Identification of children at very low risk of clinically-important brain injuries after head trauma: a prospective cohort study

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Summary

Background CT imaging of head-injured children has risks of radiation-induced malignancy. Our aim was to identify children at very low risk of clinically-important traumatic brain injuries (ciTBI) for whom CT might be unnecessary.

Methods We enrolled patients younger than 18 years presenting within 24 h of head trauma with Glasgow Coma Scale scores of 14–15 in 25 North American emergency departments. We derived and validated age-specific prediction rules for ciTBI (death from traumatic brain injury, neurosurgery, intubation >24 h, or hospital admission ≥2 nights).

Findings We enrolled and analysed 42 412 children (derivation and validation populations: 8502 and 2216 younger than 2 years, and 25 283 and 6411 aged 2 years and older). We obtained CT scans on 14 969 (35·3%); ciTBIs occurred in 376 (0·9%), and 60 (0·1%) underwent neurosurgery. In the validation population, the prediction rule for children younger than 2 years (normal mental status, no scalp haematoma except frontal, no loss of consciousness or loss of consciousness for less than 5 s, non-severe injury mechanism, no palpable skull fracture, and acting normally according to the parents) had a negative predictive value for ciTBI of 1176/1176 (100·0%, 95% CI 99·7–100 0) and sensitivity of 25/25 (100%, 86·3–100·0). 167 (24·1%) of 694 CT-imaged patients younger than 2 years were in this low-risk group. The prediction rule for children aged 2 years and older (normal mental status, no loss of consciousness, no vomiting, non-severe injury mechanism, no signs of basilar skull fracture, and no severe headache) had a negative predictive value of 3798/3800 (99·95%, 99·81–99·99) and sensitivity of 61/63 (96·8%, 89·0–99·6). 446 (20.1%) of 2223 CT-imaged patients aged 2 years and older were in this low-risk group. Neither rule missed neurosurgery in validation populations.

Interpretation These validated prediction rules identified children at very low risk of ciTBIs for whom CT can routinely be obviated.

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Introduction

Traumatic brain injury is a leading cause of death and disability in children worldwide. In the USA, head trauma in individuals aged 18 years and younger results in about 7400 deaths, over 60 000 hospital admissions, and over 600 000 emergency department visits every year.[1,2] Children with clinically-important traumatic brain injury (ciTBI) needing acute intervention, especially neurosurgery, should be identified rapidly. CT is the reference standard for emergently diagnosing traumatic brain injuries, although some brain injuries are not seen on CT.[3,4] About 50% of children assessed in North American emergency departments for head trauma undergo CT[5,6] (Faul M, Centers for Disease Control and Prevention, personal communication). Between 1995 and 2005, CT use more than doubled.[6,7] Furthermore, many traumatic brain injuries identified on CT do not need acute intervention, and some are false positives or non-traumatic findings. Clinical studies using abnormal CT findings as the outcome measure for identifying children with traumatic brain injuries might promote excessive CT use. Children with apparently minor head trauma (Glasgow Coma Scale [GCS] scores of 14–15) are the group most frequently assessed. These children commonly undergo neuroimaging and account for 40–60% of those with traumatic brain injuries seen on CT.[8–11] Less than 10% of CT scans in children with minor head trauma, however, show traumatic brain injuries. Furthermore, injuries needing neurosurgery are very uncommon in children with GCS scores of 14–15.[10–13]

Reduction of CT use is important because ionising radiation from CT scans can cause lethal malignancies.[14–16] The estimated rate of lethal malignancies from CT is between 1 in 1000 and 1 in 5000 paediatric cranial CT

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Panel 1: Case report form

Mechanism of injury
- Occupant in motor vehicle crash (with documentation of ejection, rollover, death of other passenger, speed, restraint use)
- Pedestrian struck by vehicle
- Bicycle rider struck by automobile (with documentation of helmet use)
- Bicycle collision or fall (with documentation of helmet use)
- Other wheeled transport crash (with documentation if motorised or not)
- Fall to ground from standing, walking, or running
- Walked or ran into stationary object
- Fall from height (with estimated height)
- Fall down stairs (with number of stairs)
- Sport-related (with documentation of sport type, helmet use)
- Assault
- Head struck by object (unintentional)
- Other mechanism of injury

Clinical variables: history and symptoms
- Post-traumatic amnesia: inability to recall entire traumatic event
- History of loss of consciousness: a period of unconsciousness, categorised by duration (<5 s, 5–60 s, 1–5 min, and >5 min)
- Post-traumatic seizure: tonic and/or clonic jerking activity occurring after the traumatic event, categorised as occurring within or after 30 min of the injury, with duration categorised
- Headache : categorised as currently present or not, severity (mild [barely noticeable], moderate, or severe [intense]), location of headache, and timing of onset
- Vomiting: classified according to the presence or absence of a history of vomiting, number of episodes (once, twice, or more than two episodes), and when vomiting started
- Dizziness: any sensation of vertigo, sense of physical imbalance, or postural instability while in the emergency department
- Parental report of whether the patient is acting normally: whether patient is at baseline or not

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Clinical variables: physical examination findings
- GCS score: applied to patients older than 2 years of age[23]
- Paediatric GCS score: applied to children aged 2 years or younger[24]
- Other signs of altered mental status: defined by agitation, somnolence, repetitive questioning, or slow response to verbal communication
- Bulging anterior fontanelle: if fontanelle open
- Signs of basilar skull fracture: such as retro-auricular bruising (Battle's sign), periorbital bruising (raccoon eyes), haemotympanum, cerebral spinal fluid otorrhoea, or cerebral spinal fluid rhinorrhoea
- Palpable skull fracture: on digital inspection, or unclear on the basis of swelling or distortion of the scalp
- Scalp haematoma: swelling of the scalp (including the forehead), recorded by size as small (barely palpable <1 cm), medium (1–3 cm) or large (>3 cm), by location (frontal, temporal–parietal, or occipital), and by character (boggy or firm)
- Neurological deficits: any abnormality of the cranial nerves, motor or sensory examinations, or deep tendon reflexes
- Suspected alcohol or drug intoxication

Other information collected on case report form
- Any signs of trauma above the clavicles (and location): including lacerations, abrasions, and haematomas
- Presence of other substantial (non-cranial) trauma: fractures, intra-abdominal injuries, intrathoracic injuries, or lacerations requiring operating-room repair*
- Was the patient observed in the emergency department after initial evaluation to decide whether to obtain CT?
- Indications for CT scan (if CT obtained)
- Disposition: home, general ward, intensive care unit, operating room, death

*Isolated head trauma is defined by the absence of any of these factors.

scans, with risk increasing as age decreases.[14,15] Clear data for CT use, however, are unavailable, therefore resulting in substantial practice variation.[17] Previous predictive models[8,10,18–20] are limited by small sample sizes, no validation, and/or no independent assessment of preverbal children (<2 years of age). Therefore, creation and validation of accurate, generalisable prediction rules for identifying children at very low risk of ciTBI are needed. A systematic review[21] of head CT prediction rules has recently emphasised the need for a large prospective study of children with minor head trauma to derive and validate a precise rule, and has specifically recommended deriving a separate rule for very young children.

Our aim was to derive and validate prediction rules for ciTBI to identify children at very low risk of ciTBI after blunt head trauma for whom CT might be unnecessary.

Methods

Patients and setting

We did a prospective cohort study of patients younger than 18 years with head trauma in 25 emergency departments of a paediatric research network.[22] The study was approved by the Human Subjects Research Committee at each site with waiver of consent at some sites and verbal consent for telephone follow-up at others. We enrolled the derivation population from June, 2004, to March, 2006, and the validation population from March through September, 2006.

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Inclusion and exclusion criteria

Children presenting within 24 h of head trauma were eligible. We excluded children with trivial injury mechanisms defined by ground-level falls or walking or running into stationary objects, and no signs or symptoms of head trauma other than scalp abrasions and lacerations. Patients were also excluded if they had penetrating trauma, known brain tumours, pre-existing neurological disorders complicating assessment, or neuroimaging at an outside hospital before transfer. Patients with ventricular shunts, bleeding disorders, and GCS scores less than 14 were enrolled but are being analysed separately. Eligible patients not enrolled were identified by review of emergency department patient logs. We compared enrolled and missed patients to assess enrolment bias.

Standardised assessments and quality assurance

Trained site investigators and other emergency department physicians recorded patient history, injury mechanism, and symptoms and signs on a standardised data form (panel 1) before knowing imaging results (if imaging was done). Amnesia, headache, and dizziness were not recorded for children younger than 2 years. At each site, about 4% of patients had a separate, independent assessment done by another emergency department physician within 60 min of the first assessment to check inter-rater reliability. Quality-assurance practices included double and random triple data entry, and annual site monitoring visits.

Outcome measures

We defined ciTBI a priori as death from traumatic brain injury, neurosurgery, intubation for more than 24 h for traumatic brain injury, or hospital admission of 2 nights or more associated with traumatic brain injury on CT (panel 2). We defined this outcome to exclude brief intubations for imaging or overnight admission for minor CT findings. We sought a meaningful measure for clinical decision making, which also accounted for the imperfect specificity of CT (ie, false-positive scans that might result in overnight hospital admissions). Site investigators, unaware of emergency department data, verified outcomes by medical record review.

CT scans were obtained at the emergency department clinician's discretion with helical CT scanners, with radiographic slices separated by 10 mm or less. CT scans were interpreted by site faculty radiologists. A study paediatric radiologist, unaware of clinical data, made definitive interpretations of inconclusive CT scans.

Follow-up procedures

Patients were admitted to the hospital at emergency department physician discretion. Records of admitted patients were reviewed by research coordinators and site investigators to assess CT results and presence of ciTBIs. To identify missed traumatic brain injuries, research coordinators did standardised telephone surveys of guardians of patients discharged from the emergency department between 7 and 90 days after the emergency department visit. Medical records and imaging results were obtained if a missed traumatic brain injury was suggested at follow-up. If a ciTBI was identified, the patient's outcome was classified accordingly. If we were unable to contact the patient's guardian, we reviewed the medical record, emergency department process improvement records, and county morgue records, to ensure that

Panel 2: Traumatic brain injury outcome definitions

Clinically-important traumatic brain injury (ciTBI)

Defined by any of the following descriptions:

- Death from traumatic brain injury
- Neurosurgical intervention for traumatic brain injury
    - Intracranial pressure monitoring
    - Elevation of depressed skull fracture
    - Ventriculostomy
    - Haematoma evacuation
    - Lobectomy
    - Tissue debridement
    - Dura repair
    - Other
- Intubation of more than 24 h for traumatic brain injury*
- Hospital admission of 2 nights or more for the traumatic brain injury in association with traumatic brain injury on CT†
    - Hospital admission for traumatic brain injury defined by admission for persistent neurological symptoms or signs such as persistent alteration in mental status, recurrent emesis due to head injury, persistent severe headache, or ongoing seizure management

Traumatic brain injury on CT

Defined by any of the following descriptions:

- Intracranial haemorrhage or contusion
- Cerebral oedema
- Traumatic infarction
- Diffuse axonal injury
- Shearing injury
- Sigmoid sinus thrombosis
- Midline shift of intracranial contents or signs of brain herniation
- Diastasis of the skull
- Pneumocephalus
- Skull fracture depressed by at least the width of the table of the skull‡

*The 24-h period of endotracheal intubation for traumatic brain injury was used to avoid misclassification of patients who might need brief intubation for airway protection for CT imaging, transfer between hospitals, or caused by altered consciousness from anticonvulsant medication use. †The 2-night definition was created to exclude those children routinely admitted for overnight observation because of minor CT findings that do not need any specific intervention.[10] ‡Skull fractures were not regarded as traumatic brain injuries on CT unless the fracture was depressed by at least the width of the skull. This is because children with isolated non-depressed skull fractures typically do not need specific therapy or hospital admission.[25,26]

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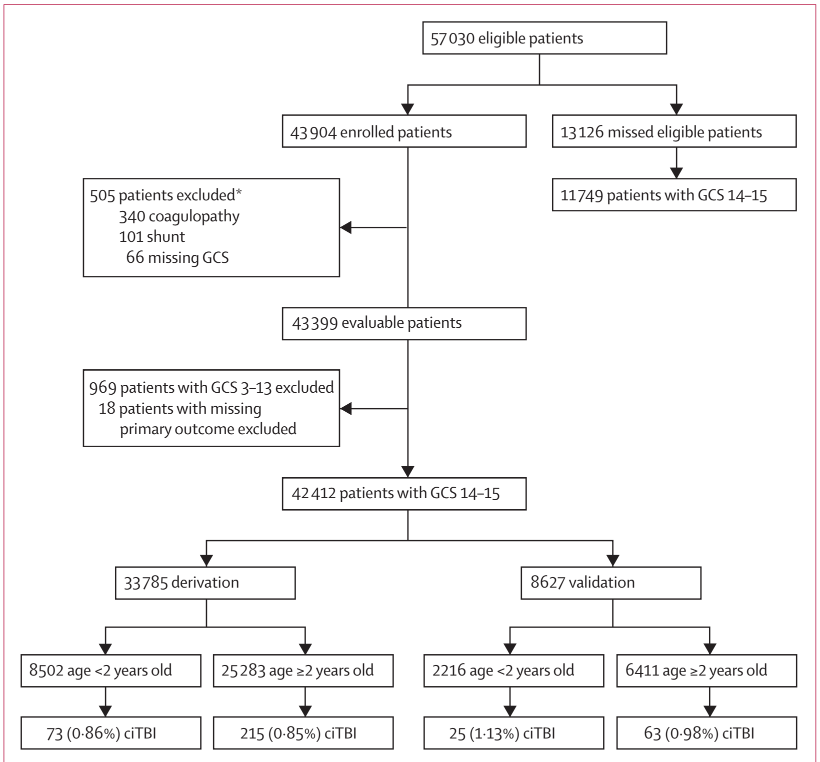

Figure 1: **Flow chart**
GCS=Glasgow Coma Scale. ciTBI=clinically-important traumatic brain injury. *Two patients had more than one exclusion.

no discharged patient was subsequently diagnosed with ciTBI.

