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

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See Comment page 1127

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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

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 no discharged patient was subsequently diagnosed with ciTBI.

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]

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.

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 patients were intubated

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

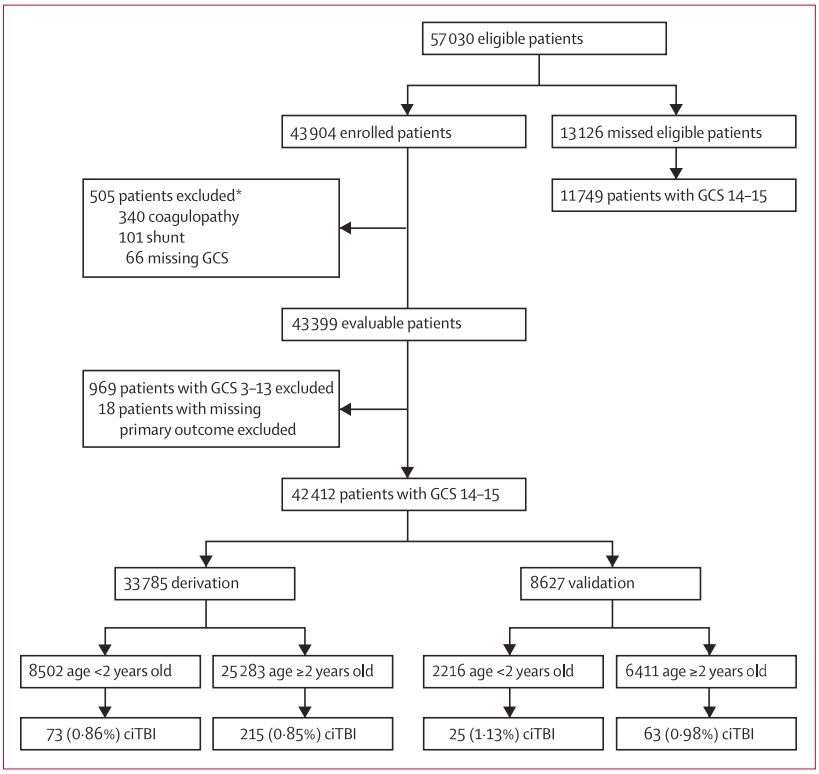


Figure 1: **Flow chart**
GCS=Glasgow Coma Scale. ciTBI=clinically-important traumatic brain injury. *Two patients had more than one exclusion.

	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**

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

	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.

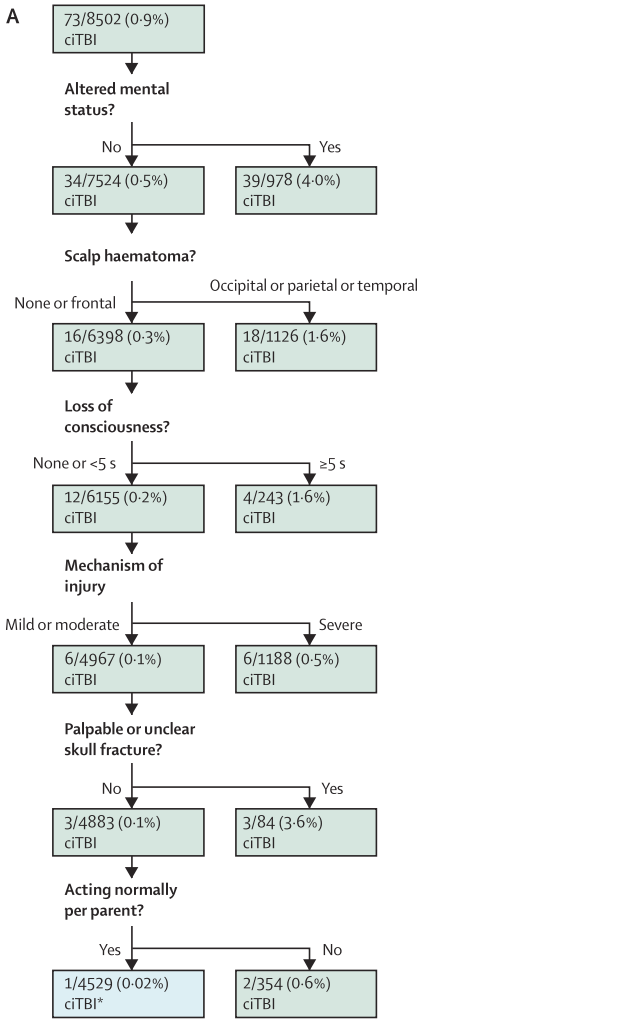
Table 3: **Bivariable analysis of tree predictor variables of ciTBI for children aged 2 years and older**

