TITLE: Accuracy of clinician practice compared to PECARN, CATCH and CHALICE head injury decision rules in children. A prospective cohort study.

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ABSTRACT

Study objective: Three clinical decision rules for head injuries in children (Pediatric Emergency Care Applied Research Network [PECARN], Canadian Assessment of Tomography for Childhood Head Injury [CATCH], and Children's Head Injury Algorithm for the Prediction of Important Clinical Events [CHALICE]) have been shown to have high performance accuracy. The utility of any of these in a particular setting depends on preexisting clinician accuracy. We therefore assess the accuracy of clinician practice in detecting clinically important traumatic brain injury.

Methods: This was a planned secondary analysis of a prospective observational study of children younger than 18 years with head injuries at 10 Australian and New Zealand centers. In a cohort of children with mild head injuries (Glasgow Coma Scale score 13 to 15, presenting in <24 hours) we assessed physician accuracy (computed tomography [CT] obtained in emergency departments [EDs]) for the standardized outcome of clinically important traumatic brain injury and compared this with the accuracy of PECARN, CATCH, and CHALICE.

Results: Of 20,137 children, 18,913 had a mild head injury. Of these patients, 1,579 (8.3%) received a CT scan during the ED visit, 160 (0.8%) had clinically important traumatic brain injury, and 24 (0.1%) underwent neurosurgery. Clinician identification of clinically important traumatic brain injury based on CT performed had a sensitivity of 158 of 160, or 98.8% (95% confidence interval [CI] 95.6% to 99.8%) and a specificity of 17,332 of 18,753, or 92.4% (95% CI 92.0% to 92.8%). Sensitivity of PECARN for children younger than 2 years was 42 of 42 (100.0%; 95% CI 91.6% to 100.0%), and for those 2 years and older, it was 117 of 118 (99.2%; 95% CI 95.4% to 100.0%); for CATCH (high/medium risk), it was 147 of 160 (91.9%; 95% CI 86.5% to 95.6%); and for CHALICE, 148 of 160 (92.5%; 95% CI 87.3% to 96.1%).

Conclusion: In a setting with high clinician accuracy and a low CT rate, PECARN, CATCH, or CHALICE clinical decision rules have limited potential to increase the accuracy of detecting clinically important traumatic brain injury and may increase the CT rate.

INTRODUCTION

Background

A number of clinical decision rules have been designed to assist clinicians in determining which children with head injuries are at higher or lower risk of an intracranial injury, and should therefore undergo computed tomography (CT) or do not require neuroimaging.1-6 Some studies have assessed and compared the accuracy of different pediatric head injury clinical decision rules in prospective data sets.3,7-10 However, in addition to comparative prima facie accuracy, several other elements are important when one assesses which rule, if any, should be implemented in a particular setting. These may include baseline CT rate11-13 and effects of rule implementation,14,15 the medicolegal climate, shared decision making with families,16 availability of CT imaging and neurosurgical support, possibility to observe disease progression or recovery,17,18 and factors such as pre-existing clinician accuracy without the clinical decision rules.8,19 Before the derivation of head injury clinical decision rules, physician accuracy was reported to be low,5,20 instigating both the need for clinical decision rules and acceptance of their use.

We recently completed a study on the comparative accuracy of 3 high-quality clinical decision rules, 3 the prediction rule for the identification of children at very low risk of clinically important traumatic brain injury developed by the Pediatric Emergency Care Applied Research Network (PECARN), 4 the Canadian Assessment of Tomography for Childhood Head Injury (CATCH) rule, 5 and the Children's Head Injury Algorithm for the Prediction of Important Clinical Events (CHALICE). 6 In a comparison cohort of 18,913 head-injured children with Glasgow Coma Scale (GCS) score 13 to 15, the point sensitivities of the rules in our external validation cohort were high.

Importance

In settings with high baseline CT rates and high variability of CT rates, as has been reported in the United States and Canada,11,12 clinical decision rules may assist in safely reducing CT rates.15,16 In settings with low CT rates, such as that reported in Australia,3,13,21 the introduction of clinical decision rules has the potential to increase neuroimaging, with unclear benefit in detecting intracranial injuries.3,19 Key to understanding the benefits of clinical decision rules in a particular setting will be to know clinician accuracy without formal use of clinical decision rules.22

Goals of This Investigation

Using a large cohort of mildly head-injured children (GCS score 13 to 15) in a setting with low CT imaging rates, we set out to assess clinician accuracy (sensitivity and specificity) according to whether a CT was performed during the initial emergency department (ED) visit. We then compared clinician accuracy with the accuracy of PECARN, CATCH, and CHALICE, using a single outcome measure across all rules, clinically important traumatic brain injury.