Selection of predictors

We adhered to established prediction rule methods,[27,28] and STAndards for the Reporting of Diagnostic accuracy studies (STARD) guidelines for diagnostic accuracy studies. For rule derivation, we evaluated the injury mechanisms and clinical variables in panel 1, the kappa statistics of which had point estimates of 0·5 or more, with lower bounds of the one-sided 95% CI of 0·4 or more (indicating at least moderate inter-observer agreement),[29] calculated on those patients with two independent assessments. Only dizziness and scalp haematoma had insufficient inter-observer agreement.[30] Injury mechanisms were divided a priori into three categories: severe (motor vehicle crash with patient ejection, death of another passenger, or rollover; pedestrian or bicyclist without helmet struck by a motorised vehicle; falls of more than 1·5 m (5 feet) for children aged 2 years and older and more than 0·9 m (3 feet) for those younger than 2 years; or head struck by a high-impact object), mild (ground-level falls or running into stationary objects), and moderate (any other mechanism). The composite variable altered mental status was defined a priori by GCS score lower than 15, agitation, sleepiness, slow responses, or repetitive questioning.

For more on **STARD guidelines** see http://www.stard-statement.org/

Statistical analysis

Preverbal (<2 years of age) and verbal (2 years and older) children were analysed separately because of young patients' greater sensitivity to radiation, minimal ability to communicate, and different mechanisms and risks for traumatic brain injury.[9,15,31,32] Because the main goal of these analyses was to identify children at very low risk of ciTBI in whom CT can be avoided, we aimed to maximise the negative predictive value and sensitivity of the prediction rules. We regarded a child to be at very low risk of ciTBI if none of the predictors in the derived rules was present. We derived the rules with binary recursive partitioning (CART PRO 6.0; San Diego, CA, USA, Salford Systems).[33] We used ten-fold cross validation to create stable prediction trees, and standard Gini splitting rules.[33] To keep risks of misclassification of patients with ciTBIs to a minimum, we assigned a relative cost of 500 to 1 for failure to identify a patient with ciTBI versus incorrect classification of a patient without ciTBI.[10] To validate the rules, we examined rule performance in the same age validation cohort. We report test characteristics for each rule in the validation groups and calculated 95% CIs with exact methods.

Role of the funding source

The sponsors had no role in study design, study conduct, data collection, data interpretation, and report preparation. The corresponding author has access to all data and had final responsibility for the decision to submit for publication.

Results

Of 57 030 eligible patients, we enrolled 43 904 (77%; figure 1). Of 42 412 patients eligible for analysis, mean age was 7·1 years (SD 5·5) and 10 718 (25%) were younger than 2 years. The injury mechanisms were: fall from height (n=11 665, 27%), fall from ground level or ran into stationary object (n=7106, 17%), occupant in motor vehicle crash (n=3717, 9%), head struck by an object (n=3124, 7%), assault (n=2981, 7%), sport-related (n=2934, 7%), fall down the stairs (n=2858, 7%), bicycle collision or fall (n=1668, 4%), pedestrian struck by vehicle (n=1303, 3%), other wheeled transport crash (n=852, 2%), bicyclist struck by automobile (n=524, 1%), other (n=3397, 8%), and unknown (n=283, 1%). Isolated head trauma occurred in 90%, and 41 071 (97%) had GCS scores of 15. Patient characteristics and outcomes were similar between derivation and validation populations (table 1). However, frequencies of most predictor variables differed significantly between children with and without ciTBI (tables 2 and 3).

CT scans were obtained on 14 969 (35·3%) patients, of whom 780 (5·2%, 95% CI 4·9–5·6) had traumatic brain injuries on CT. 376 of 42 412 patients (0·9%, 0·8–1·0) had ciTBIs, with similar percentages in both age groups, and in derivation and validation populations. Of the 376 with ciTBIs, 60 (15·9%) underwent neurosurgery. Eight

	Age <2 years (n=10 718)		Age ≥2 years (n=31 694)	
	Derivation (n=8502)	Validation (n=2216)	Derivation (n=25 283)	Validation (n=6411)
Severity of injury mechanism*				
Mild	1262/8424 (15·0%)	309/2186 (14·1%)	4505/25 128 (17·9%)	1030/6361 (16·2%)
Moderate	5322/8424 (63·2%)	1384/2186 (63·3%)	17 865/25 128 (71·1%)	4553/6361 (71·6%)
Severe	1840/8424 (21·8%)	493/2186 (22·6%)	2758/25 128 (11·0%)	778/6361 (12·2%)
History of LOC				
Known or suspected	425/8179 (5·2%)	116/2119 (5·5%)	4701/24 275 (19·4%)	1044/6120 (17·1%)
LOC duration				
No LOC	7754/8113 (95·6%)	2003/2102 (95·3%)	19574/22489 (87·0%)	5076/5706 (89·0%)
<5 s	61/8113 (0·8%)	20/2102 (1·0%)	679/22489 (3·0%)	147/5706 (2·6%)
5–60 s	173/8113 (2·1%)	46/2102 (2·2%)	1331/22489 (5·9%)	272/5706 (4·8%)
1–5 min	79/8113 (1·0%)	24/2102 (1·1%)	781/22489 (3·5%)	181/5706 (3·2%)
>5 min	46/8113 (0·6%)	9/2102 (0·4%)	124/22489 (0·6%)	30/5706 (0·5%)
Headache	..	..	10296/21997 (46·8%)	2379/5498 (43·3%)
Severity of headache				
No headache	..	..	11701/21193 (55·2%)	3119/5301 (58·8%)
Mild	..	..	4262/21193 (20·1%)	986/5301 (18·6%)
Moderate	..	..	4572/21193 (21·6%)	1050/5301 (19·8%)
Severe	..	..	658/21193 (3·1%)	146/5301 (2·8%)
History of vomiting	1271/8446 (15·0%)	294/2190 (13·4%)	3236/25102 (12·9%)	756/6374 (11·9%)
Number of vomiting episodes				
0	7175/8389 (85·5%)	1896/2178 (87·1%)	21866/24964 (87·6%)	5618/6328 (88·8%)
1	548/8389 (6·5%)	128/2178 (5·9%)	1144/24964 (4·6%)	268/6328 (4·2%)
2	241/8389 (2·9%)	67/2178 (3·1%)	661/24964 (2·6%)	139/6328 (2·2%)
>2	425/8389 (5·1%)	87/2178 (4·0%)	1293/24964 (5·2%)	303/6328 (4·8%)
Acting abnormally according to parent	1166/8142 (14·3%)	273/2152 (12·7%)	3792/23177 (16·4%)	966/5935 (16·3%)
GCS score				
14	366/8502 (4·3%)	92/2216 (4·2%)	720/25283 (2·8%)	163/6411 (2·5%)
15	8136/8502 (95·7%)	2124/2216 (95·8%)	24563/25283 (97·2%)	6248/6411 (97·5%)
Altered mental status†	978/8444 (11·6%)	232/2205 (10·5%)	3427/25083 (13·7%)	850/6364 (13·4%)
Signs of basilar skull fracture	42/8408 (0·5%)	15/2187 (0·7%)	179/25052 (0·7%)	51/6344 (0·8%)
Palpable skull fracture (or unclear exam)	288/8488 (3·4%)	80/2210 (3·6%)	541/25220 (2·1%)	135/6393 (2·1%)
Scalp haematoma	3713/8458 (43·9%)	1000/2201 (45·4%)	9530/25085 (38·0%)	2472/6376 (38·8%)
Location of scalp haematoma				
No haematoma	4745/8417 (56·4%)	1201/2191 (54·8%)	15555/24967 (62·3%)	3904/6344 (61·5%)
Frontal	2340/8417 (27·8%)	629/2191 (28·7%)	4593/24967 (18·4%)	1191/6344 (18·8%)
Temporal or parietal	833/8417 (9·9%)	226/2191 (10·3%)	2541/24967 (10·2%)	636/6344 (10·0%)
Occipital	499/8417 (5·9%)	135/2191 (6·2%)	2278/24967 (9·1%)	613/6344 (9·7%)
Outcomes				
TBI on CT‡	214/2632 (8·1%)	68/694 (9·8%)	382/9420 (4·1%)	116/2223 (5·2%)
ciTBI‡	73/8502 (0·9%)	25/2216 (1·1%)	215/25283 (0·9%)	63/6411 (1·0%)
Neurosurgery	14/8502 (0·2%)	5/2216 (0·2%)	30/25283 (0·1%)	11/6411 (0·2%)

Data are n/N (%). LOC=loss of consciousness. GCS=Glasgow Coma Scale. TBI=traumatic brain injury. ciTBI=clinically-important traumatic brain injury. *Injury mechanism categories defined as follows: severe (motor vehicle crash with patient ejection, death of another passenger, or rollover; pedestrian or bicyclist without helmet struck by a motorised vehicle; falls of more than 1·5 m (5 feet) for patients aged 2 years and older, or more than 0·9 m (3 feet) for those younger than 2 years; or head struck by a high-impact object), mild (ground-level falls or running into stationary objects), and moderate (any other mechanism). †Defined as GCS=14 or: agitation, somnolence, repetitive questioning, or slow response to verbal communication. ‡See panel 2 for definition.

Table 1: **Distribution of prediction rule variables and outcomes, according to age group and study phase**

patients were intubated for more than 24 h for traumatic brain injury and no patients died from the injury.

3821 (9·0%) patients were admitted to the hospital. Of the 38 591 discharged, we successfully contacted 30 478 (79·0%) and reviewed medical records, trauma registries, process improvement reports, and morgue records for the remaining patients. 96 patients not imaged in the emergency department returned to a health-care facility

	ciTBI (n=98)	No ciTBI (n=10 620)	Difference
Severity of injury mechanism			
Mild	4/92, 4·3% (1·2 to 10·8)	1567/10 518, 14·9% (14·2 to 15·6)	–10·6% (–14·8 to –6·3)
Moderate	42/92, 45·7% (35·2 to 56·4)	6664/10 518, 63·4% (62·4 to 64·3)	–17·7% (–27·9 to –7·5)
Severe	46/92, 50·0% (39·4 to 60·6)	2287/10 518, 21·7% (21·0 to 22·5)	28·3% (18·0 to 38·5)
History of LOC			
Known or suspected	20/80, 25·0% (16·0 to 35·9)	521/10 218, 5·1% (4·7 to 5·5)	19·9% (10·4 to 29·4)
LOC duration			
No LOC	60/77, 77·9% (67·0 to 86·6)	9697/10 138, 95·7% (95·2 to 96·0)	–17·7% (–27·0 to –8·5)
<5 s	2/77, 2·6% (0·3 to 9·1)	79/10 138, 0·8% (0·6 to 1·0)	1·8% (–1·7 to 5·4)
5–60 s	8/77, 10·4% (4·6 to 19·5)	211/10 138, 2·1% (1·8 to 2·4)	8·3% (1·5 to 15·1)
1–5 min	4/77, 5·2% (1·4 to 12·8)	99/10 138, 1·0% (0·8 to 1·2)	4·2% (–0·7 to 9·2)
>5 min	3/77, 3·9% (0·8 to 11·0)	52/10 138, 0·5% (0·4 to 0·7)	3·4% (–0·9 to 7·7)
Acting abnormally according to parent	38/82, 46·3% (35·3 to 57·7)	1401/10 212, 13·7% (13·1 to 14·4)	32·6% (21·8 to 43·4)
GCS score			
14	33/98, 33·7% (24·4 to 43·9)	425/10 620, 4·0% (3·6 to 4·4)	29·7% (20·3 to 39·0)
15	65/98, 66·3% (56·1 to 75·6)	10 195/10 620, 96·0% (95·6 to 96·4)	–29·7% (–39·0 to –20·3)
Altered mental status*	50/97, 51·5% (41·2 to 61·8)	1160/10 552, 11·0% (10·4 to 11·6)	40·6% (30·6 to 50·5)
Palpable skull fracture (or unclear exam)	34/98, 34·7% (25·4 to 45·0)	334/10 600, 3·2% (2·8 to 3·5)	31·5% (22·1 to 41·0)
Scalp haematoma	64/97, 66·0% (55·7 to 75·3)	4649/10 562, 44·0% (43·1 to 45·0)	22·0% (12·5 to 31·4)
Location of scalp haematoma			
No haematoma	33/97, 34·0% (24·7 to 44·3)	5913/10 511, 56·3% (55·3 to 57·2)	–22·2% (–31·7 to –12·8)
Frontal	7/97, 7·2% (2·9 to 14·3)	2962/10 511, 28·2% (27·3 to 29·1)	–21·0% (–26·2 to –15·7)
Temporal or parietal	47/97, 48·5% (38·2 to 58·8)	1012/10 511, 9·6% (9·1 to 10·2)	38·8% (28·9 to 48·8)
Occipital	10/97, 10·3% (5·1 to 18·1)	624/10 511, 5·9% (5·5 to 6·4)	4·4% (–1·7 to 10·4)

Data are n/N, percentage (95% CI). ciTBI=clinically-important traumatic brain injury. LOC=loss of consciousness. GCS=Glasgow Coma Scale. *Defined as GCS=14 or: agitation, somnolence, repetitive questioning, or slow response to verbal communication.

Table 2: **Bivariable analysis of tree predictor variables of ciTBI for children younger than 2 years**

for reasons related to the same traumatic event and were imaged with CT. Traumatic brain injuries were seen in five (5·2%). One patient was admitted for 2 nights for a cerebral contusion.