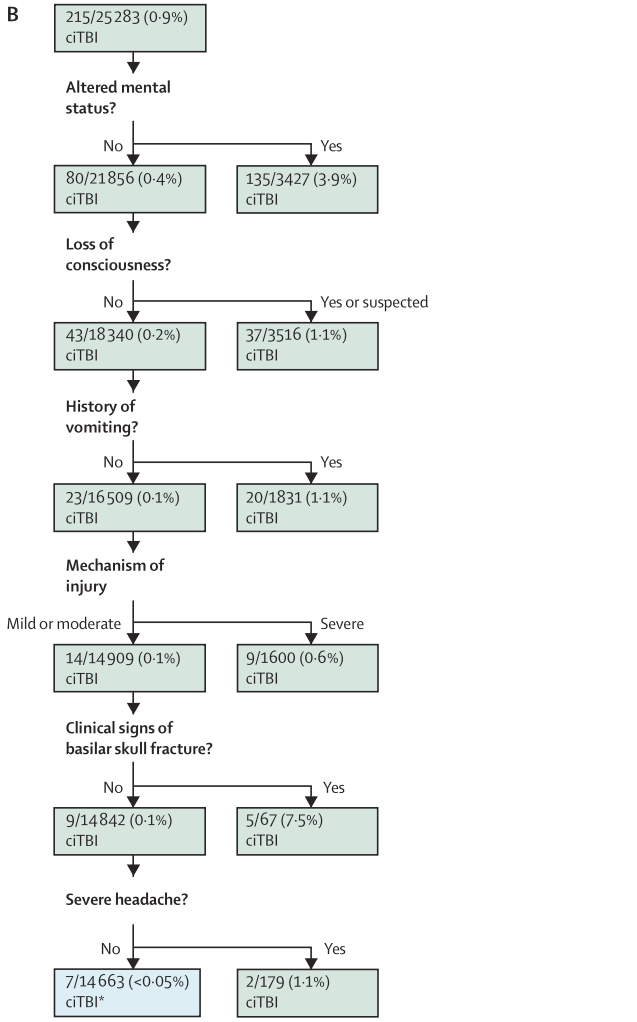
derivation and 2223 (34·7%) in the validation groups. Of these CTs, 1992 (21·1%) and 446 (20·1%) were in children with none of the six predictors (in derivation and validation groups, respectively), representing a very low risk group of children in whom CTs could be obviated. In the validation group, 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





	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)

	Derivation			Validation		
	ciTBI	No ciTBI	Total	ciTBI	No ciTBI	Total
Any predictor present	208	10412	10620	61	2550	2611
No predictor present	7	14656	14663	2	3798	3800
Total	**215**	**25068**	**25283**	**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

