PECARN prediction rules for CT imaging of children presenting to the emergency department with blunt abdominal or minor head trauma: a multicentre prospective validation study

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Summary

Background The intra-abdominal injury and traumatic brain injury prediction rules derived by the Pediatric Emergency Care Applied Research Network (PECARN) were designed to reduce inappropriate use of CT in children with abdominal and head trauma, respectively. We aimed to validate these prediction rules for children presenting to emergency departments with blunt abdominal or minor head trauma.

Methods For this prospective validation study, we enrolled children and adolescents younger than 18 years presenting to six emergency departments in Sacramento (CA), Dallas (TX), Houston (TX), San Diego (CA), Los Angeles (CA), and Oakland (CA), USA between Dec 27, 2016, and Sept 1, 2021. We excluded patients who were pregnant or had pre-existing neurological disorders preventing examination, penetrating trauma, injuries more than 24 h before arrival, CT or MRI before transfer, or high suspicion of non-accidental trauma. Children presenting with blunt abdominal trauma were enrolled into an abdominal trauma cohort, and children with minor head trauma were enrolled into one of two age-segregated minor head trauma cohorts (younger than 2 years vs aged 2 years and older). Enrolled children were clinically examined in the emergency department, and CT scans were obtained at the attending clinician's discretion. All enrolled children were evaluated against the variables of the pertinent PECARN prediction rule before CT results were seen. The primary outcome of interest in the abdominal trauma cohort was intra-abdominal injury undergoing acute intervention (therapeutic laparotomy, angiographic embolisation, blood transfusion, intravenous fluid for ≥2 days for pancreatic or gastrointestinal injuries, or death from intra-abdominal injury). In the age-segregated minor head trauma cohorts, the primary outcome of interest was clinically important traumatic brain injury (neurosurgery, intubation for >24 h for traumatic brain injury, or hospital admission ≥2 nights for ongoing symptoms and CT-confirmed traumatic brain injury; or death from traumatic brain injury).

Findings 7542 children with blunt abdominal trauma and 19 999 children with minor head trauma were enrolled. The intra-abdominal injury rule had a sensitivity of $100 \cdot 0\%$ (95% CI $98 \cdot 0-100 \cdot 0$; correct test for 145 of 145 patients with intra-abdominal injury undergoing acute intervention) and a negative predictive value (NPV) of $100 \cdot 0\%$ (95% CI $99 \cdot 9-100 \cdot 0$; correct test for 3488 of 3488 patients without intra-abdominal injuries undergoing acute intervention). The traumatic brain injury rule for children younger than 2 years had a sensitivity of $100 \cdot 0\%$ (93 · 1–100 · 0; 42 of 42) for clinically important traumatic brain injuries and an NPV of $100 \cdot 0\%$; $99 \cdot 9-100 \cdot 0$; 2940 of 2940), whereas the traumatic brain injury rule for children aged 2 years and older had a sensitivity of $98 \cdot 8\%$ ($95 \cdot 8-99 \cdot 9$; 168 of 170) and an NPV of $100 \cdot 0\%$ ($99 \cdot 9-100 \cdot 0$; 6015 of 6017). The two children who were misclassified by the traumatic brain injury rule were admitted to hospital for observation but did not need neurosurgery.

Interpretation The PECARN intra-abdominal injury and traumatic brain injury rules were validated with a high degree of accuracy. Their implementation in paediatric emergency departments can therefore be considered a safe strategy to minimise inappropriate CT use in children needing high-quality care for abdominal or head trauma.

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Introduction

Blunt intra-abdominal injuries and traumatic brain injuries result in substantial morbidity and continue to be leading causes of death in children and adolescents.^{1,2} 1–2% of injured children who are evaluated in emergency departments have intra-abdominal injuries or traumatic

brain injuries that require acute intervention.³⁴ In the late 1990s to early 2000s, CT became the referencestandard diagnostic test to diagnose intra-abdominal injuries and traumatic brain injuries.⁵ The rapid expansion of CT use that followed was problematic. A weak evidence base to inform the use of CT in

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Research in context

Evidence before this study

Although we did not conduct a systematic review of the available literature before undertaking this study, the available evidence suggests that both abdominal and cranial CT are overused in the evaluation of injured children globally. Furthermore, as CT-related ionising radiation can cause malignancies, CT use should be avoided when not indicated. In 2017, the Paediatric Research in Emergency Departments International Collaborative (PREDICT) network validated the existing paediatric traumatic brain injury prediction rules in a multicentre cohort. The PECARN traumatic brain injury rule had sensitivities of 100% for children younger than 2 years and 99% for children aged 2 years and older. By comparison the Canadian Assessment of Tomography for Childhood Head injury (CATCH) and the Children's Head injury Algorithm for the prediction of Important Clinical Events (CHALICE) head injury rules had sensitivities of 95.2% and 92.3%, respectively, for children of all ages. To the best of our knowledge, the PECARN intra-abdominal injury rule has not been prospectively validated.