Of 54 161 eligible patients with GCS scores of 14–15, 11 749 (21·7%) were missed. When enrolled and missed patients were compared, differences in mean age (7·1 *vs* 7·8 years), percentage of patients younger than 2 years (25·3% *vs* 21·6%), and percentage of patients with GCS score of 15 (96·8% *vs* 98·6%) were small. CT scans were obtained in 14 969 (35·3%) of 42 412 enrolled patients and 4212 (35·9%) of 11 721 missed patients (p=0·20); 780 (5·2%) of 14 969 enrolled patients and 207 (4·9%) of 4212 missed patients had traumatic brain injuries on CT (p=0·44).

In the derivation and validation groups for children younger than 2 years, 4529 (53·3%) of 8502, and 1176 (53·1%) of 2216 patients, respectively, had none of the six predictors in the rule (figure 2A): altered mental status, non-frontal scalp haematoma, loss of consciousness for 5 s or more, severe injury mechanism, palpable skull fracture, or not acting normally according to the parent. CTs were obtained in 2632 (31·0%) patients in the derivation group and 694 (31·3%) in the validation group. Of these CTs, 668 (25·4%) and 167 (24·1%) were in children with none of the six predictors (in derivation and validation groups, respectively). This group of children has a very low risk of ciTBI and CTs could be obviated. In the validation group, the prediction rule (ie, no predictors present *vs* any predictors) had a negative predictive value of 1176/1176 (100%, 95% CI 99·7–100·0) and sensitivity of 25/25 (100%, 86·3–100·0). No child with ciTBI in the validation group was misclassified. Among all enrolled children younger than 2 years who had either altered mental status or palpable skull fractures, the risk of ciTBI was 4·4%. The risk of ciTBI for those with any of the other four predictors in the rule was 0·9%, and for those with none of the six predictors was less than 0·02%.

In the derivation and validation groups for children aged 2 years and older, 14 663 (58·0%) of 25 283, and 3800 (59·3%) of 6411, respectively, had none of the six predictors in the rule (figure 2B): abnormal mental status, any loss of consciousness, history of vomiting, severe injury mechanism, clinical signs of basilar skull fracture, or severe headache. Although the predictor vomiting was assessed in several different forms (presence, number, and timing), its simple presence was identified as the most useful form in the prediction tree. CTs were obtained in 9420 (37·3%) patients in the

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	ciTBI (n=278)	No ciTBI (n=31416)	Difference
Severity of injury mechanism			
Mild	17/275, 6·2% (3·6 to 9·7)	5518/31 214, 17·7% (17·3 to 18·1)	–11·5% (–14·4 to –8·6)
Moderate	160/275, 58·2% (52·1 to 64·1)	22 258/31 214, 71·3% (70·8 to 71·8)	–13·1% (–19·0 to –7·3)
Severe	98/275, 35·6% (30·0 to 41·6)	3438/31 214, 11·0% (10·7 to 11·4)	24·6% (19·0 to 30·3)
History of LOC			
Known or suspected	139/241, 57·7% (51·2 to 64·0)	5606/30 154, 18·6% (18·1 to 19·0)	39·1% (32·8 to 45·3)
LOC duration			
No LOC	102/161, 63·4% (55·4 to 70·8)	24 548/28 034, 87·6% (87·2 to 88·0)	–24·2% (–31·7 to –16·7)
<5 s	7/161, 4·3% (1·8 to 8·8)	819/28 034, 2·9% (2·7 to 3·1)	1·4% (–1·7 to 4·6)
5–60 s	21/161, 13·0% (8·3 to 19·2)	1582/28 034, 5·6% (5·4 to 5·9)	7·4% (2·2 to 12·6)
1–5 min	26/161, 16·1% (10·8 to 22·8)	936/28 034, 3·3% (3·1 to 3·6)	12·8% (7·1 to 18·5)
>5 min	5/161, 3·1% (1·0 to 7·1)	149/28 034, 0·5% (0·4 to 0·6)	2·6% (–0·1 to 5·3)
Headache	163/222, 73·4% (67·1 to 79·1)	12 512/27 273, 45·9% (45·3 to 46·5)	27·5% (21·7 to 33·4)
Severity of headache			
No headache	59/189, 31·2% (24·7 to 38·4)	14 761/26 305, 56·1% (55·5 to 56·7)	–24·9% (–31·5 to –18·3)
Mild	25/189, 13·2% (8·7 to 18·9)	5223/26 305, 19·9% (19·4 to 20·3)	–6·6% (–11·5 to –1·8)
Moderate	81/189, 42·9% (35·7 to 50·2)	5541/26305, 21·1% (20·6 to 21·6)	21·8% (14·7 to 28·9)
Severe	24/189, 12·7% (8·3 to 18·3)	780/26 305, 3·0% (2·8 to 3·3)	9·7% (5·0 to 14·5)
History of vomiting	97/273, 35·5% (29·9 to 41·5)	3895/31 203, 12·5% (12·1 to 12·9)	23·1% (17·4 to 28·7)
Number of vomiting episodes			
0	176/266, 66·2% (60·1 to 71·8)	27 308/31 026, 88·0% (87·6 to 88·4)	–21·9% (–27·6 to –16·2)
1	40/266, 15·0% (11·0 to 19·9)	1372/31 026, 4·4% (4·2 to 4·7)	10·6% (6·3 to 14·9)
2	13/266, 4·9% (2·6 to 8·2)	787/31 026, 2·5% (2·4 to 2·7)	2·4% (–0·3 to 5·0)
>2	37/266, 13·9% (10·0 to 18·7)	1559/31 026, 5·0% (4·8 to 5·3)	8·9% (4·7 to 13·1)
GCS score			
14	74/278, 26·6% (21·5 to 32·2)	809/31 416, 2·6% (2·4 to 2·8)	24·0% (18·9 to 29·2)
15	204/278, 73·4% (67·8 to 78·5)	30 607/31 416, 97·4% (97·2 to 97·6)	–24·0% (–29·2 to –18·9)
Altered mental status*	174/278, 62·6% (56·6 to 68·3)	4103/31 169, 13·2% (12·8 to 13·5)	49·4% (43·7 to 55·1)
Signs of basilar skull fracture	37/275, 13·5% (9·6 to 18·1)	193/31 121, 0·6% (0·5 to 0·7)	12·8% (8·8 to 16·9)

Data are n/N, percentage (95% CI). ciTBI=clinically-important traumatic brain injury. LOC=loss of consciousness. GCS=Glasgow Coma Scale. *Defined as GCS=14 or: agitation, somnolence, repetitive questioning, or slow response to verbal communication.

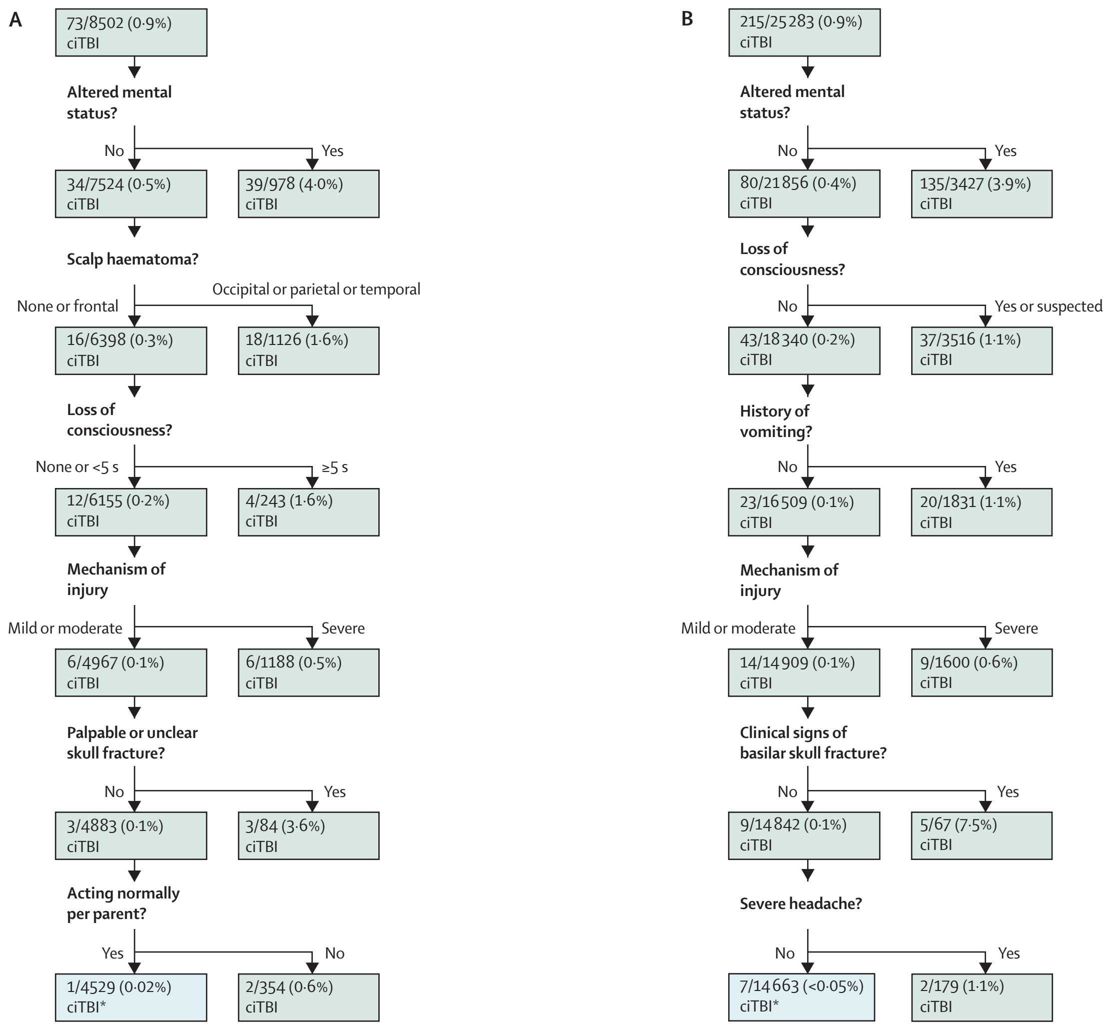
Table 3: **Bivariable analysis of tree predictor variables of ciTBI for children aged 2 years and older**

derivation and 2223 (34·7%) in the validation groups. Of these CTs, 1992 (21·1%) and 446 (20·1%) were in children with none of the six predictors (in derivation and validation groups, respectively), representing a very low risk group of children in whom CTs could be obviated. In the validation group, the prediction rule had a negative predictive value of 3798/3800 (99·95%, 99·81–99·99), and sensitivity of 61/63 (96·8%, 89·0–99·6).

In the validation group for children aged 2 years and older, two children with ciTBIs were classified as low risk. Neither required neurosurgery. One was a non-helmeted bicyclist who sustained multisystem trauma including substantial pulmonary injuries. He had a moderate headache and a large frontal scalp haematoma. CT showed a small frontal subdural haematoma. The second patient was a non-helmeted inline skater who skated down more than ten steps, and had a moderate headache and a large frontal scalp haematoma. CT showed occipital lobe contusions and a linear fracture. This patient was admitted for 2 nights. Among all enrolled children aged 2 years and older who had either altered mental status or signs of basilar skull fractures, the risk of ciTBI was 4·3%. The risk of ciTBI for those with any of the other four predictors in the rule was 0·9%, and for those with none of the six predictors was less than 0·05%.

Point estimates for the test characteristics of the prediction rules in both age groups were similar between derivation and validation populations. Furthermore, the CIs around these point estimates were substantially narrower in the large derivation populations (figure 2).

Although we derived rules to identify children at very low risk for ciTBIs, these rules did well for identifying children without traumatic brain injuries on CT. When assessing those who had CT scans in the validation groups, for patients younger than 2 years, the prediction rule had a negative predictive value for traumatic brain injury on CT of 167/167 (100·0%, 97·8–100·0) and sensitivity of 68/68 (100·0%, 94·7–100·0). For patients aged 2 years and older, the prediction rule had a negative



A

	Derivation			Validation		
	ciTBI	No ciTBI	Total	ciTBI	No ciTBI	Total
Any predictor present	72	3901	3973	25	1015	1040
No predictor present	1	4528	4529	0	1176	1176
Total	**73**	**8429**	**8502**	**25**	**2191**	**2216**

	Derivation	Validation
Prediction rule sensitivity (95% CI)	98·6% (92·6–99·97)	100·00% (86·3–100·00)
Prediction rule specificity (95% CI)	53·7% (52·6–54·8)	53·7% (51·6–55·8)
Negative predictive value (95% CI)	99·9% (99·88–99·999)	100·00% (99·7–100·00)
Positive predictive value (95% CI)	1·8% (1·4–2·3)	2·4% (1·6–3·5)
Negative likelihood ratio (95% CI)	0·03 (0·001–0·14)	0·0 (0–0·26)

B

	Derivation			Validation		
	ciTBI	No ciTBI	Total	ciTBI	No ciTBI	Total
Any predictor present	208	10 412	10 620	61	2550	2611
No predictor present	7	14 656	14 663	2	3798	3800
Total	**215**	**25 068**	**25 283**	**63**	**6348**	**6411**

	Derivation	Validation
Prediction rule sensitivity (95% CI)	96·7% (93·4–98·7)	96·8% (89·0–99·6)
Prediction rule specificity (95% CI)	58·5% (57·9–59·1)	59·8% (58·6–61·0)
Negative predictive value (95% CI)	99·95% (99·9–99·98)	99·95% (99·81–99·99)
Positive predictive value (95% CI)	2·0% (1·7–2·2)	2·3% (1·8–3·0)
Negative likelihood ratio (95% CI)	0·06 (0·03–0·11)	0·05 (0·01–0·19)

Figure 2: **Prediction tree for ciTBI in children younger than 2 years (A) and in those aged 2 years and older (B) in the derivation group**
ciTBI=clinically-important traumatic brain injury. *This box indicates children at very low risk of ciTBI in whom CT scans could be obviated.

predictive value for traumatic brain injury on CT of 439/446 (98·4%, 96·8–99·4) and a sensitivity of 109/116 (94·0%, 88·0–97·5).

