence of basilar skull fracture</td>
<td>Positive CT scan findings; deterioration</td>
<td>All patients had at least 1 CT scan performed; 12 (3.4%) of 348 patients had positive CT scan findings; no discharged patients were readmitted</td>
<td>GCS not broken into subgroups; patient selection not defined; follow-up not defined</td>
<td>X</td>
</tr>
<tr>
<td>Moran, 1994</td>
<td>Retrospective</td>
<td>200 patients; compared scene GCS score to ED GCS score, LOC/amnesia, and focal deficit</td>
<td>Positive CT scan findings</td>
<td>96 (48%) patients had CT scan performed</td>
<td>Not all patients received CT scans; poor documentation; &lt;50% had CT scans performed; selection bias (all air transports)</td>
<td>X</td>
</tr>
<tr>
<td>Murshid, 1994</td>
<td>Retrospective</td>
<td>566 patients aged 1 month to 80 y; presentation within 24 h of injury; all had skull radiographs performed</td>
<td>Deterioration</td>
<td>64 (11%) patients had skull fracture; 3 patients with fracture required surgery; 127 (22%) patients had CT scans performed</td>
<td>Not all patients had CT scans performed; not clear whether any patients with intracranial injury had normal skull radiograph findings</td>
<td>X</td>
</tr>
<tr>
<td>Nagurney, 1998</td>
<td>Retrospective</td>
<td>1,649 patients aged &gt;15 y; CT followed Masters criteria for moderate risk; elderly defined as &gt;59 y; nonelderly defined as 16–59 y</td>
<td>Positive CT scan findings; need for neurosurgery</td>
<td>318 elderly patients; 1,231 nonelderly patients; ratio of men to women was 3:1 in nonelderly patients and 1:1 in elderly patients; 64 (20%) elderly patients and 170 (13%) nonelderly patients had positive CT findings; 11 (3%) elderly patients and 33 (2%) nonelderly patients needed neurosurgery; focally abnormal neurologic examination imparted a risk ratio for abnormal CT scan findings of 4.4 in elderly patients and 7.75 in nonelderly patients</td>
<td>GCS scores not provided; selection bias; abnormal neurologic examination included old lesions; no follow-up; concludes that elderly patients are at higher risk on the basis of age alone, but does not break down correlation of age with GCS score (ie, the elderly group may have had lower GCS scores)</td>
<td>III</td>
</tr>
<tr>
<td>Nagy, 1999</td>
<td>Prospective</td>
<td>1,170 patients with GCS score of 15 in the trauma center with history of LOC/amnesia; all had CT scans performed and were admitted for 24-h observation</td>
<td>Positive CT scan findings; deterioration</td>
<td>1,170 (78%) of 1,485 patients with blunt head injury; 247 (21%) patients positive for ETOH or drugs; 39 (3.3%) patients with positive CT scan findings; 21 (1.8%) had change in therapy based on CT scan findings, including 4 (0.34%) neurosurgeries; no patient deteriorated; recommends discharge if CT scan findings are normal</td>
<td>969 (81%) patients had unknown LOC; 39 (3.3%) patients with positive CT scan findings (low) and 21 (1.8%) with change in therapy (high) suggests selection bias</td>
<td>II</td>
</tr>
<tr>
<td>Nee, 1999</td>
<td>Retrospective</td>
<td>5,416 patients; all ages</td>
<td>Skull fracture</td>
<td>Higher incidence of vomiting in patients with a skull fracture</td>
<td>No CT scans performed; no follow-up</td>
<td>X</td>
</tr>
<tr>
<td>Pozzati, 1980</td>
<td>Case series</td>
<td>30 patients between the ages of 10–72 y</td>
<td>No discussion of initial presentation or CT scan findings</td>
<td>No discussion of initial presentation or CT scan findings</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Reinus, 1993</td>
<td>Retrospective</td>
<td>373 consecutive trauma patients age &gt;14 y; inclusion not well defined</td>
<td>Positive CT scan findings</td>