Added value of this study

In this prospective multicentre study, we validated both the PECARN intra-abdominal injury and traumatic brain injury prediction rules in cohorts of children presenting to any of six paediatric trauma centres with blunt abdominal or minor head trauma between Dec 27, 2016, and Sept 1, 2021. The primary outcome of interest for the abdominal trauma cohort was intra-abdominal injury undergoing acute intervention, and the primary outcome of interest for the head trauma cohort was clinically important traumatic brain injury. Rigorous methods to test the prediction rules in large and diverse cohorts confirmed high sensitivities, acceptable inter-rater agreement, and overall high test accuracies for the PECARN intraabdominal injury and traumatic brain injury rules. Use of abdominal and head CT scans was lower in the validation cohorts than in the original derivation cohorts, indicating an early impact of PECARN rule implementation in participating trauma centres. However, some children in whom the rule was negative (CT scan not indicated) nevertheless underwent abdominal CT scanning; similarly, some of those younger than 2 years and those aged 2 years and older still underwent head CT despite a negative rule. Finally, this study adds information on CT use in children who are positive for any of the prediction rule variables. Across all cohorts, while less than a third of children with only one positive variable within the rule had a CT scan, CT use increased in all cohorts as the number of positive rule variables increased.

Implications of all the available evidence

The PECARN prediction rules for intra-abdominal injury and traumatic brain injury can be regarded as a safe strategy for minimising radiation exposure in children presenting to emergency departments with low-risk trauma to the head and abdomen while delivering high-quality care for their injuries. Unnecessary use of CT scans continues to place children at risk of radiation-induced malignancies, and further research is therefore needed to identify factors that promote evidence-based use of CT in injured children. Finally, in those children who are positive for the prediction rules, CT scanning is not mandated but guidance is provided, and future research is needed to determine when CT is truly indicated.

diagnosis resulted in an overuse of CT for injured children in emergency departments worldwide. Despite the use of radiation-minimising software, CT confers a risk of radiation-induced malignancies, some of which are lethal, with incidence ranging from 18 cases per 10000 cranial CT scans to 34 cases per 10000 abdominal CT scans.⁶⁻⁹ There is an urgent need to improve clinician diagnostic accuracy, promote safe use of CT in injured children, and ultimately, prevent unnecessary radiation exposure.¹⁰⁻¹²

The Pediatric Emergency Care Applied Research Network (PECARN) has derived highly accurate clinical prediction rules for identifying children at very low risk for intra-abdominal injury undergoing acute intervention³ and two age-based rules for clinically important traumatic brain injuries.⁴ These prediction rules identify children who are at such low risk of serious injuries that abdominal or cranial CT scanning is unnecessary. A positive score (ie, at least one variable in the rule scores positive) suggests a non-negligible risk of serious injury, in which case CT scanning should be considered. To assist clinicians in providing evidence-based care to injured children, PECARN investigators have also provided guidance on caring for children for whom CT is not recommended (rule scores negative) and for whom CT is potentially necessary (rule scores positive).^{3,4,13-20} Importantly, however, not all children with a positive score require CT, and obtaining CT scans for any patient with a positive rule score is an inappropriate use of the prediction rule and might increase unnecessary CT use. Thus, CT rates in the derivation and validation studies must be evaluated to ensure the prediction rules have the intended impact of decreasing unnecessary CT use.

Before their clinical implementation and dissemination, the prediction rules require prospective validation in at least one large multicentre study.²¹⁻²⁴ The PECARN intra-abdominal injury rule has, to the best of our knowledge, not been prospectively validated to date. The PECARN traumatic brain injury rules have been validated in several small prospective cohorts and in one large multicentre cohort from the Paediatric Research in Emergency Departments International Collaborative (PREDICT) network, the results of which were published in 2017.²⁵⁻²⁹ This PECARN traumatic brain

injury rule validation study began before it became known from the PREDICT study that the PECARN traumatic brain injury rules have sensitivities of 100% for children younger than 2 years and 99% for children aged 2 years and older. Furthermore, PREDICT showed sensitivities of 95.2% for the Canadian Assessment of Tomography for Childhood Head injury (CATCH) rule and 92.3% for the Children's Head injury Algorithm for the prediction of Important Clinical Events (CHALICE) head injury rule. However, PREDICT evaluated several head injury prediction rules at once, possibly limiting its focus on PECARN.25 A large multicentre study solely focused on validating the PECARN traumatic brain injury rules is therefore in order. The aim of this study was to validate the PECARN intra-abdominal injury and traumatic brain injury rules in a large multicentre cohort of injured children.

Methods

Study design and participants

We conducted a prospective, multicentre cohort study of children with blunt abdominal or minor head trauma, or both. The study was approved by the Institutional Review Board (IRB) of the University of California, Davis, which served as the central IRB. The study protocol has been published.³⁰ Study reporting follows the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.