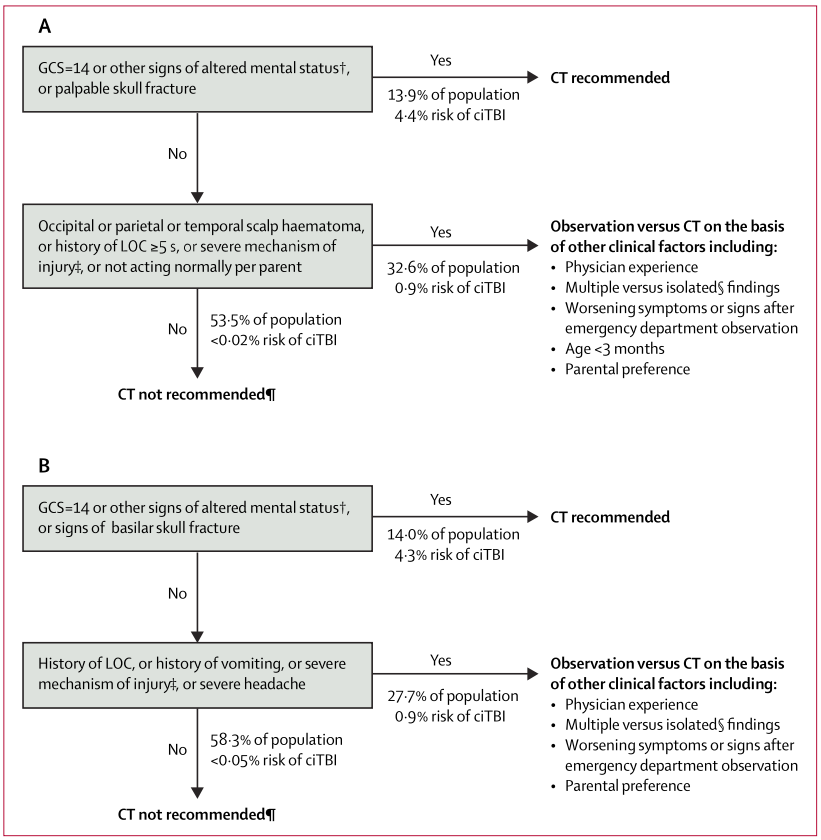


Figure 3: **Suggested CT algorithm for children younger than 2 years (A) and for those aged 2 years and older (B) with GCS scores of 14–15 after head trauma***

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.

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.

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

Atlantic Health System/Morristown Memorial Hospital (M Gerardi); Bellevue Hospital Center (M Tunik, J Tsung); Calvert Memorial Hospital (K Melville); Children's Hospital, Boston (L Lee); Children's Hospital of Buffalo (K Lillis); Children's Hospital of Michigan (P Mahajan); Children's Hospital of New York—Presbyterian (P Dayan); Children's Hospital of Philadelphia (F Nadel); Children's Memorial Hospital (E Powell); Children's National Medical Center (S Atabaki, K Brown); Cincinnati Children's Hospital Medical Center (T Glass); DeVos Children's Hospital (J Hoyle); Harlem Hospital Center (A Cooper); Holy Cross Hospital (E Jacobs); Howard County Medical Center (D Monroe); Hurley Medical Center (D Borgialli); Medical College of Wisconsin/Children's Hospital of Wisconsin (M Gorelick, S Bandyopadhyay); St Barnabas Health Care System (M Bachman, N Schamban); SUNY-Upstate Medical University (J Callahan); University of California Davis Medical Center (N Kuppermann, J Holmes); University of Maryland (R Lichenstein); University of Michigan (R Stanley); University of Rochester (M Badawy, L Babcock-Cimpello); University of Utah/Primary Children's Medical Center (J Schunk); Washington University/St Louis Children's Hospital (K Quayle, D Jaffe). *PECARN Steering Committee* N Kuppermann, E Alpern, J Chamberlain, J M Dean, M Gerardi, J Goepp, M Gorelick, J Hoyle, D Jaffe, C Johns, N Levick, P Mahajan, R Maio, K Melville, S Miller, D Monroe, R Ruddy, R Stanley, D Treloar, M Tunik, A Walker. *MCHB/EMSC liaisons* D Kavanaugh, H Park. *Central Data Management and Coordinating Center (CDMCC)* M Dean, R Holubkov, S Knight, A Donaldson. *Data Analysis and Management Subcommittee (DAMS)* J Chamberlain, M Brown, H Corneli, J Goepp, R Holubkov, P Mahajan, K Melville, E Stremski, M Tunik. *Grants and Publications Subcommittee (GAPS)* M Gorelick, E Alpern, J M Dean, G Foltin, J Joseph, S Miller, F Moler, R Stanley, S Teach. *Protocol Concept Review and Development Subcommittee (PCRADS)* D Jaffe, K Brown, A Cooper, J M Dean, C Johns, R Maio, N C Mann, D Monroe, K Shaw, D Teitelbaum, D Treloar. *Quality Assurance Subcommittee (QAS)* R Stanley, D Alexander, J Brown, M Gerardi, M Gregor, R Holubkov, K Lillis, B Nordberg, R Ruddy, M Shults, A Walker. *Safety and Regulatory Affairs Subcommittee (SRAS)* N Levick, J Brennan, J Brown, J M Dean, J Hoyle, R Maio, R Ruddy, W Schalick, T Singh, J Wright.

Conflicts of interest

We declare that we have no conflicts of interest.

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