<td>Multivariate analysis using logistic regression on data set; abnormal neurologic examination, intoxication, amnesia, or a history of focal neurologic deficit give a negative predictive value of 98% and a sensitivity of 91% for abnormal CT scan findings; 4 (9.1%) of 44 lesions would be missed using the scheme, but none required intervention</td>
<td>Inclusion/exclusion not defined; focal neurologic deficit included a history of deficit per patient; examination performed by house staff; small number of patients</td>
<td>II/NA</td>
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<tr>
<td>Riesgo, 1997</td>
<td>Case series</td>
<td>3 cases of delayed epidural after MTBI; initial GCS score &gt;12</td>
<td>Deterioration</td>
<td>Case 1: GCS score 15; initial CT scan was positive for fracture; deterioration after 30 h. Case 2: GCS score 14; initial CT scan findings were negative; deterioration after 6 h. Case 3: GCS score 13; initial CT scan was positive for occipital fracture; deterioration after 16 h.</td>
<td>Case series</td>
<td>III</td>
</tr>
<tr>
<td>Royal College of Radiologists, 1980</td>
<td>Prospective sample</td>
<td>5,858 patients; all ages</td>
<td>Skull fracture</td>
<td></td>
<td>No GCS; no correlation with clinical course</td>
<td>X</td>
</tr>
<tr>
<td>Saunders, 1986</td>
<td>Prospective</td>
<td>47 consecutive patients; inclusion/exclusion not specified</td>
<td>Remembering discharge instructions; deterioration</td>
<td>1 patient was discharged with normal examination results and skull radiographs; developed subdural hematoma; neurosurgery was performed; patient left with a deficit; observation at home is an illusion</td>
<td>Small number of patients; no CT scans performed</td>
<td>III</td>
</tr>
<tr>
<td>Schnyoll, 1993</td>
<td>Prospective</td>
<td>264 patients; all ages; inclusion: patients with head injury presenting within 2 weeks</td>
<td>Positive CT scan findings</td>
<td>9 high-yield criteria reviewed</td>
<td>More than 100,000 patients; only 264 cases identified; no set protocol</td>
<td>X</td>
</tr>
<tr>
<td>Servadei, 1988</td>
<td>Retrospective analysis of prospective database</td>
<td>98 patients aged &gt;14 y; GCS score of 14/15; headache, vertigo, vomiting, or prolonged LOC did not distinguish surgical group from nonsurgical group</td>
<td>Positive CT scan findings; surgical lesion</td>
<td>47 patients with positive skull fracture; 51 patients with no skull fracture</td>
<td>Unclear who was studied or time of observation/ follow-up; high number of positive skull fractures suggests selection bias</td>
<td>X</td>
</tr>
<tr>
<td>Servadei, 1989</td>
<td>Prospective</td>
<td>158 consecutive patients admitted with extradural hematoma</td>
<td>Skull fracture in 126 (80%) patients; parietal, temporal, or tempo-parietal location in 99 (63%) patients with extradural hematomas</td>
<td>Reason for referral and time out from injury not documented nor initial care given</td>
<td>Reason for referral and time out from injury not documented nor initial care given</td>
<td>X</td>
</tr>
<tr>
<td>Shackford, 1992</td>
<td>Retrospective, multicenter</td>
<td>2,166 patients; GCS score &gt;12; management at discretion of the trauma center; sample size calculation 2,300</td>
<td>Positive CT scans; deterioration</td>
<td>2,166 (78%) patients had CT scans performed; 468 (22%) had positive CT scan findings; 332 patients had a normal neurologic examination and normal CT scan findings, no neurosurgery; 1,170 had normal CT scan findings, none required craniotomy; 2,112 had a normal neurologic examination, and 59 required craniotomy. Of 1,899 patients with GCS score of 15, 282 (14.8%) had positive CT scan findings; 62 (3.2%) had craniotomy. Sensitivity of CT scans was 100%; positive predictive value was 10%; negative predictive value was 100%; sensitivity was 51%. 1 patient who was discharged from ED with normal examination and no CT scan returned with uncomplicated subdural hematoma. Abnormal neurologic examination associated with positive CT scan findings. “Patients with an MTBI and abnormal results on neurologic examination should be admitted because 1 in 4 will require treatment.” “Admission to the hospital does not guarantee skilled neurologic observation.”</td>