The study was conducted at six level-1 paediatric trauma centres (highest level of trauma care with availably of all necessary specialists) in Sacramento (CA), Dallas (TX), Houston (TX), San Diego (CA), Los Angeles (CA), and Oakland (CA), USA (five did not participate in the original derivation studies). Children and adolescents younger than 18 years with blunt abdominal or minor head trauma (Glasgow Coma Scale [GCS] scores of 14-15), or both, evaluated at any of the six emergency departments from Dec 27, 2016, to Sept 1, 2021, were eligible for inclusion, following the same criteria as the derivation studies (panel 1).34 Additional exclusion criteria in the head trauma cohort included presence of a ventricular-peritoneal or atrial shunt, pre-existing brain tumour, or known bleeding disorder.4 Eligible children who were not enrolled were identified by review of emergency department patient records to calculate an enrolment rate. This rate was assessed during the initial 17 months of enrolment. We also measured enrolment rates during three randomly selected time periods in the subsequent 40 study months.

Procedures

The attending clinicians enrolled eligible children. Because this study sought to validate the prediction rules (rather than the individual components of the rules), we followed methodological recommendations for validating clinical prediction rules.^{22,4} The clinician overseeing

Panel 1: Inclusion and exclusion criteria for abdominal trauma and head trauma cohorts

Abdominal trauma cohort inclusion criteria (any of the following):

- Blunt torso trauma from a major mechanism of injury
 - Motor vehicle collision: exceeding 96 km/h, ejection, or rollover
 - Automobile versus pedestrian or bicycle: automobile speed greater than 40 km/h
 - Falls from height greater than 6 m
 - Crush injuries to the torso
 - Physical assault involving the abdomen
- Reduced level of consciousness (Glasgow Coma Scale score <15) in association with blunt torso trauma
- Blunt traumatic event with either paralysis of limbs or multiple long bone fractures
- History and physical examination suggestive of intraabdominal injury following blunt torso trauma

Minor head trauma cohort inclusion criteria (any of the following):

- Blunt head trauma from non-trivial mechanisms (falls from standing or running into stationary objects were excluded if there was no evidence of significant head trauma)
- Glasgow Coma Scale score 14-15
- Cranial CT performed following blunt head trauma

Exclusion criteria (both cohorts; any of the following):

- Penetrating trauma (eg, gunshot or knife wounds)
- Injury occurred more than 24 h before arrival at emergency department
- Patient transferred with previous CT or MRI imaging
- Known pregnancy
- Pre-existing neurological disorder complicating physical examination assessment
- High suspicion of non-accidental trauma

a patient's care used a standardised case report form to document whether the pertinent clinical prediction rule was positive or negative; this was completed before knowledge of CT results, if performed. For those children who were positive for a prediction rule, the clinicians would further document whether the individual rule variables were positive, negative, or unknown (panel 2). Clinicians were not required by protocol to follow any specific recommendations based on prediction rule negativity or positivity. A convenience sample was drawn for an inter-rater reliability test, whereby a second clinician assessed prediction rules' outcomes within 1 h of the enrolment examination.

All imaging was obtained at the discretion of the treating clinicians. If obtained, CT results were abstracted from the radiologists' final interpretations. Inconclusive CT results were categorised by the treating clinicians. Those children who were discharged from the emergency

Panel 2: Variables in the PECARN intra-abdominal injury and traumatic brain injury prediction rules

Intra-abdominal injury prediction rule—negative if none of the following variables is present (CT not warranted)

- Abdominal pain
- Vomited since the time of injury
- Glasgow Coma Scale score <14
- Absent or decreased breath sounds
- Evidence of thoracic wall trauma (eg, erythema, abrasions, ecchymosis, subcutaneous air, or laceration)
- Evidence of abdominal wall trauma (eg, seat belt sign, erythema, abrasions, ecchymosis, subcutaneous air, or laceration)
- Abdominal tenderness

Traumatic brain injury prediction rule for children younger than 2 years—negative if none of the following variables is present (CT not warranted)

- Glasgow Coma Scale score <15 or signs of altered mental status (slow response, agitation, sleepiness, confusion, or repetitive questioning)
- Non-frontal scalp haematoma (parietal, temporal, or occipital)
- History of loss of consciousness for ≥5 s
- Evidence of palpable skull fracture or unclear fracture due to scalp swelling
- Acting abnormally according to the parent or guardian
- 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; fall greater than 90 cm; or head struck by a high-impact object)

Traumatic brain injury prediction rule for children aged 2 years and older—negative if none of the following variables is present (CT not warranted)

- Glasgow Coma Scale score <15 or signs of altered mental status (slow response, agitation, sleepiness, confusion, or repetitive questioning)
- History of any loss of consciousness
- Vomiting since the time of the injury
- Clinical signs of basilar skull fracture
- Severe headache (8–10 on a 1–10 subjective numerical severity scale)
- 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; fall greater than 1.5 m; or head struck by a high-impact object)

department were followed up at least 7 days after the index emergency department visit. During follow-up after discharge, a child's guardian was contacted by text or telephone to determine whether any discharged children had subsequently been diagnosed with an intra-abdominal injury or traumatic brain injury. If follow-up was unsuccessful, we reviewed the patient's medical records for subsequent medical evaluations.^{3,4} Those patients who were admitted to hospital for further treatment at the treating clinicians' discretion were followed up by review of medical records to ascertain final diagnoses, treatments, and outcomes. Children were considered admitted to hospital if they had been admitted to the ward, operating suite, intensive care, or observation units.