MATERIALS AND METHODS

Study Design and Setting

This was a planned substudy of a prospective multicentre observational study that enrolled children younger than 18 years with head injury of any severity who presented to 10 pediatric EDs in Australia and New Zealand between April 2011 and November 2014.3,23 All EDs are members of the Paediatric Research in Emergency Departments International Collaborative research network.24

The study sites had a census ranging from 19,000 to 78,000 children treated annually. Seven of the 10 EDs were regional trauma centers. At any one time during the study period, approximately 520 ED clinicians, including senior staff, pediatric and emergency trainees, and nurse practitioners, worked at participating EDs.

We assessed clinician accuracy for predicting the standardized outcome of clinically important traumatic brain injury (death from traumatic brain injury, need for neurosurgery, intubation >24 hours for traumatic brain injury, and hospital admission >2 nights for traumatic brain injury in association with traumatic brain injury on CT)4 by conducting a CT in the ED. Secondarily, we also assessed whether either a CT was conducted or the patient underwent a period of observation with a length of stay of 4 hours or greater.

The study was approved by the institutional ethics committees at each participating site. We obtained informed verbal consent from parents or guardians apart from instances of significant life-threatening or fatal injuries, in which participating ethics committees granted a waiver of consent.

The trial protocol was published in detail elsewhere.23 The study was registered with the Australian New Zealand Clinical Trials Registry and followed the Standards for Reporting of Diagnostic Accuracy

studies guidelines25 and attempted to fulfill the methodological standards for interpreting clinical decision rules.26

Selection of Participants

Patients were enrolled by the treating ED clinician, who collected demographic, epidemiologic, and clinical data on a standardized case report form before any neuroimaging. ED clinicians decided to obtain a head CT in the ED in accordance with their clinical judgment. Site investigators, research assistants, and participating ED clinicians received formal training before and during the study. ED clinicians and research assistants were not blinded to the purpose of the study.

Methods of Measurement

In addition to the data collected by the ED clinician, a research assistant recorded ED and hospital management data after the visit and conducted a telephone follow-up for patients who had not undergone neuroimaging. Up to 6 follow-up call attempts were made up to 90 days after injury. In addition, data of any patients who had representations to the study hospitals leading to a CT scan within the follow-up period before the telephone call were used to assess outcomes. Any patients who had presented to other hospitals (as identified at telephone follow-up) had neuroimaging and neurosurgery reports requested for review.

Outcome Measures

Primary outcome was clinically important traumatic brain injury defined as above. Traumatic brain injury on CT was defined by any of the following: intracranial hemorrhage or contusion, cerebral edema, 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, and skull fracture depressed by at least the width of the table of the skull.

Neurosurgical intervention for traumatic brain injury included intracranial pressure monitoring, elevation of depressed skull fracture, ventriculostomy, hematoma evacuation, lobectomy, tissue debridement, dura repair, and other procedures.

We used GCS score as assigned by the ED clinician on his or her assessment in the analysis. We used senior site radiologist reports to determine the results of CT scans and operative reports to determine neurosurgical interventions performed.

Primary Data Analysis

Data were entered into Epidata (The Epidata Association, Odense, Denmark), and later REDCap,27 and analyzed with Stata (version 13; StataCorp, College Station, TX). Descriptive statistics were calculated for key variables, with 95% confidence intervals (CIs) where relevant. Accuracy was calculated with sensitivity, specificity, and positive and negative predictive value, with 95% CIs. A sample size calculation had been conducted for the parent study3,23; no additional sample size calculation was conducted for this substudy, and data for all available patients who fulfilled inclusion criteria were used for analysis.

RESULTS

Characteristics of Study Subjects

A total of 29,433 patients presented to the ED with head injury of any severity, of whom 5,203 were missed. Of 20,137 evaluable patients, 18,913 had a GCS score of 13 to 15 and presented within 24 hours (Figure). Mean age in this cohort was 5.7 years (SD 4.6 years). Most injuries were due to falls (70.5%). Overall, 1,691 patients (8.9%) received a CT scan at any time in relation to the head injury, 1,579 (8.3%) received a CT scan at any time in relation to the head injury, 1,579 (8.3%) received a CT scan during their initial ED visit, and 24 (0.1%) underwent neurosurgery. CT rates at 8 hospitals were between 5.6% and 11.3%; one hospital had a low rate of 1.0% and one of 16.2%. One patient died, and 160 (0.9%) had a clinically important traumatic brain injury (Table 1). Of the 18,913 patients, 4,710 (24.9%) had a length of stay greater than or equal to 4 hours. Of these patients, 1,497 (31.8%) were observed in the ED only, and 3,213 (68.2%) were admitted to a ward setting. After discharge, of the 17,294 patients who received a follow-up call, 2,189 consulted a clinician in follow-up in various settings.