<td>Not all centers followed same protocol; GCS scores not correlated with CT scan findings; only 1,454 (76.5%) of 1,899 patients with GCS score of 15 had CT scans performed; limited follow-up</td>
<td>III</td>
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</table>
### Evidentiary Table (continued)

<table>
<thead>
<tr>
<th>Article, y</th>
<th>Design</th>
<th>Patients</th>
<th>Outcome Measure</th>
<th>Findings</th>
<th>Limitations</th>
<th>Class of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Snoey, 1994</td>
<td>Case series</td>
<td>3 patients with normal neurologic examinations and normal CT scan findings who were discharged</td>
<td>Deterioration</td>
<td>Average of 47 days from discharge and development of neurologic deficits</td>
<td></td>
<td>III</td>
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<tr>
<td>Stein, 1990</td>
<td>Retrospective</td>
<td>658 patients with GCS score &gt;12 who presented to trauma center within 6 hours of injury</td>
<td>Positive CT scan findings; deterioration</td>
<td>658 patients aged &gt;3 y (454 with GCS score of 15); none of 542 patients with normal CT scan findings deteriorated; none needed surgery; abnormal CT scan findings—GCS score of 15: 59 (13.0%) of 454; GCS score of 14: 32 (22.5%) of 142; GCS score of 13: 25 (40.3%) of 62; 17 (3.7%) of 454 patients with GCS score of 15 required neurosurgery</td>
<td>No set protocol; selection toward sicker patients</td>
<td>III</td>
</tr>
<tr>
<td>Stein, 1991</td>
<td>Retrospective</td>
<td>658 patients</td>
<td>Positive CT scan findings; deterioration</td>
<td>Cost analysis</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Stein, 1992</td>
<td>Retrospective</td>
<td>1,538 MTBI during 4 y period; all had normal or &quot;near normal&quot; examinations</td>
<td>Positive CT scan findings; deterioration</td>
<td>265 (17.2%) patients had positive CT scan findings; of 209 patients with intracranial lesions, 95 (45.5%) had a concomitant skull fracture; none of 1,339 patients with normal CT scan findings deteriorated; screening strategy using skull radiographs would have missed 23 of 36 patients needing surgery</td>
<td>Selection bias; unknown how many patients were not scanned; unknown power analysis</td>
<td>III</td>
</tr>
<tr>
<td>Stiell, 2001</td>
<td>Prospective cohort; derivation study</td>
<td>3,121 patients aged &gt;15 y; 2,489 (80%) patients with a GCS score of 15; all had LOC, amnesia, or disorientation; structured, standardized data sheet used</td>
<td>Clinically significant brain injury, (ie, neurosurgical lesion, need for intracranial pressure monitoring, intubation)</td>
<td>348 (11%) patients had any acute brain injury shown on CT scan; 44 (1%) needed neurosurgical intervention; derived CT head rule with 5 high-risk predictors: failure to reach GCS score of 15 within 2 hours, suspected open skull fracture, sign of basal skull fracture, vomiting more than once, age &gt;64 y; high-risk factors were 100% sensitive for predicting need for neurosurgery and would decrease need for head CT scan by 68%</td>
<td>2,078 (67%) patients were scanned; 1,043 (33%) had a structured assessment survey for clinically important lesion at 14 days after discharge; only 172 patients who did not have a CT scan performed were followed up (172 randomly selected patients); solitary contusions &lt;5 mm, localized SAH &lt;1 mm, smear subdural hematomas &lt;4 mm thick, isolated pneumocephaly, and closed depressed skull fracture not through the inner table were not considered clinically important (based on survey consensus); no patients who had a CT scan performed were followed up based on the assumption from a survey and 1 abstract that their lesions were unimportant; needs validations; did not address the outcome measure used in this policy</td>