Outcomes

The primary outcome of interest for the abdominal trauma cohort was intra-abdominal injury undergoing acute intervention.3 Intra-abdominal injury was defined as an injury to the spleen, liver, urinary tract (kidney to bladder), pancreas, gastrointestinal tract (stomach to sigmoid colon including the mesentery), gallbladder, adrenal gland, abdominal vascular structure, or fascial defect (eg, traumatic abdominal wall hernia). Acute intervention for intra-abdominal injury was defined as therapeutic intervention at laparotomy, angiographic embolisation of a bleeding abdominal organ or vascular structure, blood transfusion for anaemia from abdominal haemorrhage, administration of intravenous fluids for at least two nights to maintain hydration in children unable to eat or drink because of pancreatic or gastrointestinal injuries, or death from the intra-abdominal injury.

The primary outcome of interest for the head trauma cohort was clinically important traumatic brain injury.⁴ Clinically important traumatic brain injury was defined as any intracranial injury identified by CT (appendix p 5) that required neurosurgery, endotracheal intubation for more than 24 h for the traumatic brain injury, or hospital admission for at least two nights to manage the head trauma in association with traumatic brain injury, or death due to traumatic brain injury.⁴

Statistical analysis

The sample size requirements for each of the abdominal trauma and head trauma cohorts were similar. We planned the validation of each prediction rule to have an 80% probability of obtaining a one-sided 95% CI above 99.5% when the rule's true negative predictive value is at least 99.8% and to have a 90% probability of obtaining a one-sided 95% CI greater than 95.0% when the rule's true sensitivity is at least 98%. We estimated that a sample size of 2360 children with rule negative results would fulfil the negative predictive value requirement for each rule. A sample size of 55 children with the outcome of interest would fulfil the sensitivity requirement.

Continuous variables are reported as medians with IQRs. To evaluate prediction rule performance, we calculated sensitivity, specificity, and positive and negative predictive values including exact binomial 95% CIs. Sensitivity was calculated as patients with the outcome of interest and positive for the rule divided by patients with the outcome of interest. Specificity was calculated as

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patients without the outcome of interest and negative for the rule divided by patients without the outcome of interest. The positive predictive value was calculated as patients with the outcome of interest who are positive for the rule divided by patients positive for the rule. The negative predictive value was calculated as patients without the outcome of interest who are negative for the rule divided by patients who are negative for the rule divided by patients who are negative for the rule.

Inter-rater reliability was measured with the κ statistic. 31 95% CIs around the κ statistic were calculated as described by Fleiss. 32

The positive diagnostic likelihood ratio was calculated as the sensitivity divided by (100–specificity). The negative likelihood ratio was calculated as (100–sensitivity) divided by the specificity. 95% CIs for diagnostic likelihood ratios were estimated using the method and software described by Marill and colleagues.³³

Study data were managed in REDCap.³⁴ Diagnostic likelihood ratios were evaluated with R statistical software. All other data analysis was done in Stata (version 15).

Role of the funding source

The funder had no role in data collection, data analysis, data interpretation, writing of the manuscript, or the decision to submit the manuscript for publication.

Results

7542 children were enrolled in the abdominal trauma cohort. The median age was 9.7 years (IQR 5.2-13.6); 4290 (56.9%) patients were male and 3252 (43.1%) were female.

5647 children were enrolled in the head trauma cohort younger than 2 years. The median age was 0.9 years (IQR 0.6-1.4); 3065 (54.3%) patients were male and 2582 (45.7%) were female. 14352 children were enrolled in the head trauma cohort aged 2 years and older. The median age was 8.2 years (IQR 4.5-12.9); 8755 (61.1%) patients were male and 5577 (38.9%) were female.

Patient enrolment rates (during the selected times of monitoring) were 2082 (81.6%) of 2551 for the abdominal trauma cohort, 1571 (75.0%) of 2095 for the head trauma cohort younger than 2 years, and 3913 (78.9%) of 4961 for the head trauma cohort aged 2 years and older.

CT was obtained for 2440 of 7542 children in the abdominal trauma cohort (32.4%; 95% CI 31.3-33.4), 1175 of 5647 children in the head trauma cohort younger than 2 years (20.8%; 95% CI 19.8-21.9), and 5098 of 14352 children in the head trauma cohort aged 2 years and older (35.5%; 95% CI 34.7-36.3). Detailed enrolment data are presented in the appendix (pp 2–4). Patient demographics, mechanisms of injury, CT use, and emergency department disposition are described in table 1.