Discussion

We derived and validated prediction rules for ciTBIs in a large, diverse population of children with minor head trauma. The large sample size allowed the derivation and validation of separate rules for children younger than 2 years and aged 2 years and older. The two rules are simple and intuitive, consist of readily available findings, and have a very high negative predictive value for identifying children without ciTBIs for whom CT scans could be omitted. Among all children enrolled, those with none of the six variables in the rules for whom CT scans could routinely be avoided accounted for 25% of

CTs in those younger than 2 years and 20% of CTs in those aged 2 years and older.

Data to guide clinical decision making for children with head trauma are urgently needed because head trauma is common and CT use is increasing.[6,7,15] Children sustaining minor head trauma infrequently have traumatic brain injuries and rarely need neurosurgery. The small risk of ciTBI after minor head trauma should be balanced against the risks of ionising radiation of CT.[15,34] Improved methods to assess head-injured children and evidence-based use of CT are research priorities.[15,32,34–36] CT scans are the source of two-thirds of the collective radiation from diagnostic imaging,[37] and an estimated one million children every year in the USA are unnecessarily imaged with CT.[15]

Many of the predictors identified in our rules have been studied previously with conflicting results, and variables identified as predictors of traumatic brain injuries in some studies were not predictive in others.[8–11,18–20,31,32] These conflicting results are partly attributable to insufficiently large sample sizes to produce precise risk estimates. Additionally, the lack of validation studies compromises the generalisability of previous rules. The current study is very large, allowing sufficient statistical power to generate robust and generalisable rules. Their accuracy was confirmed by validation populations. Furthermore, as recommended by the investigators of a recent systematic review of paediatric head CT prediction rules,[21] we validated the rules in a diverse population, and derived and validated a separate rule for preverbal children (<2 years of age).

Another important feature of our analysis is that we excluded children with GCS scores of less than 14, in whom the risk of traumatic brain injury on CT is more than 20%.[8,10,11,19,20] This substantial risk outweighs the radiation risk from CT, and therefore CT use in this group is not controversial. Inclusion of these patients with low GCS scores artificially increases rule performance. Similarly, our study also excluded asymptomatic children with very-low-risk injury mechanisms, to avoid overinflating the negative predictive value.

CT is the reference standard for rapid detection of traumatic brain injuries, but might also identify minor or unrelated findings irrelevant for acute management. Definitions of ciTBIs in children have not been agreed upon, although some previous prediction studies have excluded minor CT findings.[8,19] Conversely, CT imaging might miss some injuries identifiable by other modalities,[3,4] and children might need hospital admission for traumatic brain injury despite normal CT scans.[10] In our study, we used a patient-oriented composite outcome measure, which included both CT results and clinical outcomes. The use of a patient-oriented outcome overcomes the imperfect sensitivity and specificity of CT for identifying traumatic brain injuries, and allows minor and incidental CT findings to be ignored.

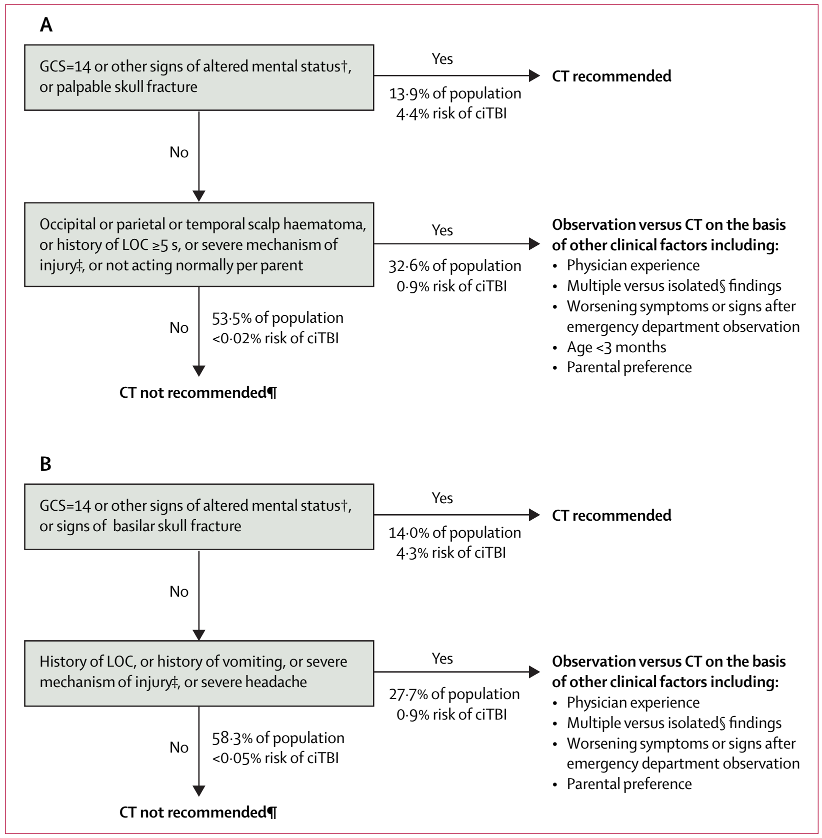


Figure 3*: Suggested CT algorithm for children younger than 2 years (A) and for those aged 2 years and older (B) with GCS scores of 14–15 after head trauma

GCS=Glasgow Coma Scale. ciTBI=clinically-important traumatic brain injury. LOC=loss of consciousness. *Data are from the combined derivation and validation populations. †Other signs of altered mental status: agitation, somnolence, repetitive questioning, or slow response to verbal communication. ‡Severe mechanism of injury: motor vehicle crash with patient ejection, death of another passenger, or rollover; pedestrian or bicyclist without helmet struck by a motorised vehicle; falls of more than 0·9 m (3 feet) (or more than 1·5 m [5 feet] for panel B); or head struck by a high-impact object. §Patients with certain isolated findings (ie, with no other findings suggestive of traumatic brain injury), such as isolated LOC,[39,40] isolated headache,[41] isolated vomiting,[41] and certain types of isolated scalp haematomas in infants older than 3 months,[31,42] have a risk of ciTBI substantially lower than 1%. ¶Risk of ciTBI exceedingly low, generally lower than risk of CT-induced malignancies. Therefore,CT scans are not indicated for most patients in this group.

Children younger than 2 years are the most sensitive to radiation, increasing the importance of CT reduction. Clinicians' confidence in assessing very young patients is also usually lower than for older patients, especially outside of children's hospitals. Furthermore, centres participating in this study were mainly paediatric hospitals with rates of CT use substantially lower than those in non-children's hospitals.[17] The potential reduction in CT use by application of these prediction rules could therefore be greater in general hospitals, where most children seeking emergency care in the USA are assessed.[38]

We identified a large group of children in whom CT can be avoided. Although the overall rate of CT use in this study was lower than that of the US national average,[6] application of the prediction rules might nonetheless result in substantial reduction of CT use in centres similar to those participating in our study. The extent of this reduction is unclear, however, as not all children outside of the very-low-risk category need CT. Data from the prediction trees (figure 2) suggest that children with minor head trauma can be grouped into three risk categories, which can inform CT decision making (figure 3). Altered mental status and signs of skull fracture are branch points in the prediction trees with high risks for ciTBIs. Children with either of these findings in each of these rules, respectively, had more than 4% risk of ciTBI. We, therefore, recommend CT scans for these children (14% of the combined derivation and validation populations). By contrast, children younger than 2 years and those 2 years and older with none of the variables in the appropriate prediction trees have less than 0·02% or less than 0·05% risk of ciTBI, respectively, suggesting that CT scans are not indicated for most children in these low-risk groups (57% of the total study population). The rest of the children with any of the other four predictors in the rule (29% of the total study population) have a 0·9% risk of ciTBI, and decisions about CT use for this group should be based on other factors. For example, those with isolated loss of consciousness (ie, with no other findings suggestive of traumatic brain injury),[39,40] isolated headache,[41] isolated vomiting,[41] and certain isolated scalp haematomas in infants older than 3 months,[31,42] have a risk of ciTBI substantially lower than 1% and observation without CT might be appropriate for most of these children. CT should be more strongly considered for children with multiple findings, worsening symptoms or signs, and for infants younger than 3 months. Clinician experience and parental preference should also be taken into account in CT decision making for this intermediate-risk group. For this group, the rules are assistive rather than directive,[43] empowering clinicians and parents with traumatic brain injury risk data for informed decision making about CT use and alternative management strategies.

Our study has limitations. We did not obtain CT scans on all patients because we could not ethically justify exposing children to radiation if the clinician did not think CT was indicated. We obtained follow-up, however, which is an acceptable alternative when definitive testing is not feasible or ethical.[44] To generate the trees, we assigned a relative cost of 500 to 1 for failure to identify ciTBI versus incorrect classification of a patient without ciTBI. Assignment of a higher relative cost could improve rule sensitivity (at the risk of losing specificity). When we re-analysed the data with a cost ratio of 1000 to 1, however, the variable sequence in the tree did not change. Sensitivities of the derived prediction rules were high but not perfect, which is difficult to achieve in a study of this size. The high rule sensitivities, however, were almost identical in both the derivation and validation populations, increasing the validity of the rule. As with other decision-support tools, however, these rules are meant to inform clinician, not to replace their decision making.[43] The CT rate in this network was less than the US national average, probably because of clinician experience at paediatric centres. The effect of the rule on reduction of CT use might therefore be greater in general emergency departments. Future investigations will be needed to assess the changes in CT use that result from widespread application of the rules. Finally, because the study aim was to identify ciTBIs for purposes of acute management, we did not assess long-term neurocognitive outcomes.

Overall, in this study of more than 42 000 children with minor blunt head trauma, we derived and validated highly accurate prediction rules for children at very low risk of ciTBIs for whom CT scans should be avoided. Application of these rules could limit CT use, protecting children from unnecessary radiation risks. Furthermore, these rules provide the necessary data to assist clinicians and families in CT decision making after head trauma.

Contributors

NK conceived the study, obtained grant funding, and together with JFH, PSD, JDH, SMA, JMD, JPM, and DHW designed the study. NK, JFH, PSD, JDH, SMA, FMN, DM, RMS, DAB, MKB, JES, KSQ, PM, RL, KAL, MGT, ESJ, JMC, MHG, TFG, LKL, MCB, AC, ECP, MJG, KAM, SLW-G obtained data and provided supervision for the study. RH and NK, together with JFH and PSD did the data analysis, and together with JMD and SJZ interpreted the data. NK drafted the report, and all authors critically revised the report.

PECARN study participants

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Conflicts of interest

We declare that we have no conflicts of interest.

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A Clinical Decision Rule for Cranial Computed Tomography in Minor Pediatric Head Trauma

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Objectives: To develop a sensitive clinical decision rule with a high negative predictive value for the use of cranial computed tomography (CT) in minor pediatric head trauma, to identify clinical features predictive of neurosurgical intervention, and to assess clinicians' predictive abilities to determine the presence or absence of intracranial injury based on history and physical examination alone.

Design: Prospective observational study.

Setting: Four level I pediatric trauma centers.

Participants: One thousand patients younger than 21 years with minor head trauma undergoing cranial CT.

Main Outcome Measure: Intracranial injury as demonstrated by CT and neurosurgical intervention.

Results: Of 1000 patients in the study, the mean age was 8.9 years, and 64.1% were male; 6.5% (65 of 1000) had positive findings on CT, and 9.2% (6 of 65) of these required neurosurgical intervention. Recursive partitioning identified the following variables in the decision rule: dizziness, skull defect, sensory deficit, mental status change, bicycle-related injury, age younger than 2 years, Glasgow Coma Scale score less than 15, and evidence of a basilar skull fracture. For detection of intracranial injury, the decision rule had a sensitivity of 95.4% (95% confidence interval [CI], 86.2%-98.8%), a specificity of 48.9% (95% CI, 46.6%-52.1%), and a negative predictive value of 99.3% (95% CI, 98.1%-99.8%).

Conclusions: We developed a sensitive clinical decision rule with a high NPV for detection of intracranial injury in minor pediatric head trauma. If validated, this rule could provide a useful adjunct to the physician's clinical assessment by reducing variations in practice and unnecessary cranial CT.

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HEAD TRAUMA IS THE MOST common cause of trauma-related morbidity in children, accounting for more than 1 million emergency department visits per year in the United States.[1,2] Computed tomography (CT) has added substantially to the management of head trauma in adults and children by allowing earlier detection of intracranial injuries (ICIs). Cranial CT is obtained liberally in pediatric and adult patients with head trauma because evidence suggests that patients can be safely discharged home after negative findings on CT provided that the patients are neurologically normal.[3-5] Minor head trauma has been defined as a history of a loss of consciousness (LOC) or posttraumatic amnesia and a Glasgow Coma Scale score greater than 12.[3,6] Approximately 83% to 97% of CT findings are negative in the setting of minor head trauma.[7] Recommendations in adults with minor head trauma range from obtaining cranial CT in every patient with LOC and amnesia for the event, to imaging only those patients with LOC longer than 5 minutes or with focal neurologic deficits.[3,8-12] Clinical criteria for neuroimaging after minor head trauma in children remain unclear, and there is no consensus regarding patient selection for CT.[13-17] While some authors emphasized LOC, amnesia, skull fracture, scalp lacerations, or changes in behavior as reliable indicators of ICI, others found no consistent clinical predictors of positive CT findings in children who do not otherwise have grossly obvious signs of intracranial pathologic conditions.[18-24] Clinical decision aids for neuroimaging derived in recent prospective studies[25-29] will need to be further validated before they can be widely implemented by clinicians.