Main Results

Clinicians performed a CT scan during the initial ED visit for 158 of 160 patients with clinically important traumatic brain injury (sensitivity 158/160, 98.8% [95% CI 95.6% to 99.8%]; specificity 17,332/18,753, 92.4% [95% CI 92.0% to 92.8%]). Clinicians did not miss any patients when assessed in terms of whether they performed a CT scan or observed the patient 4 hours or greater, with a lower specificity. Clinician sensitivity and specificity for neurosurgery were high (Table 2).

The 2 patients with clinically important traumatic brain injury who did not receive a CT scan on their initial ED visit included a 13-year-old boy who was hit in the head by a small ball. He presented to the ED after vomiting more than 3 times. He had no loss of consciousness and his GCS score was 15. He was observed in the hospital for 7 hours and discharged home. He re-presented 1 week later with ongoing headache and vomiting. Subsequent CT and magnetic resonance imaging (MRI) showed a temporal skull fracture and a small epidural bleeding event in a preexisting malformation. He did not require neurosurgery and was admitted for greater than 2 days. The second patient was a 16-year-old boy who was kneed in the head during game play. He presented with amnesia and mild headache and vomited more than 3 times. He had no loss of consciousness and presented with a GCS score of 15. During the initial visit, he was observed for 5 hours and then discharged home. He re-presented 1 week later with ongoing headache. CT and MRI showed a small subdural bleeding event and a sinus fracture with a cerebrospinal fluid leak. He did not require neurosurgery and was admitted for greater than 2 days.

Table 3 shows the accuracy of clinician practice and the accuracy of PECARN, CATCH, and CHALICE clinical decision rules in detecting clinically important traumatic brain injury.³ Clinician accuracy did not differ from the 3 rules in terms of sensitivity and negative predictive value, with overlapping 95% Cls. However, clinicians had greater specificity and positive predictive value (Table 3). PECARN for children younger than 2 years, PECARN for children 2 years or older, CATCH, and CHALICE missed 0, 1, 13, and 12 patients, respectively, in terms of detecting clinically important traumatic brain injury in comparison to the 2 patients missed by clinicians using no clinical decision rule. One of the 13 CATCH and 2 of the 12 CHALICE patients required neurosurgery.

LIMITATIONS

This study was conducted at mostly tertiary Australian and New Zealand pediatric centers with pediatric emergency physicians on staff and so may not be representative of care at general and mixed EDs. Although we do not know whether clinicians in this study followed one of the known clinical decision rules or incorporated elements of them, in a survey before conducting this study we found that none of the known head injury clinical decision rules predominated in senior clinician practice or local hospital guidelines.22 However, it is possible that both the Hawthorne effect and the act of collecting the data for the predictor variables of high-quality clinical decision rules prompted clinicians to be better at identifying important traumatic brain injury; neither ED clinicians nor research assistants were blinded

to the purpose of the study, which may have introduced bias. This does not, however, explain why the neuroimaging rate was very low compared with the projected rates based on the clinical decision rules.3

Both the cohort we used to assess clinician accuracy and the outcome measure used were compromise solutions. We chose to focus on head injuries with GCS score 13 to 15 because they represent the population of greatest diagnostic difficulty for clinicians.5,8,20,28 Clinically important traumatic brain injury was chosen as a clinically meaningful primary outcome measure because it included, in addition to death from head injury and neurosurgery, important clinical outcomes of admission for some length of time because of head-injury-related symptoms and intubation for head injury beyond an initial phase that may have been related to obtaining a CT scan.4

We lost approximately 10% of head-injured children to follow-up, who were excluded from analysis. It is unlikely that patients with clinically important traumatic brain injury would have been missed because the study sites typically represented the local neurosurgical referral centers.

Calculations of clinical decision rule accuracy were based on missing predictor variables' being presumed to be negative. However, when patients with missing predictor variables were excluded, the key accuracy results were unchanged.³ Patients were unequally distributed across sites, with most patients, 26.5% and 21.8%, respectively, treated at the 2 hospitals with both the highest annual censuses and the longest recruitment periods. We could not assess clustering by ED clinician because the names of individual clinicians were not collected.