503 (6.7%) of 7542 children in the abdominal trauma cohort had CT-positive intra-abdominal injuries. Injuries involved the liver (n=220 [43.7%]), spleen (n=170 [33.8%]), gastrointestinal tract (n=115 [22.9%]), kidneys (n=96

	Abdominal trauma age <18 years (N=7542)	Head trauma age <2 years (N=5647)	Head trauma age ≥2 years (N=14 352)
Age, years	9.7 (5.2–13.6)	0.9 (0.6–1.4)	8.2 (4.5–12.9)
Sex			
Female	3252 (43·1%)	2582 (45.7%)	5577 (38.9%)
Male	4290 (56·9%)	3065 (54·3%)	8775 (61.1%)
Race or ethnicity*			
American Indian or Alaska Native	57 (0.8%)	42 (0.7%)	109 (0.8%)
Asian	244 (3·2%)	300 (5·3%)	619 (4.3%)
Black	1776 (23.5%)	823 (14.6%)	2646 (18.4%)
Native Hawaiian or Pacific Islander	17 (0.2%)	27 (0.5%)	61 (0.4%)
White	3894 (51.6%)	2857 (50.6%)	7333 (51.1%)
Other or multiple	977 (13.0%)	1145 (20.3%)	2553 (17.8%)
Unknown	576 (7.6%)	384 (6.8%)	892 (6.2%)
Hispanic	3006 (39.9%)	2837 (50.2%)	6552 (45.7%)
Social Deprivation Index score†			
1-25	912 (12·1%)	417 (7·4%)	1597 (11.1%)
26–50	1208 (16.0%)	771 (13.7%)	2271 (15.8%)
51-75	1452 (19·3%)	955 (16.9%)	2425 (16.9%)
76–100	3955 (52.4%)	3498 (61.9%)	8040 (56.0%)
Mechanism of injury			
Motor vehicle collision	3835 (50.8%)	309 (5·5%)	3151 (22.0%)
Auto versus pedestrian	821 (10.9%)	40 (0.7%)	639 (4.5%)
Motorised vehicle	724 (9.6%)	11 (0.2%)	618 (4.3%)
Fall (elevation)	929 (12.3%)	4183 (74.1%)	3793 (26.4%)
Fall (ground) or run into object	174 (2.3%)	631 (11.2%)	2982 (20.8%)
Fall (stairs)	89 (1.2%)	232 (4.1%)	303 (2.1%)
Bicyclist	421 (5.6%)	8 (0.1%)	623 (4.3%)
Assault	145 (1.9%)	13 (0.2%)	445 (3.1%)
Object struck abdomen	151 (2.0%)	5 (0.1%)	28 (0.2%)
Object struck head	107 (1.4%)	187 (3.3%)	1516 (10.6%)
Other	146 (1.9%)	28 (0.5%)	254 (1.8%)
Admitted to hospital	3198 (42.4%)	417 (7.4%)	2411 (16.8%)
Setting of first CT scan			
Emergency department	2440/2490 (98.0%)	1175/1203 (97.7%)	5098/5156 (98.9%)
Hospital	45/2490 (1.8%)	5/1203 (0.4%)	22/5156 (0.4%)
After emergency department or hospital discharge	5/2490 (0.2%)	23/1203 (1.9%)	36/5156 (0.7%)

Data are n (%), n/N (%) when N does not include the entire cohort, or median (IQR). *Race was not documented for one patient in the abdominal cohort and for 208 patients in the head injury cohorts. Ethnicity was not documented for 872 patients in the abdominal cohort and for 1562 in the head injury cohorts. †Social Deprivation Index is a composite measure of seven demographic characteristics based on the patient's zip code that describes household hardship. Severity of the subject's deprivation and the score are linearly related. Severity of deprivation increases as the score increases.

Table 1: Patient characteristics in validation cohorts for abdominal trauma and head trauma

[19.1%]), adrenal glands (n=87 [17.3%]), pancreas (n=20 [4.0%]), and fascia (n=11 [2.2%]). 324 children with intraabdominal injuries had haemoperitoneum (64.4%; 95% CI 60.1–68.6). 145 children with intra-abdominal injuries underwent acute intervention (1.9%; 95% CI 1.6-2.3; appendix p 5). Performance for the rule in children with abdominal injuries undergoing acute intervention are presented in table 2. Rule performance for any intra-abdominal injury, regardless of intervention,

Intra-abdominal injury (age <18 years); N=7542	Traumatic brain injury (age <2 years); N=5647	Traumatic brain injury (age ≥2 years); N=14352
100.0% (98.0–100.0; 145/145)	100.0% (93.1-100.0; 42/42)	98.8% (95.8–99.9; 168/170)
47.2% (46.0-48.3; 3488/7397)	52.5% (51.1-53.8; 2940/5605)	42.4% (41.6-43.2; 6015/14182)
100.0% (99.9–100.0; 3488/3488)	100% (99·9–100·0; 2940/2940)	100.0% (99.9–100.0; 6015/6017)
3.6% (3.0-4.2); 145/4054	1.6% (1.1-2.1; 42/2707)	2.0% (1.7-2.3; 168/8335)
0.000 (0.000–0.042)	0.000 (0.000–0.126)	0.028 (0.000-0.077)
1.892 (1.835-1.928)	2.103 (1.942-2.146)	1.716 (1.673–1.749)
	Intra-abdominal injury (age <18 years); N=7542	Intra-abdominal injury (age <18 years); N=7542 Traumatic brain injury (age <2 years); N=5647 100.0% (98.0-100.0; 145/145) 100.0% (93.1-100.0; 42/42) 47.2% (46.0-48.3; 3488/7397) 52.5% (51.1-53.8; 2940/5605) 100.0% (99.9-100.0; 3488/3488) 100% (99.9-100.0; 2940/2940) 3.6% (3.0-4.2); 145/4054 1.6% (1.1-2.1; 42/2707) 0.000 (0.000-0.042) 0.000 (0.000-0.126) 1.892 (1.835-1.928) 2.103 (1.942-2.146)