The frequency of pediatric CT almost doubled between 1996 and 1999, with approximately 2.7 million cases of pediatric CT performed annually in the United States.[30-32] Early exposure to radiation poses a significant associated risk. Estimated lifetime cancer mortality risk from CT may be an order of magnitude higher in a 1-year-old child than in an adult.[31-33] With radiation-attributable cancer risk as high as 1 case in 1400 among infants exposed to cranial CT,[31,33] the National Cancer Institute and the Food and Drug Administration have made recommendations to decrease radiation exposure and the risk of subsequent cancers by eliminating unnecessary CT.[32,34] Cost-benefit analyses of the liberal use of CT in closed head trauma have shown additional costs and risks for the many patients in the pediatric population who require sedation for the procedure.[35] Increased length of stay in the emergency department and potential parental dissatisfaction must also be considered.

Variation in practice with respect to CT of the child with minor head trauma persists.[36] Clinical decision rules seek to reduce variability in medical management by providing evidence-derived guidelines for clinical care, improving the overall efficacy of health care.[37,38] The Canadian CT Head Rule was developed to address variation in clinical management and neuroimaging in adult blunt head trauma, the effects of which are under investigation.[6,39,40] Similar studies[41,42] have resulted in improved testing strategies for ankle injuries, bacteremia, and simple febrile seizures. The primary objective of our study was to develop a clinical decision rule for the use of cranial CT in minor pediatric head trauma that is highly sensitive and has a high negative predictive value (NPV) for the prediction of acute ICI. Secondary objectives were (1) to identify clinical features predictive of neurosurgical intervention and (2) to assess clinicians' predictive abilities to determine the presence or absence of ICI based on history and physical examination alone.

METHODS

We enrolled a prospective convenience sample of patients from birth to 21 years of age with closed head trauma undergoing cranial CT. Patients were enrolled from 1 of 4 participating level I pediatric trauma centers between March 1, 1997, and March 30, 2000. Patients were excluded from enrollment if they had a prior CT scan at a referring hospital and if they had a Glasgow Coma Scale score (GCS) less than 13 determined by the treating physician at the participating trauma center. The institutional review boards of all sites approved the project. Because this was an observational study, a waiver of informed consent was allowed.

A standardized data collection survey was completed by a pediatric emergency medicine–trained attending or fellow physician (including S.M.A., J.J.B, K.E.S., M.A.C., and J.M.C. and others) before cranial CT. A pilot study using this instrument was performed from January 4, 1997, to February 25, 1997. Clinical variables for the final survey were obtained by literature review and by group consensus among a panel of pediatric emergency medicine–trained physicians (including S.M.A., K.E.S., M.A.C., and J.M.C. and others). A witness cosignature on survey completion was required before access to CT results, ensuring that predictor variables from clinical and historical findings of the examining physician were recorded without knowledge of the outcome of CT. Variables assessed included amnesia, dizziness, headache, intoxication, lethargy, seizure, vomiting, behavior change, scalp hematoma, scalp lacerations, palpable skull defect, mechanism of injury, sensory or motor deficit, signs of basilar skull fracture, and the presence and duration of LOC. Loss of consciousness was determined by witnessed report, and behavior change was defined as any change in behavior by report of the patient's parent or caregiver. Amnesia, dizziness, and headache were determined by patient report. Other signs and symptoms were determined by the treating physician.

Included in the data collection was the physician's estimate of the probability of ICI. We obtained data on the patient's procedures, final disposition, length of hospital stay, and other diagnostic test results by medical record review. A pediatric neuroradiologist interpreted cranial CT images. Intracranial injury was defined as subdural, epidural, subarachnoid, intraparenchymal, and intraventricular hemorrhages, as well as contusions and cerebral edema. The secondary outcome was defined as the performance of any neurosurgical procedure, including craniotomy, craniectomy, evacuation, or intracranial pressure monitoring.

Commercially available software (SPSS version 20; SPSS Inc, Chicago, Illinois) was used for statistical analysis. Univariate analyses were used to determine the strength of association between each variable and the primary outcome to select the best variables for the multivariate analyses. The univariate techniques were chosen according to the type of data (χ^2 test with continuity correction for nominal data, Mann-Whitney test for ordinal variables, and unpaired 2-tailed t test for continuous variables, using pooled or separate variance estimates as appropriate).

Those variables found to be strongly associated ($P < .05$) with the outcome measure were combined using recursive partitioning analyses. Recursive partitioning is a multivariate statistical approach that creates a branching decision tree by dividing the patient population into subgroups with and without the outcome of interest based on the contents of predictor variables in the subgroups. Recursive partitioning was performed using commercially available software (KnowledgeSEEKER version 3.1; Angoss Software International, Toronto, Ontario, Canada).[38]

The derived decision rule was cross-validated by comparing the classification of each patient with his or her actual status for the primary outcomes, allowing an estimate of the sensitivity and specificity of the rule with 95% confidence intervals (CIs). Clinicians' predictions of ICI were scored on a 5-point Likert-type scale (very likely, likely, unable to determine, unlikely, and very unlikely).

Sample size calculations were based on prior data estimating a 12% incidence of positive CT findings among patients with head trauma having a GCS of 13 to 15.[7] We determined that we would need approximately 1040 patients to create a decision rule with a lower 95% CI for sensitivity.

RESULTS

Demographic data and clinical findings of the study group are given in **Tables 1**, **2**, and **3**. There were 1151 patients enrolled initially. One hundred fifty-one patients had a GCS less than 13 and were excluded from further analysis. Of the remaining 1000 patients, the mean age was 8.9 years, 64.1% were male, and 18.8% of patients were younger than 2 years. Slightly more than half (54.6%) arrived via the emergency medical services system.

Sixty-five patients (6.5%) had positive findings on CT indicating ICI (Table 2), and 9.2% (6 of 65) of these required subsequent neurosurgical intervention (0.6% overall in the study group). Intracranial hemorrhages were the most frequent types of ICI, with a finding of subdural hematoma in 26 of 65 patients with ICI (40.0%). As expected, multiple intracranial injuries were also common, occurring in 14 of 65 patients (21.5%). One pa-

Table 1. Characteristics of the Entire Study Group vs the Patients With Intracranial Injury

Characteristic	No. (%) of Study Group (N=1000)	No. (%) of Patients With Intracranial Injury (n=65)
Age, y		
<2	188 (18.8)	27 (41.5)
≥2	812 (81.2)	38 (58.5)
Male sex	641 (64.1)	40 (61.5)
Method of arrival		
Ambulance	445 (44.5)	32 (49.2)
Helicopter	101 (10.1)	8 (12.3)
Other	454 (45.4)	25 (38.5)

Table 2. Cranial Computed Tomographic Findings in the Patients With Intracranial Injury[a]

Finding	No. (%) of Patients With Intracranial Injury (n=65)
Subdural hematoma	26 (40.0)
Contusion	18 (27.7)
Subarachnoid hematoma	15 (23.1)
Epidural hematoma	11 (16.9)
Cerebral edema	2 (3.1)
Other intracranial injury	8 (12.3)

[a]Some patients had more than 1 intracranial injury.

tient had an equivocal CT finding that suggested artifact or contusion. To determine a conservative decision rule, we elected to include this patient in the group with ICI. Of 65 patients who had positive CT findings, 6 patients required neurosurgical intervention (during the admission): 5 patients underwent craniectomy with evacuation, and 1 patient received placement of an intracranial pressure monitor.

Table 3 gives the association of each predictor variable with the outcome of ICI using odds ratios (ORs) and 95% CIs. Among 10 categories denoting injury mechanism, falls were the primary cause of minor head trauma in our population, accounting for 44.4% of total cases, with an OR for ICI of 2.10 (95% CI, 1.26-3.52). Motor vehicle crashes were the second most common cause of injury (20.4%) but were unassociated with ICI (OR, 0.45; 95% CI, 0.20-1.01). Seizure, skull defect, sensory deficit, scalp laceration, and mental status change demonstrated higher risk for ICI than other symptoms of concern such as LOC, headache, and vomiting. Children younger than 2 years were more likely to have a positive CT finding (OR, 3.42; 95% CI, 2.03-5.75).

Recursive partitioning resulted in the following rule for optimal prediction of ICI (**Figure**): dizziness, sensory deficit, GCS less than 15, mental status change, bicycle-related injury, age younger than 2 years, skull defect on examination, and evidence of a basilar skull fracture (Battle sign, rhinorrhea, hemotympanum, periorbital ecchymosis, or cerebrospinal fluid otorrhea). In this decision rule, pediatric patients who meet GCS definitions for minor head trauma and have at least 1 of the historical or clinical criteria listed are at higher risk for ICI. Children without any of these risk factors are unlikely to have ICI.

Table 3. Univariate Association of Predictor Variables

Variable	Patients Without Intracranial Injury (n=935)	Patients With Intracranial Injury (n=65)	Odds Ratio (95% Confidence Interval)
From the History			
Mechanism of injury			
Motor vehicle crash	197	7	0.45 (0.20-1.01)
Restrained	55	2	0.51 (0.12-2.13)
Unrestrained	60	2	0.46 (0.11-1.94)
Pedestrian struck	82	3	0.50 (0.15-1.64)
Fall	404	40	2.10 (1.26-3.52)
Intentional injury	24	1	0.59 (0.08-4.45)
Contact	88	3	0.47 (0.14-1.51)
Child abuse	5	0	. . .
Bicycle	57	5	1.28 (0.50-3.32)
Other	156	8	0.70 (0.33-1.50)
Unknown	4	1	3.64 (0.40-33.0)
Loss of consciousness	311	15	0.60 (0.33-1.09)
Amnesia	301	15	0.63 (0.35-1.14)
Mental status change	139	18	2.19 (1.24-3.89)
Lethargy	263	24	1.50 (0.89-2.52)
Seizure	50	7	2.14 (0.93-4.92)
Headache	358	17	0.57 (0.32-1.01)
Vomiting	315	17	0.70 (0.39-1.23)
Dizziness	94	5	0.75 (0.29-1.90)
Drug or alcohol intoxication	8	1	1.81 (0.22-14.7)
From the Physical Examination			
Sensory deficit	4	2	7.39 (1.33-41.1)
Skull defect	24	5	3.16 (1.17-8.58)
Basal skull fracture	22	3	2.01 (0.59-6.89)
Scalp			
Hematoma	248	28	2.10 (1.26-3.50)
Laceration	96	2	0.28 (0.07-1.15)
Glasgow Coma Scale score			
15	806	46	0.39 (0.21-0.72)
14	104	13	1.99 (0.96-3.87)
13	25	6	4.46 (1.42-11.78)

For the detection of ICI in 1000 study patients, the decision rule had a sensitivity of 95.4% (95% CI, 86.2%-98.8%), a specificity of 48.9% (95% CI, 45.6%-52.1%), and an NPV of 99.3% (95% CI, 98.1%-99.8%) (Figure). Three of 65 patients who had ICI findings on CT were not identified by the decision rule, although none required neurosurgical intervention. **Table 4** gives a description of these patients, including the patient with the equivocal CT finding of contusion vs artifact.

The sensitivity of the clinician's predictions of ICI based on history and physical examination was 14.8% (95% CI, 7.1%-27.7%), which was significantly lower compared with that of the decision rule (95.4%) (**Table 5**).

COMMENT

We developed a clinical decision rule for cranial CT in minor pediatric head trauma with high sensitivity for the

Decision rule	Intracranial injury	
	Yes	No
ICI predicted	62	478
ICI not predicted	3	457
	65	**935**

Decision rule statistics (95% confidence intervals)

Sensitivity = 62/65 = 95.4% (86.2%-98.8%)
Specificity = 457/935 = 48.9% (45.6%-52.1%)
Negative predictive value = 99.3% (98.1%-99.8%)
Positive predictive value = 11.5% (9.0%-14.5%)

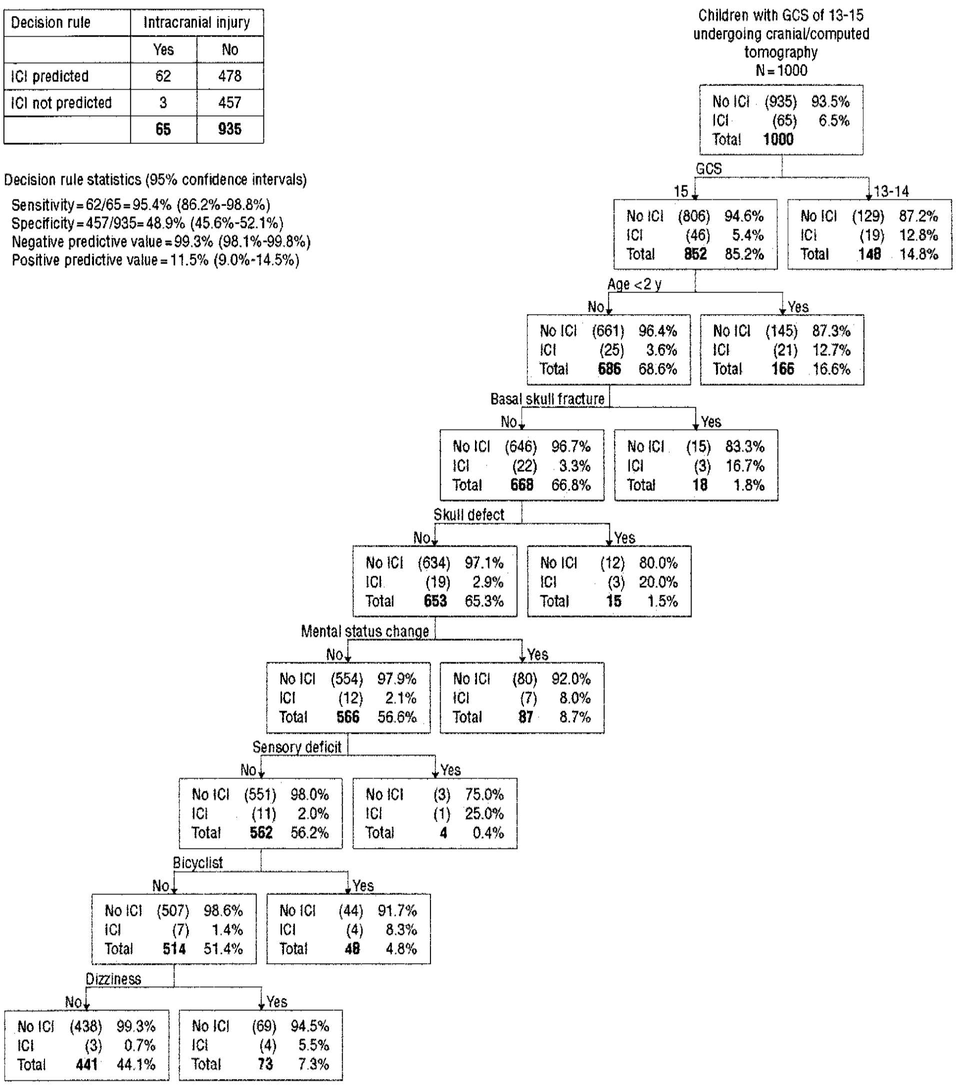

Figure. Pediatric head computed tomography decision rule. GCS indicates Glasgow Coma Scale score; ICI, intracranial injury.