<td>II</td>
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</table>
### Evidentiary Table (continued)

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<tr>
<td>Taheri, 1993</td>
<td>Prospective</td>
<td>407 patients; 310 patients with GCS score of 15; age &gt;13 y</td>
<td>Deterioration</td>
<td>290 of 310 patients with LOC; 336 skull film radiographs; 16 fractures; 184 patients had CT scans performed; 76 had positive CT scan finding</td>
<td>No clear protocol; unclear presentations; no follow-up</td>
<td>X</td>
</tr>
<tr>
<td>Vilke, 2000</td>
<td>Prospective</td>
<td>Convenience sample; 58 patients with GCS score of 15; age &gt;13 y; clinically sober with LOC/amnesia; standardized neurologic examination, including mental status, followed by CT</td>
<td>Positive CT scan findings</td>
<td>71% of patients presented within 3 h of trauma; 82% of patients presented within 24 h of trauma; 55 of 58 patients had normal CT scan findings; 23 of 58 patients had focal findings; 3 (5.2%) patients had positive CT scan findings; 2 patients had normal neurologic examination results, including 1 (1.7%) who required neurosurgery (patient had temporal parietal hematoma and left facial swelling); 23 patients had abnormal neurologic examination results (10 had abnormal 3-object recall, 8 had abnormal cerebellar); conclude that significant brain injury cannot be excluded despite normal neurologic examination</td>
<td>Small number of patients; strengths are a structured neurologic examination and performance of CT on all patients</td>
<td>II</td>
</tr>
<tr>
<td>Voss, 1995</td>
<td>Retrospective</td>
<td>606 patients who returned to the hospital after discharge for traumatic brain injury</td>
<td>Positive CT scan findings or neurosurgery</td>
<td>28,364 patients with head injuries during a 5-year period; age &gt;13 y; 11,700 skull film radiographs (obtained in all patients with LOC/amnesia); 606 (2.1%) patients returned within mean of 6 days; 539 had an initial skull film, of which 97 (18%) were positive; 33 (34%) of 97 had positive CT scan findings, and 16 (16.5%) of 97 had neurosurgery; only predictor of need for neurosurgery was a positive vault fracture</td>
<td>Initial GCS score not presented; no set protocol; most patients did not have initial CT scans performed</td>
<td>X</td>
</tr>
<tr>
<td>Williams, 1990</td>
<td>Retrospective analysis</td>
<td>215 patients; 78 patients with closed head injury with normal CT scan findings; 77 patients with closed head injury with positive CT scan findings or depressed skull fracture; 50 patients with GCS score of 9–12</td>
<td>Neuropsychiatric testing: verbal fluency, verbal memory, information processing speed, and recognition memory</td>
<td>Patients with complicated MTBI had longer periods of impaired consciousness, PTA, impaired verbal fluency, and impaired verbal memory compared with patients with MTBI; surgery did not have an effect on outcome measures; depressed skull fracture had no effect on outcome; study concludes that presence of a lesion on CT scan predicts more complicated course and has implications for follow-up</td>
<td>Unclear how patients were selected</td>
<td>II</td>
</tr>
<tr>
<td>Zimmerman, Retrospective 1978</td>
<td>286 patients (adults and children) with acute head trauma</td>
<td>Positive skull film radiograph or CT scan findings</td>
<td>68% of patients with positive CT scan findings had a skull fracture</td>
<td>GCS not given</td>
<td>X</td>
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**PTA,** Posttraumatic amnesia; **NA,** not applicable; **PCS,** postconcussive syndrome; **ETOH,** ethanol; **SAH,** subarachnoid hemorrhage.