Two patients with clinically important traumatic brain injury were not identified by the PECARN rule (appendix p 8). Sensitivity was calculated as patients with the outcome of interest and positive for the rule divided by patients with the outcome of interest. Specificity was calculated as patients without the outcome of interest and negative for the rule divided by patients without the outcome of interest. The negative predictive value was calculated as patients without the outcome of interest who are negative for the rule divided by patients without the outcome of interest. The negative predictive value was calculated as patients without the outcome of interest who are negative for the rule divided by patients who are negative for the rule divided by patients who are negative for the rule divided by patients with the outcome of interest who are negative for the rule divided by patients positive for the rule. The negative diagnostic likelihood ratio was calculated as (100 - sensitivity) divided by the specificity. The positive diagnostic likelihood ratio was calculated as (100 - sensitivity) divided by the specificity. The positive diagnostic likelihood ratio was calculated as (100 - sensitivity) divided by the specificity. The positive diagnostic likelihood ratio was calculated as (100 - sensitivity). PECARN=Pediatric Emergency Care Applied Research Network.

Table 2: Test characteristics for the PECARN prediction rules for children with blunt abdominal or head trauma

is presented in the appendix (p 5). 35 patients had solid organ injuries, but their prediction rule was documented as negative. Types and grades of solid organ injuries not identified by the rule are presented in the appendix (p 6). Of the 42 solid organ injuries that were not identified by the prediction rule, 40 (95%; 95% CI 84–99) were grade I–III injuries.

3488 (46.2%) of 7542 children had a negative rule for intra-abdominal injury; of these, 440 underwent abdominal CT (12.6%; 95% CI 11.5-13.8). The five most common reasons for requesting CT in this cohort were mechanism of injury, trauma surgery request, abnormal liver enzymes, femur fracture, and young age (appendix p 6).

Abdominal CT scans were obtained for 2000 of 4054 (49.3%; 95% CI 47.8–50.9) children with a positive prediction rule. Abdominal CT scan use stratified by the number of positive rule variables is presented in the appendix (p 7). Inter-rater reliability of the intraabdominal injury rule in a convenience sample (n=444) was acceptable, with raw agreement of 85% and κ =0.69 (95% CI 0.62–0.76).³¹

176 $(3 \cdot 1\%)$ of 5647 children in the head trauma cohort younger than 2 years had CT-positive traumatic brain injuries. Injury types were extra-axial haematomas (n=52 [29.5%]), subdural haematomas (n=52 [29.5%]), epidural haematomas (n=28 [15.9%]), subarachnoid haemorrhages (n=48 [27.2%]), cerebral contusions or haemorrhages (n=27 [15.3%]), intraventricular haemorrhages (n=8 [4.5%]), skull fractures depressed more than the width of the skull (n=20 [11.4%]), skull (n=14 [8.0%]), and pneumocephalus diastasis (n=5 $[2 \cdot 3\%]$). 15 (8 \cdot 5\%) children had cerebral oedema or shift in brain structures. 42 children had clinically important traumatic brain injuries (0.7%; 95% CI 0.5-1.0; appendix p 7). Performance of the traumatic brain injury rule for clinically important traumatic brain injury in children younger than 2 years is presented in table 2. Rule performance for any CT-positive traumatic brain injury, regardless of intervention, is presented in the appendix (p 8). 2940 ($52 \cdot 1\%$) children had a negative rule outcome for traumatic brain injury; of these, 122 ($4 \cdot 1\%$; 95% CI $3 \cdot 5 - 4 \cdot 9$) underwent cranial CT. The five most common reasons for CT in this cohort were young age, vomiting, parental request, seizure, and trauma surgery request (appendix p 6).