detection of ICI. In this study, the clinical decision rule was found to be far more sensitive than the clinician's overall judgment of whether an ICI would be demonstrated on CT and had better NPV for the outcomes of interest. We believe that the liberal use of cranial CT, as recommended by several previous retrospective studies,[12,15] does not outweigh the costs and risks associated with this procedure compared with the overall incidence of clinically significant ICI. Children without any of the 8 risk factors in our decision rule are at low risk for ICI and their conditions can be managed with close outpatient observation. Blind application of the rule to all patients with minor head trauma is not recommended. Given that the cohort of patients enrolled in this study all underwent CT, we selected for patients who were likely at higher risk for ICI. This clinical decision rule should be used as an additional tool to help guide clinicians who are considering cranial CT in a child with minor head trauma.

The clinical decision rule derived in this study is based on prospectively collected data and is consistent with expert consensus on several fronts. In our study, sensory deficit, GCS less than 15, palpable skull defect, mental status change, age younger than 2 years, and signs of basilar skull fracture were associated with higher risk for ICI than other signs or symptoms of concern such as LOC, amnesia, headache, and vomiting. Stiell et al[6] published a decision rule for CT in adults with minor head injury. High-risk factors in this rule were age 65 years or older, signs of basilar skull fracture, 2 or more episodes of vomiting, suspected open or depressed skull fracture, and failure to reach a GCS of 15 within 2 hours. We similarly found that signs of basilar or depressed skull fracture contributed to our decision rule, which is also consistent with the association between skull fracture in children and increased ICI risk found by Oman et al,[27] Dunning et al,[28] and Quayle et al.[43] The results of a study conducted by Palchak et al[25] agreed with our findings that abnormal mental status and signs of skull fracture were high-risk factors for traumatic brain injury in children but differed from our study in that they found an increased risk of traumatic brain injury associated with vomiting. Haydel and Shembekar[26] concluded that CT was indicated for minor head trauma if 1 of the following 6 findings was present: emesis, headache, posttraumatic seizure, drug or alcohol intoxication, deficits in short-term memory, or physical evidence of trauma above the clavicles. Davis et al[23] did not find a reliable association between LOC and ICI, although scalp lacerations and neurologic deficits were statistically significant indicators. Similarly, Falimirski et al[18] concluded that LOC alone was not predictive of significant injury and was not an absolute indication for cranial CT. Similar to our study, Greenes and Schutzman[19,20,44] found that those younger than 2 years are at increased risk for ICI, with as many as 48% of injuries being occult or asymptomatic. Several characteristics unique to this younger age group may increase their likelihood of ICI, including higher incidence of skull fractures and increased risk for nonaccidental trauma.[17,20,44,45] Published guidelines have been developed separately for children 2 years and older by the American Academy of Pediatrics and for children younger than 2 years by expert consensus and literature review.[44,46,47] The decision rule derived in our study identifies a cohort of children at low risk for ICI. These data are consistent with previous literature highlighting an increased risk associated with age younger than 2 years.[44-47] Children in this age category fall outside of the low-risk criteria. This does not imply that all patients not meeting low-risk criteria (including age <2 years) should undergo cranial CT. Clinical decision rules are best used for decision support and should not replace clinical judgment.

We found that predictors such as fall, seizure, drug or alcohol intoxication, and scalp hematoma were statistically significant in univariate analysis but did not contribute in multivariate analysis. We also found that bicycle injuries placed children in a higher risk category for ICI. This may be unique to our patient population, most of whose injuries occurred in an urban environment and without protective headgear.

There are several limitations to our study. The injury rates from our study may underestimate those of the general population. We sought to develop a sensitive decision rule to detect ICI in children with minor head trauma and a GCS of 13 or higher who would undergo CT using pertinent historical and clinical data available to the emergency department physician, including mechanism of injury. This may exclude a proportion of patients with minor head trauma who did not undergo CT and may have had positive findings. However, we presume that the rates of ICI in this population are lower than those in our study group. Enrollment was dependent on practicing clinicians; therefore, we did not capture all eligible children with minor head trauma seen during the study period. We used the classical definition of minor head trauma as those patients with a GCS score exceeding 12. Although we acknowledge that there is some controversy surrounding this definition and that many clinicians believe that a GCS of 13 should be classified as moderate head trauma, we followed the recommendations of Stiell et al.[6]

Table 4. Patients With Positive Intracranial Injury Findings on Computed Tomography in Whom the Decision Rule Was Negative[a]

Age, y	Computed Tomographic Findings	Mechanism of Injury	Symptoms
13.9	Small interhemispheric subdural hemorrhage above and below the tentorium and posterior falx	Fall	Amnesia, loss of consciousness, or headache
2.1	Subarachnoid hemorrhage	Fall	Emesis or behavior change
6.5	Small focus of increased density in the occipitoparietal region representing a small contusion or an artifact	Motor vehicle crash, pedestrian struck	Behavior change

[a]None required neurosurgical intervention.

Table 5. Clinician's Ability to Predict Intracranial Injury[a]

	Intracranial Injury	
Variable	Yes (n=54)	No (n=866)
Clinician's prediction of the likelihood of intracranial injury		
Likely	8	64
Unlikely	46	802
Sensitivity	14.8% (95% confidence interval, 7.1%-27.7%)	
Specificity	92.6% (95% confidence interval, 90.6%-94.2%)	
Positive predictive value	11.1% (95% confidence interval, 5.3%-21.3%)	
Negative predictive value	94.6% (95% confidence interval, 85.8%-98.3%)	

[a]Values do not sum to 920 because the clinicians completing the data collection survey did not complete this item.

Methodological advantages of this study over prior investigations are the prospective data collection and multicenter patient enrollment. The patients in this study represent populations from various sites and yield more generalizable results. If validated, our decision rule has the potential to reduce unnecessary cranial CT. The magnitude of this reduction depends on local practice regarding neuroimaging after minor head trauma. In many centers, routine CT in all patients with minor head trauma has emerged as the standard of emergency care. The results of this study suggest that implementation of the decision rule in centers with practice like those in the study would avoid CT in 46.3% of all patients with minor head trauma. Only 0.7% would have missed traumatic CT abnormalities, none of which required surgery. In addition to reducing radiation exposure risk, hospital charges for nonenhanced cranial CT in the United States range from $500 to $900; therefore, this could also result in significant cost savings.[48] Assessment of the effectiveness of such a rule requires prospective validation and measure of interobserver reliability, which we plan to perform in a future study.

Despite the importance of this study and others in refining the clinical indicators for CT, 2 important clinical questions remain. First, what is the significance of positive CT findings that do not require neurosurgical intervention? Is the detection of a clinically insignificant intracranial hemorrhage or contusion worth the risks of irradiation and sedation? Second, how useful are negative CT findings in symptomatic children? Prior studies have demonstrated behavioral changes in mildly head-injured patients, and some authors have recommended subsequent neurodevelopmental testing of these patients.[49-51] Attempts should be made to identify children at risk for long-term sequelae who may benefit from neuropsychologic testing and closer outpatient monitoring. In the future, functional imaging and psychometric testing may replace CT for the assessment of the child with minor head trauma.

Given the numbers of closed head injuries in children, if validated and implemented, this study could affect care by reducing unnecessary CT. A decrease in the frequency of cranial CT can lead to a decrease in radiation exposure, health care costs, the use of conscious sedation with its associated risks and costs, and the amount of time each patient spends in the emergency department.

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AMERICAN ACADEMY OF PEDIATRICS

The Management of Minor Closed Head Injury in Children

Committee on Quality Improvement, American Academy of Pediatrics

Commission on Clinical Policies and Research, American Academy of Family Physicians

ABSTRACT. The American Academy of Pediatrics (AAP) and its Committee on Quality Improvement in collaboration with the American Academy of Family Physicians (AAFP) and its Commission on Clinical Policies and Research, and in conjunction with experts in neurology, emergency medicine and critical care, research methodologists, and practicing physicians have developed this practice parameter. This parameter provides recommendations for the management of a previously neurologically healthy child with a minor closed head injury who, at the time of injury, may have experienced temporary loss of consciousness, experienced an impact seizure, vomited, or experienced other signs and symptoms. These recommendations derive from a thorough review of the literature and expert consensus. The methods and results of the literature review and data analyses including evidence tables can be found in the technical report. This practice parameter is not intended as a sole source of guidance for the management of children with minor closed head injuries. Rather, it is designed to assist physicians by providing an analytic framework for the evaluation and management of this condition. It is not intended to replace clinical judgment or establish a protocol for all patients with a minor head injury, and rarely will provide the only appropriate approach to the problem.

The practice parameter, "The Management of Minor Closed Head Injury in Children," was reviewed by the AAFP Commission on Clinical Policies and Research and individuals appointed by the AAFP and appropriate committees and sections of the AAP including the Chapter Review Group, a focus group of office-based pediatricians representing each AAP District: Gene R. Adams, MD; Robert M. Corwin, MD; Diane Fuquay, MD; Barbara M. Harley, MD; Thomas J. Herr, MD, Chair; Kenneth E. Matthews, MD; Robert D. Mines, MD; Lawrence C. Pakula, MD; Howard B. Weinblatt, MD; and Delosa A. Young, MD.

The supporting data are contained in a technical report available at http://www.pediatrics.org/cgi/content/full/104/6/e78.

ABBREVIATIONS. AAP, American Academy of Pediatrics; AAFP, American Academy of Family Physicians; CT, cranial computed tomography; MRI, magnetic resonance imaging.

The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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Minor closed head injury is one of the most frequent reasons for visits to a physician.[1] Although >95 000 children experience a traumatic brain injury each year in the United States,[2] consensus is lacking about the acute care of children with minor closed head injury. The evaluation and management of injured children may be influenced by local practice customs, settings where children are evaluated, the type and extent of financial coverage, and the availability of technology and medical staffing.

Because of the magnitude of the problem and the potential seriousness of closed head injury among children, the AAP and the American Academy of Family Physicians (AAFP) undertook the development of an evidence-based parameter for health care professionals who care for children with minor closed head injury. In this document, the term Subcommittee is used to denote the Subcommittee on Minor Closed Head Injury, which reports to the AAP Committee on Quality Improvement, and the AAFP Commission on Clinical Policies, Research, and Scientific Affairs.

While developing this practice parameter, the Subcommittee attempted to find evidence of benefits resulting from 1 or more patient management options. However, at many points, adequate data were not available from the medical literature to provide guidance for the management of children with mild head injury. When such data were unavailable, we did not make specific recommendations for physicians and other professionals but instead we presented a range of practice options deemed acceptable by the Subcommittee.

An algorithm at the end of this parameter presents recommendations and options in the context of direct patient care. Management is discussed for the initial evaluation of a child with minor closed head injury, and the disposition after evaluation. These recommendations and options may be modified to fit the needs of individual patients.

PURPOSE AND SCOPE

This practice parameter is specifically intended for previously neurologically healthy children of either sex 2 through 20 years of age, with isolated minor closed head injury.

The parameter defines children with minor closed head injury as those who have normal mental status at the initial examination, who have no abnormal or focal findings on neurologic (including fundoscopic) examination, and who have no physical evidence of skull fracture (such as hemotympanum, Battle's sign, or palpable bone depression).

This parameter also is intended to address children who may have experienced temporary loss of consciousness (duration <1 minute) with injury, may have had a seizure immediately after injury, may have vomited after injury, or may have exhibited signs and symptoms such as headache and lethargy. The treatment of these children is addressed by this parameter, provided that they seem to be normal as described in the preceding paragraph at the time of evaluation.

This parameter is not intended for victims of multiple trauma, for children with unobserved loss of consciousness, or for patients with known or suspected cervical spine injury. Children who may otherwise fulfill the criteria for minor closed head injury, but for whom this parameter is not intended include patients with a history of bleeding diatheses or neurologic disorders potentially aggravated by trauma (such as arteriovenous malformations or shunts), patients with suspected intentional head trauma (eg, suspected child abuse), or patients with a language barrier.

The term brief loss of consciousness in this parameter refers to a duration of loss of consciousness of 1 minute or less. This parameter does not make any inference that the risk for intracranial injury changes with any specific length of unconsciousness lasting <1 minute. The treatment of children with loss of consciousness of longer duration is not addressed by this parameter.