In the head trauma cohort aged 2 years and older, 433 (3.0%) of 14352 children had CT-positive traumatic brain injuries. Injury types were unspecified extra-axial haematomas (n=73 $[16\cdot9\%]),$ subdural haematomas (n=143 [33.0%]), epidural haematomas (n=79 [18.2%]), subarachnoid haemorrhages (n=113 [26.1%]), cerebral contusions or haemorrhages (n=122 $[28 \cdot 2\%]),$ intraventricular haemorrhages (n=14 [3.2%]), skull fractures depressed by more than the width of the skull (n=31 [7.2%]), skull diastasis (n=58 [13.4%]), and pneumocephalus (n=140 [32.3%]). 45 children (10.4%) had cerebral oedema or shift in brain structures. 170 children had clinically important traumatic brain injuries (1.2%; 95% CI 1.0-1.4; appendix p 7). Performance of the traumatic brain injury prediction rule for clinically important traumatic brain injury in children aged 2 years and older is presented in table 2. Rule performance for any CT-positive traumatic brain injury, regardless of intervention, is presented in the appendix (p 8). In this older age head trauma cohort, 6017 (41.9%) children had a negative rule outcome for traumatic brain injury rule, 532 (8.8%; 95% CI 8.1–9.6) of whom underwent cranial CT. The five most common reasons for CT scanning in these children were mechanism of injury, scalp haematoma, trauma surgery request, headache, and parental request (appendix p 6). The two children with clinically important traumatic brain injuries who were misclassified by the prediction rule are described in the appendix (p 8). Neither underwent neurosurgery.

Among children who were positive for the rule in the head trauma cohorts, cranial CT scans were obtained for 1053 of 2707 children younger than 2 years (38.9%; 95% CI 37.1–40.8) and for 4566 of 8335 children aged 2 years and older (54.8%; 95% CI 53.7–55.9). Cranial CT scan use stratified by the number of positive variables in each rule is presented in the appendix (p 7). Inter-rater reliability of the traumatic brain injury rule was acceptable. In a convenience sample from the head trauma cohort younger than 2 years (n=206), the raw agreement was 76% and κ 0.50 (95% CI 0.38–0.62). In a convenience sample from the head trauma cohort of children aged 2 years and older (n=595), the raw agreement was 81% and κ 0.57 (95% CI 0.50–0.64).³¹

Discussion

In this prospective study we validated the PECARN intraabdominal injury and traumatic brain injury prediction rules in a new large multicentre cohort of children with abdominal and minor head trauma. Both rules performed with high sensitivities and accuracies. Importantly, CT use across both validation populations was reduced compared with the original derivation studies.³⁴ With this robust evidence base, these clinical prediction rules can now be widely disseminated in clinical practice to support high-quality clinical care and avoid unnecessary radiation exposure for children with abdominal and minor head trauma.

Unlike the PECARN traumatic brain injury prediction rules, the PECARN intra-abdominal injury prediction rule had not previously undergone prospective validation. The results of this large prospective multicentre validation study confirmed the rule to be stable and accurate, as all children with intra-abdominal injuries undergoing acute intervention were identified by the rule. The validated PECARN intra-abdominal injury prediction rule is the first of its kind for children with abdominal trauma. The only other prediction rule for abdominal evaluation of injured children to have been derived in a multicentre dataset has not been prospectively validated.^{35,36}

Although clinical prediction rules should not be adopted until validated in multicentre studies, evidence from this validation study suggests that some clinicians were already following the PECARN intra-abdominal injury rule to guide decisions around abdominal CT. In the original derivation study, 25% of children who were deemed very low risk by the prediction rule (PECARN rule negative) underwent abdominal CT. In this validation study, with similar intra-abdominal injury prevalence, only 13% of children without any rule variables underwent abdominal CT. Abdominal CT use also decreased from 61% among children with at least one positive PECARN risk variable in the original derivation study to 32% in this validation study, indicating that the decrease in the use of CT scans was not limited to those at very low risk of intra-abdominal injury undergoing acute intervention. This result might likewise be due to clinical guidance for treating children who test positive for at least one PECARN risk factor.^{3,13} These findings highlight the impact of the PECARN intraabdominal injury prediction rule even before the validation was done.

Despite the reduction in abdominal CT scans among children at very low risk, there is further room to safely decrease CT use in children with blunt abdominal trauma, as 13% of children who were negative for the prediction rule nevertheless underwent abdominal CT scanning. Research of factors associated with the use of CT scans in children at very low risk of important intraabdominal injuries would help further decrease unnecessary CT use.

Since the original derivation study, the PECARN traumatic brain injury rules have undergone various levels of validation in several prospective studies,25-29 and modelling suggests they are cost-effective.37 The multicentre validation PREDICT study showed excellent test characteristics of the PECARN rules in more than 15000 children with minor blunt head trauma.25 PREDICT also showed that the PECARN traumatic brain injury rules performed somewhat better than CATCH³⁸ and CHALICE,39 two prominent paediatric head injury rules derived from multicentre cohorts.25 Here we confirm the promising sensitivity results of the derivation studies by detecting all clinically important traumatic brain injuries among children younger than 2 years and nearly all clinically important traumatic brain injuries among children aged 2 years and older. The two children with clinically important traumatic brain injuries misclassified by the PECARN rule in this validation study did not undergo intubation or neurosurgery but were admitted to hospital for more than 2 nights for observation. Furthermore, analysis of a large database with more than 11000 children suggested that implementation of the PECARN traumatic brain injury rules is safe (ie, no missed cases of neurosurgery or intensive care unit admission).40

This validation study was designed and executed with methodological rigour, not only to specifically validate the PECARN prediction rules but to assess the inter-rater reliability of the rules (as opposed to the inter-rater reliability of the rule components).²¹⁻²⁴ The large sample size, acceptable inter-rater reliability, and excellent test performance will alleviate reservations against the use of the PECARN traumatic brain injury rules.