Finally, this parameter refers only to the management of children evaluated by a health care professional immediately or shortly after (within 24 hours) injury. This parameter is not intended for the management of children who are initially evaluated >24 hours after injury.

METHODS FOR PARAMETER DEVELOPMENT

The literature review encompassed original research on minor closed head trauma in children, including studies on the prevalence of intracranial injury, the sensitivity and specificity of different imaging modalities, the utility of early diagnosis of intracranial injury, the effectiveness of various patient management strategies, and the impact of minor closed head injury on subsequent child health. Research was included if it had data exclusively on children or identifiable child-specific data, if cases were comparable with the case definition in the parameter, and if the data were published in a peer-reviewed journal. Review articles and articles based solely on expert opinion were excluded.

An initial search was performed on several computerized databases including Medline (1966–1993) using the terms head trauma and head injury. The search was restricted to infants, children, and adolescents, and to English-language articles published after 1966. A total of 422 articles were identified. Titles and abstracts were reviewed by the Subcommittee and articles were reviewed if any reviewer considered the title relevant. This process identified 168 articles that were sent to Subcommittee members with a literature review form to categorize study design, identify study questions, and abstract pertinent data. In addition, reference lists in the articles were reviewed for additional sources, and 125 additional articles were identified. After excluding review articles and other studies not meeting entry criteria, a total of 64 articles were included for review. All articles were reabstracted by the methodologists and the data summarized on evidence tables. Differences in case definition, outcome definition, and study samples precluded pooling of data among studies.

The published data proved extremely limited for a number of study questions, and direct queries were placed to several authors for child-specific data. Because these data have not been formally published, the Subcommittee does not rest strong conclusions on them; however, they are included in the Technical Report. The Technical Report produced along with this practice parameter contains supporting scientific data and analysis including evidence tables and is available at http://www.pediatrics.org/cgi/content/full/104/6/e78.

SUMMARY

Initial Evaluation and Management of the Child With Minor Closed Head Injury and No Loss of Consciousness

Observation

For children with minor closed head injury and no loss of consciousness, a thorough history and appropriate physical and neurologic examination should be performed. Observation in the clinic, office, emergency department, or at home, under the care of a competent caregiver is recommended for children with minor closed head injury and no loss of consciousness. Observation implies regular monitoring by a competent adult who would be able to recognize abnormalities and to seek appropriate assistance. The use of cranial computed tomography (CT) scan, skull radiograph, or magnetic resonance imaging (MRI) is not recommended for the initial evaluation and management of the child with minor closed head injury and no loss of consciousness.

Initial Evaluation of the Child With Minor Closed Head Injury With Brief Loss of Consciousness

Observation or Cranial CT Scan

For children with minor closed head injury and brief loss of consciousness (<1 minute), a thorough history and an appropriate physical and neurologic examination should be performed. Observation, in the office, clinic, emergency department, hospital, or home under the care of a competent caregiver, may be used to evaluate children with minor closed head injury with brief loss of consciousness. Cranial CT scanning may also be used, in addition to observation, in the initial evaluation and management of children with minor closed head injury with loss of consciousness.

The use of skull radiographs or MRI in the initial management of children with minor closed head injury and loss of consciousness is not recommended. However, there are limited situations in which MRI and skull radiography are options (see sections on skull radiographs and on MRI).

Patient Management Considerations

Many factors may influence how management strategies influence outcomes for children with minor closed head injury. These factors include: 1) the prevalence of intracranial injury, 2) the percentage of intracranial injuries that need medical or neurosurgical intervention (ie, the percentage of these injuries that, if left undiagnosed or untreated, leads to disability or death), 3) the relative accuracy of clinical examination, skull radiographs, and CT scans as diagnostic tools to detect such intracranial injuries that benefit from medical or neurosurgical intervention, 4) the efficacy of treatment for intracranial injuries, and 5) the detrimental effect on outcome, if any, of delay from the time of injury to the time of diagnosis and intervention.

This last factor, delay of diagnosis and intervention, is particularly relevant when trying to decide between a clinical strategy of immediate CT scanning of all patients as opposed to a strategy that relies primarily on patient observation, with CT scanning reserved for rare patients whose conditions change. To our knowledge, no published studies were available for review that compared clinically meaningful outcomes (ie, morbidity or mortality) between children receiving different management regimens such as immediate neuroimaging, or observation. Although some studies were able to demonstrate the presence of intracranial abnormalities on CT scans or MRIs among children with minor head injury, no known evidence suggested that immediate neuroimaging of asymptomatic children improved outcomes for these children, compared with the outcomes for children managed primarily with examination and observation.

Initial Management of the Child With Minor Closed Head Injury and No Loss of Consciousness

Minor closed head injury without loss of consciousness is a common occurrence in childhood. Available data suggest that the risk of intracranial injury is negligible in this situation. Population-based studies have found that fewer than 1 in 5000 patients with minor closed head injury and no loss of consciousness have intracranial injuries that require medical or neurosurgical intervention. In 1 study of 5252 low-risk patients, mostly adults, none were found to have an intracranial injury after minor head injury.[3] Comparably sized studies do not exist for children. In 2 much smaller studies of children with minor head injury, among those with normal neurologic examination findings and no loss of consciousness, amnesia, vomiting, headache, or mental status abnormalities, no children had abnormal CT scan findings.[4,5]

Observation

Among children with minor closed head injury and no loss of consciousness, a thorough history and appropriate physical and neurologic examination should be performed. Subcommittee consensus was that observation, in the clinic, office, emergency department, or home under the care of a competent observer, be used as the primary management strategy. If on examination the patient's condition appears normal (as outlined earlier), no additional tests are needed and the child can be safely discharged to the care of a responsible caregiver. The recommended duration of observation is discussed in the section titled "Disposition of the Child With Minor Head Injury."

CT Scan/MRI

With such a low prevalence of intracranial injury, the Subcommittee believed that the marginal benefits of early detection of intracranial injury afforded by routine brain imaging studies such as CT or MRI were outweighed by considerations of cost, inconvenience, resource allocation, and possible side effects attributable to sedation or inappropriate interventions (eg, medical, surgical, or other interventions based on incidental CT findings in asymptomatic children).

Skull Radiographs

Skull radiographs have only a very limited role in the evaluation of children with minor closed head injury, no loss of consciousness, and no signs of skull fracture (ie, no palpable depression, hemotympanum, or Battle's sign). The substantial rate of false-positive results provided by skull radiographs (ie, a skull fracture detected on skull radiographs in the absence of intracranial injury) along with the low prevalence of intracranial injury among this specific subset of patients, leads to a low predictive value of skull radiographs. Most children with abnormal skull radiographs will not harbor significant intracranial lesions and conversely intracranial injury occurs in the absence of a skull fracture detected on skull radiographs.

There may be some clinical scenarios in which a practitioner desires imaging such as the case of a child with a scalp hematoma over the course of the meningeal artery. In situations such as these, the Subcommittee believes that clinical judgment should prevail. However, given the relatively low predictive value of skull radiographs, the Subcommittee believes that, if imaging is desired, cranial CT scan is the more satisfactory imaging modality.

Initial Management of the Child With Minor Closed Head Injury and Brief Loss of Consciousness

Among children with minor closed head injury, loss of consciousness is uncommon but is associated with an increased risk for intracranial injury. Studies performed since the advent of CT scanning suggest that children with loss of consciousness, or who demonstrate amnesia at the time of evaluation, or who have headache or vomiting at the time of evaluation, have a prevalence of intracranial injury detectable on CT that ranges from 0% to 7%.[5–8] Although most of these intracranial lesions will remain clinically insignificant, a substantial proportion of children, between 2% and 5% of those with minor head injury and loss of consciousness, may require neurosurgical intervention.[6-8] The differences in findings among studies are likely attributable to differences in selection criteria, along with random variation among studies with limited sample size. Although these findings might have been biased somewhat if more seriously injured patients were preferentially selected for CT scans, even studies in which patients were explicitly stated to be neurologically normal and asymptomatic found children with clinically significant injuries that required intervention.[6]

In past studies of children with minor head injury, patient selection may have led to overestimates of the prevalence of intracranial injury. Many of these studies looked at patients referred to emergency departments or trauma centers, patients brought to emergency departments after examination in the field by emergency personnel, or patients for whom the reason for obtaining CT scans was not clearly stated. These factors may have led to the selection of a patient population at higher risk for intracranial injury than the patients specifically addressed in this practice parameter.

As evidence of this, population-based studies before the widespread availability of CT scanning found the prevalence of clinically significant intracranial injury after minor closed head injury to be far less than estimated by the aforementioned studies. One study found a prevalence of intracranial injury that required neurosurgery to be as low as .02%.[9] This discrepancy is consistent also with the fact that many lesions currently identified with cranial CT were not recognized before the availability of this technology. Because most of these lesions do not progress or require neurosurgical intervention, most would not have been diagnosed in studies before the availability of CT scan.

Observation

As discussed earlier, the Subcommittee did not find evidence to show that immediate neuroimaging of asymptomatic children produced demonstrable benefits compared with a management strategy of initial observation alone. In light of these considerations, there was Subcommittee consensus based on limited evidence that for children who are neurologically normal after minor closed head injury with loss of consciousness, patient observation was an acceptable management option.

If the health care practitioner chooses observation alone, it may be performed in the clinic, office, emergency department, hospital, or at home under the care of a competent observer, typically a parent or suitable guardian. If the observer seems unable to follow or comply with the instructions for home observation, observation under the supervision of a health care practitioner is to be considered.

CT Scan

Data that support the routine use of CT scanning of children with minor head injury and loss of consciousness indicate that children with intracranial lesions after minor closed head injury are not easily distinguishable clinically from the large majority with no intracranial injury.[10,11] Children with nonspecific signs such as headache, vomiting, or lethargy after minor closed head injury may be more likely to have intracranial injury than children without such signs. However, these clinical signs are of limited predictive value, and most children with headache, lethargy, or vomiting after minor closed head injury do not have demonstrable intracranial injury. In addition, some children with intracranial injury do not have any signs or symptoms. Because of these findings, many investigators have concluded that the physical and neurologic examination are inadequate predictors of intracranial injury, and that cranial CT is more sensitive than physical and neurologic examinations for the diagnosis of intracranial injury.

The most accurate and rapid means of detecting intracranial injury would be with a clinical protocol that routinely obtained intracranial imaging for all children after head injury. Rapid diagnosis and treatment of subdural hematomas was found in 1 study to significantly reduce morbidity and mortality among severely injured adults.[12] However, this result was not replicated in other studies of subdural or epidural hematomas[13-15] and similar studies have not addressed less severely head injured children, or children with minor closed head injury.

CT itself is a safe procedure. However, some healthy children require sedation or anesthesia, and the benefits gained from cranial CT should be carefully weighed against the possible harm of sedating and/or anesthetizing a large number of children. In addition, CT scans obtained for asymptomatic children may show incidental findings that lead to subsequent unnecessary medical or surgical interventions. To our knowledge, no data are available that demonstrate that children who undergo CT scanning early after minor closed head injury with loss of consciousness have different outcomes compared with children who receive observation alone after injury. A clinical trial comparing the risks and benefits of immediate CT scanning with simple monitored observation for children with minor closed head injury has not been performed, primarily because intracranial injury after minor closed head injury is so rare that the cost and logistics of such a study would be prohibitive. As a result, the risk–benefit ratio for the evaluation and management modalities of CT scanning or observation is unknown.

Simple observation by a reliable parent or guardian is the management option with the least initial costs, while CT scans typically cost less than observation performed in the hospital. A study that compares costs of CT and observation strategies would need data on the cost of following up children with positive CT scans, as well as the potential costs associated with late detection and emergency therapy among those managed by observation alone.

Because of these considerations, there was Subcommittee consensus based on limited evidence that for children who are neurologically normal after minor closed head injury with loss of consciousness, cranial CT scanning along with observation was also an acceptable management option.

Skull Radiographs

Before the availability of CT imaging, skull radiographs were a common means to evaluate children with head injury. Skull radiographs may identify skull fractures, but they do not directly show brain injury or other intracranial trauma. Although intracranial injury is more common in the presence of a skull fracture, many studies have demonstrated that intracranial lesions are not always associated with skull fractures and that skull fractures do not always indicate an underlying intracranial lesion.[7,8,16]

Large studies of children and adults have shown that the sensitivity of skull radiographs for identifying intracranial injury in children is quite low (~25% in some studies). More recent studies limited to children have reported sensitivities between 50% and 100%, with the latter higher figure reported from studies of adolescent patients.[7,8,15,16] The specificity of skull radiographs for intracranial injury (the proportion of patients without intracranial injury who have normal radiographs) has been reported as between 53% and 97% in these same studies. Given the limited specificity of skull radiographs and the low prevalence of intracranial injury, the skull radiographs would likely be interpreted as abnormal for a substantial proportion of patients without intracranial injury. Furthermore, the low sensitivity of the radiographs will result in the interpretation of skull radiographs as normal for some patients with intracranial injury.

The Subcommittee consensus was that skull radiographs have only a limited role in the management of the child with loss of consciousness. If imaging is desired by the health care practitioner and if CT and skull radiographs are available, the Subcommittee believes that CT scanning is the imaging modality of choice, based on the increased sensitivity and specificity of CT scans. When CT scanning is not readily available, skull radiographs may assist the practitioner to define the extent of injury and risk for intracranial injury. In this situation, there was Subcommittee consensus that, for a child who has suffered minor closed head injury with loss of consciousness, skull radiographs are an acceptable management option. However, as noted, skull fractures may be detected on skull radiographs in the absence of intracranial injury, and intracranial injury may be present when no skull fracture is detected on skull radiographs. These limitations should be considered carefully by physicians who elect to use skull radiographs. Regardless of findings on skull films (should the physician elect to obtain them) close observation, as described previously, remains a cornerstone of patient management.