This validation study also provides evidence of the potential impact of the PECARN traumatic brain injury rules. In the 2009 derivation study, clinicians obtained cranial CT scans of low-risk head trauma (PECARN rule negative) for 15% of children younger than 2 years and for 13% of those aged 2 years and older.⁴ The validation and derivation populations had similar injury profiles, yet in the validation study, CT scans for very low-risk head trauma decreased to 5% of children younger than 2 years and 9% of those aged 2 years and older. The prediction rules might therefore have had a role in

decreasing CT use for children with very low-risk head trauma. Cranial CT use for children with at least one PECARN risk variable also decreased from 64% in the original derivation study to 36% in this validation study, further suggesting that the decrease CT use was not limited to those at very low risk of traumatic brain injury. This change in CT use is probably related to the guidance on care for those children with at least one PECARN risk factor and the recommendation that these children be observed before CT decision making.^{15-17,19,41,42}

Clinical impact must be proven for a prediction rule to reach the highest level of evidence and deemed suitable for implementation.²³ We consider the PECARN traumatic brain injury prediction rules to meet these criteria. Several studies also suggest the PECARN traumatic brain injury prediction rules can safely decrease cranial CT use in both academic and community settings and around the world.^{43–46} These studies showed a 1·7–11·8% reduction in cranial CT use, with the greatest reduction in the community hospital setting.^{43–46}

The characteristics of the population in this validation study strengthen the generalisability of the prediction rules for both intra-abdominal injury and traumatic brain injury. Five of six participating centres differed from the centres contributing patients to the derivation studies, as methodologically recommended.^{22,24} Importantly, the rates of intra-abdominal injury and traumatic brain injury were similar in the derivation and validation populations, and therefore lower CT rates in this validation study cannot be attributed to a less injured population. Compared to the derivation studies, the population enrolled for validation included different rates and types of mechanisms of injury (eg, a higher percentages of motor vehicle collisions and falls from elevations, and fewer bicycle accidents) and different distributions of race and ethnicity; for example, as a proportion of the total study population, the Hispanic population is four times higher in the validation population than in the derivation population.^{3,4} Finally, a substantial percentage of the enrolled patients were of lower socioeconomic status.

This study has certain limitations. It was conducted at paediatric trauma centres where clinician experience might differ to that of community emergency departments. Previous work, however, suggests the PECARN traumatic brain injury rules can be safely implemented in community hospitals.46,47 Similarly, the inter-rater reliability was assessed by clinicians who provide care at paediatric trauma centres, and their inter-rater reliability might differ to those who practice in community emergency departments. The PECARN intra-abdominal injury and traumatic brain injury prediction rules identify cohorts of children at very low risk who do not benefit from CT. Although the rules are focused on identifying these very low-risk patients, the presence of a PECARN risk factor does not necessitate CT imaging. If clinicians misuse these rules (ie, obtaining CT in all children for whom the

rule is positive), there is the potential for an increase in CT use. In fact, CT is not warranted in most children with isolated PECARN risk variables in either the intraabdominal injury or traumatic brain injury rule. As expected, the rates of CT scanning increased as the number of positive rule variables increased, but many children with only one or two positive variables safely avoided CT scanning. Furthermore, CT rates were higher in the older cohort of children with head trauma than in the abdominal injury cohort when only one, two, or three variables were positive. This finding suggests that clinicians were more willing to order cranial CT scans than abdominal CT scans among patients with a similar number of rule variables positive. We have previously shown specific risks and guidance for CT imaging in children with abdominal or minor head trauma, based on the number and type of positive PECARN variables.^{3,4,13-20} Most importantly, no evidence suggests that use of these prediction rules increases abdominal or cranial CT scanning. Finally, despite the substantial decrease in CT use in this validation study compared to the derivation studies, the study design does not allow us to ascertain how much of the decline in CT use is due to clinicians' use of the prediction rules rather than other temporal changes.

With these findings, both the PECARN intra-abdominal injury and traumatic brain injury rules have been externally validated in large, multicentre, diverse cohorts and have reached the highest category (Level 1) of evidence in the hierarchy of clinical prediction rules.²³ The rules show a high degree of test accuracy, giving clinicians the ability to deliver high-quality, safe clinical care. Widespread implementation is now indicated, which could continue to decrease unnecessary CT use in children with abdominal or minor head trauma.

Contributors

JFH, DJT, and NK designed the study. JFH, KY, ITU, PI, PPC, NA, MB, KAM-G, DN, ACS, GT, JSU, DJT, and NK acquired the data. JFH, DJT, DN, and NK did the statistical analysis. JFH, DN, GT, and DJT directly accessed and verified the data. All authors contributed to data interpretation. JFH drafted the manuscript, and all authors contributed to the editing, review, and approval of the manuscript.

Declaration of interests

We declare no competing interests.

Data sharing

Data for this study will be made available for qualified researchers following the execution of a data sharing agreement by contacting the corresponding author.

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