MRI

MRI is another available modality for neuroimaging. Although MRI has been shown to be more sensitive than cranial CT in detecting certain types of intracranial abnormalities, CT is more sensitive for hyperacute and acute intracranial hemorrhage (especially subarachnoid hemorrhage). CT is more quickly and easily performed than MRI, and costs for CT scans generally are less than those for MRI. The consensus of the Subcommittee was that cranial CT offered substantial advantages over MRI in the acute care of children with minor closed head injury.

As is the case with skull radiographs, there may be situations in which CT scanning is not readily available and the health care professional desires to obtain imaging studies. There was Subcommittee consensus that, for a child who has experienced minor closed head injury with loss of consciousness, MRI to evaluate the intracranial status of the child was an acceptable management option.

Disposition of Children With Minor Closed Head Injury

Children Managed by Observation Alone

Children who appear neurologically normal after minor closed head injury are at very low risk for subsequent deterioration in their condition and are unlikely to require medical intervention. Therefore, although observation is recommended for patients after the initial evaluation is completed, such observation may take place in many different settings. The strategy chosen by the health care practitioner may depend on the resources available for observation. Other factors, such as the distance and time it would take to reach appropriate care if the patient's clinical status worsened, may influence where observation occurs.

Historically, when hospitalization has been used to observe children after head injury, the length of stay averaged 12 to 48 hours. This practice was based on the reasoning that most life-threatening complications occur within 24 hours after head injury. The Subcommittee believes that a prudent duration of observation would extend at least 24 hours, and could be accomplished in any combination of locations, including the emergency department, hospital, clinic, office, or home. However, it is important for physicians, parents, and other guardians to have a high index of suspicion about any change in the patient's clinical status for several days after the injury. Parents or guardians require careful instruction to seek medical attention if the patient's condition worsens at any time during the first several days after injury.

In all cases, the health care professional is to make a careful assessment of the parent or guardian's anticipated compliance with the instructions to monitor the patient. If the caregiver is incompetent, unavailable, intoxicated, or otherwise incapacitated, other provisions must be made to ensure adequate observation of the child. These provisions may differ based on the characteristics of each case.

The physician has an important role in educating the parents or guardians of children with minor closed head injury. Understandable, printed instructions should be given to the parent or guardian detailing how to monitor the patient and including information on how and when to seek medical attention if necessary. All children discharged should be released to the care of a reliable parent or guardian who has adequate transportation and who has the capability to seek medical attention if the child's condition worsens.

Children Evaluated by Cranial CT

Neurologically normal patients with normal cranial CT scans are at extremely low risk for subsequent problems. Although there are many reports of patients with head injuries in whom extradural or intracerebral bleeding developed after an initial stable clinical period,[18-22] there are only a few reports of patients in whom extradural or intracerebral bleeding developed after a postinjury CT scan was interpreted as normal.[23-25] Most often when such cases have been described, the patients had sustained a more severe initial head injury than the patient for whom this parameter is intended, and the neurologic status of the patients was not intact at the initial examination following the injury. A number of studies have demonstrated the safety of using cranial CT as a triage instrument for neurologically normal and clinically stable patients after minor closed head injury.[26-31]

Patients may be discharged from the hospital for observation by a reliable observer if the postinjury CT scan is interpreted as normal. The length of observation should be similar to that described in the preceding section. If the cranial CT reveals abnormalities, proper disposition depends on a thorough consideration of the abnormalities and, when warranted, consultations with appropriate subspecialists.

Research Issues

Classification of Head Injury in Children and Prognostic Features

Much remains to be learned about minor closed head injury in children. The implications of clinical events such as loss of consciousness and signs or symptoms such as seizures, nausea, vomiting, and headache remain unclear. Data on patients with low-risk head injuries but with loss of consciousness, such as the data provided on a primarily adult population, are not available for children. Moreover, this practice parameter deals with clinically normal patients who did not lose consciousness at the time of injury and with patients who did lose consciousness with injury. Children with minor head injury, who have experienced loss of consciousness, vomiting or seizures have been found to have a prevalence of intracranial injury ranging from 2% to 5%. Questions remain about the selection of patients for many of these studies, and there is considerable uncertainty about the generalizability of these results to patients within this parameter.

Future studies on minor closed head injury should assess the relationship between characteristics such as these and the risk for intracranial injury among children who are clinically asymptomatic. Specifically, studies should address the question of whether such a history of loss of consciousness is associated with an increased risk for clinically significant intracranial abnormalities. Such studies should not be limited to patients seen in referral settings, but instead should cover patients from a wide range of settings, including those managed in clinics and offices, and if possible, those managed over the phone.

These studies should also address the independent prognostic value of other signs and symptoms for which the clinical significance in children is uncertain. In particular, practitioners are often faced with managing patients who are asymptomatic except for episodes of repeated vomiting or moderate to severe headache. The Subcommittee did not find evidence in the literature that helped differentiate the risk status of children with such symptoms from children without such symptoms. If studies are performed on this population, information should be collected on the presence of signs or symptoms including posttraumatic seizures, nausea with or without vomiting, posttraumatic amnesia, scalp lacerations and hematomas, headache, and dizziness, and their relationship to intracranial injury.

The Benefit of Early Detection of, and Intervention for, Intracranial Lesions in Asymptomatic Children

The outcome for asymptomatic patients found to have intracranial hematomas is of particular interest. Additional studies are needed to determine whether a strategy of immediate CT scan provides measurably improved outcomes for children with minor closed head injury compared with a strategy of observation followed by CT scan for children whose clinical status changes. Although rapid detection and neurosurgical intervention for intracranial injuries such as subdural hematomas has been shown to improve outcome in some studies of patients with more serious head injuries, it is unclear whether the same benefit would accrue to asymptomatic neurologically normal children.

A randomized, controlled trial would provide the most direct information on the risks and benefits of each management strategy. However, such a study would be extremely difficult and expensive to perform because of the rarity of adverse outcomes. Retrospective observational studies among children with minor head injury could be performed more easily and at less cost. However, correct characterization of the patient's clinical status before any treatment strategy or diagnostic procedure would be essential to eliminate bias in the evaluation of the comparison groups.

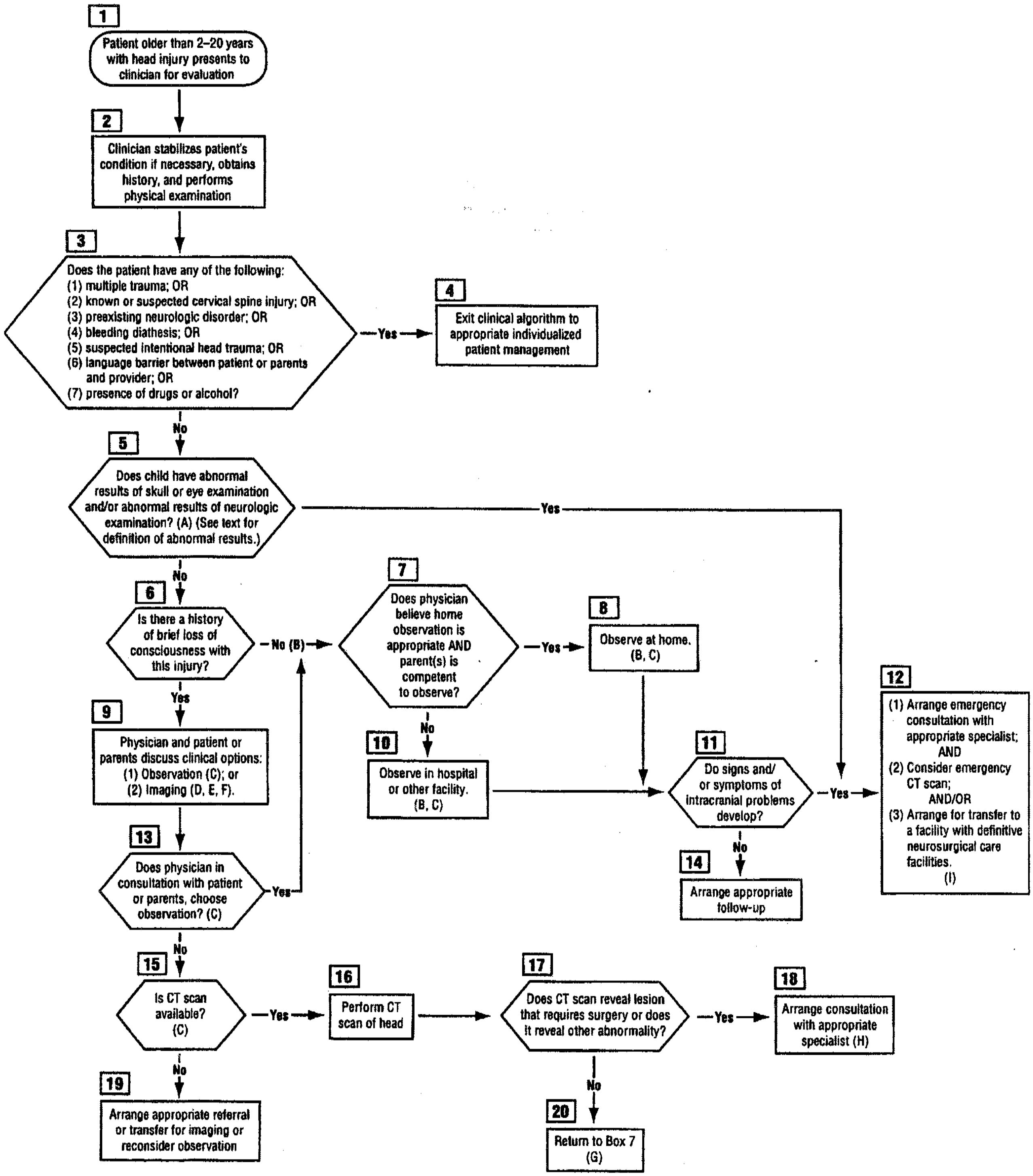
Finally, if such studies are performed to compare different diagnostic and management strategies, the outcomes should include not only mortality and short-term morbidity but also long-term outcomes such as persistent psychological problems or learning disorders.

The Management of the Asymptomatic Patient With Intracranial Hemorrhage

The optimal management and prognosis for asymptomatic patients with intracranial hemorrhage is unknown. Because surgery is not always indicated or beneficial, some neurosurgeons and neurologists now advocate an expectant approach of close observation for small intracranial and extradural hemato-

Evaluation and Triage of Children and Adolescents With Minor Head Trauma

Algorithm



mas, considering hematoma size, shift of intracranial structures, and other factors.

If all asymptomatic children with minor head injury undergo cranial CT scanning, a substantial number of patients with an abnormal result on CT may undergo surgery that is unnecessary or even harmful. Additional research is needed to determine the proper management of asymptomatic children with intracranial hemorrhage. Outcome measures should include mortality and morbidity outcomes such as seizures, learning disabilities, and behavioral disabilities.

Research Into Other Imaging Modalities

As newer modalities for neuroimaging are developed and disseminated, careful evaluation of their relative utility is necessary before they are used for patients with minor closed head injury. Although such new modalities frequently provide new and different types of information to the health care professional, it is important that they be submitted to scientific study to assess their effect on patient outcome.

Algorithm

The notes below are integral to the algorithm. The letters in parentheses correspond to the algorithm.

A. This parameter addresses the management of previously neurologically healthy children with minor closed head injury who have normal mental status on presentation, no abnormal or focal findings on neurologic (including fundoscopic) examination, and no physical evidence of skull fracture (such as hemotympanum, Battle's sign, or palpable depression).

B. Observation in the clinic, office, emergency department, or home, under the care of a competent caregiver is recommended for children with minor closed head injury and no loss of consciousness.

C. Observation in the office, clinic, emergency department, hospital, or home under the care of a competent caregiver may be used to manage children with minor closed head injury with loss of consciousness.

D. Cranial CT scanning along with observation may also be used in the initial evaluation and management of children with minor closed head injury with brief loss of consciousness.

E. If imaging is desired by the health care practitioner and if both CT and skull radiography are available, CT scanning is the imaging modality of choice, because of its increased sensitivity and specificity. When CT scanning is not readily available, skull radiographs may assist the practitioner to define the risk for intracranial injury. However skull fractures may be detected on skull radiographs in the absence of intracranial injury, and occasionally intracranial injury is present despite the absence of a skull fracture detected on skull radiographs. These limitations should be considered by physicians who elect to use skull radiographs. Whether the changed probabilities for harboring an intracranial injury based on the results of the skull radiographs is sufficient to alter the management strategy may depend on the preferences of the family and physician.

F. In some studies MRI has been shown to be more sensitive than CT in diagnosing certain intracranial lesions. However, there is currently no appreciable difference between CT and MRI in the diagnosis of clinically significant acute intracranial injury and bleeding that requires neurosurgical intervention. CT is more quickly and easily performed than MRI, and the costs for CT scans generally are less than those for MRI. Because of this, the consensus among the Subcommittee was that cranial CT offered advantages over MRI in the acute care of children with minor closed head injury.

G. Neurologically normal patients with a normal cranial CT scan are at very low risk for subsequent deterioration. Patients may be discharged from the hospital for observation by a reliable observer if the postinjury CT scan is normal. The decision to observe at home takes into consideration the delay that would ensue if the child had to return to the hospital as well as the reliability of the parents or other caregivers. Otherwise, depending on the preferences of the patient and physician, observation also may take place in the office, clinic, emergency department, or hospital.

H. If the cranial CT reveals abnormalities, proper disposition depends on a thorough consideration of the abnormalities and, when warranted, consultation with appropriate subspecialists.

I. If the child's neurologic condition worsens during observation, a thorough neurologic examination is to be performed, along with immediate cranial CT after the patient's condition is stabilized. If a repeat CT scan shows new intracranial pathologic abnormalities, consultation with the appropriate subspecialist is warranted.

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