DISCUSSION

In this multicenter study, clinician accuracy in detecting clinically important traumatic brain injury was very high, whether neuroimaging alone or the combination of neuroimaging and observation was considered as the criterion for clinician accuracy. When clinician accuracy (sensitivity 99%) was compared with 3 high-quality clinical decision rules, PECARN had similarly high point sensitivities (99% to 100%); CATCH and CHALICE had lower point sensitivities but 95% CIs overlapped across all rules and clinician practice.

The observed CT rate in our EDs was 8.3%. This would have been higher had all patients with clinical decision rule predictor variables received a CT scan. For CHALICE, the projected CT rate would have been

20.0%; for CATCH, 30.2%.3 A projected CT rate for PECARN is more difficult to determine because the clinical decision rule focuses on patients identified as low risk who do not require a CT scan; patients not at low risk may or may not undergo CT scan.4

Data from several studies have shown that the introduction of the PECARN clinical decision rule safely decreased the CTrate for head injuries in settings with higher CTrates15,16 and did not increase the CT rate in those with lower ones.14 The results of this study are similar to those of a single center study of head injuries with GCS score 13 to 15 from the United States by Easter et al.8 This demonstrated high point sensitivities for PECARN and clinician practice (defined as CT ordering) (100% [95%CI 84% to 100%]) compared with CATCH (91% [95% CI 70% to 99%]) and CHALICE (84% [95%CI 60% to 97%]); the PECARN clinical decision rule specificity was 62% (95% CI 59% to 66%) compared with clinician specificity of 50% (95% CI 47% to 53%). The accuracy of the PECARN clinical decision rule has also been compared with clinician suspicion of clinically important traumatic brain injury in the original validation cohort.29 Using clinician suspicion of clinically important traumatic brain injury at a level greater than 1% versus having at least one age-specific PECARN predictor variable, the PECARN prediction rules were more sensitive than clinician suspicion for children younger than 2 years or older (96.8% [95% CI 88.8% to 99.6%] versus 64.5% [95% CI 51.3% to 76.3%]), respectively. PECARN rule specificity was lower than clinician suspicion in both age groups.

The combination of high sensitivity, high specificity, and a low CT rate demonstrated in our study may reflect a largely tertiary setting with supervision by pediatric emergency physicians and a baseline low CT rate in Australia and New Zealand.13 Although we documented the clinician seniority in completing the data forms, we did not document whether senior clinicians were consulted and who ultimately decided whether to perform a CT scan.

Junior staff in the Australian and New Zealand setting are not mandated to review or discuss every patient with senior staff, in contrast to US practice. In Australia and New Zealand, economic pressures likely had little effect on the rate of neuroimaging in settings with universal taxpayer-funded health care; primary care providers who refer patients to EDs likely also have a limited effect on the imaging decisions of ED clinicians in this setting. Other factors that may have influenced imaging rates, such as the medicolegal climate, parental expectations, and differences in availability and practice of observation and follow-up, are difficult to quantify and compare across countries.

When we originally set out to validate and compare PECARN, CATCH, and CHALICE rules,3,23 our aim was to determine the most accurate and feasible clinical decision rule in our setting and implement it in Australia and New Zealand. As shown in this analysis, clinician accuracy in our setting was very high and the patients "missed" by clinicians both had prolonged observation periods during the initial visit. Their clinical course did not require return to the hospital inside 1 week and the findings on eventual neuroimaging did not require neurosurgery. This suggests that discharging them may not have been inappropriate.

According to the clinician accuracy data in our setting, the introduction of any one of the clinical decision rules will not improve the accuracy of diagnosis of clinically important traumatic brain injury and, depending on the rule chosen, may increase the CT rate.

Clinicians and regional or national bodies considering the introduction of one of the rules will need to consider local clinician accuracy. In settings with high clinician accuracy, PECARN, CATCH, or CHALICE clinical decision rules may have limited potential to increase the accuracy of detecting clinically important traumatic brain injury and have the potential to increase the CT rate.

Declaration of conflicts of interests

None of the authors have conflicts of interests.

Acknowledgement

We would like to thank the participating families and emergency department staff at participating sites. We would like to thank research staff from participating sites.

Funding

The study was funded by grants from the National Health and Medical Research Council (project grant GNT1046727, Centre of Research Excellence for Paediatric Emergency Medicine GNT1058560), Canberra, Australia; the Murdoch Childrens Research Institute, Melbourne, Australia; the Emergency Medicine Foundation (EMPJ-11162), Brisbane, Australia; Perpetual Philanthropic Services (2012/1140), Australia; Auckland Medical Research Foundation (No. 3112011) and the A + Trust (Auckland District Health Board), Auckland, New Zealand; WA Health Targeted Research Funds 2013, Perth, Australia; the

Townsville Hospital and Health Service Private Practice Research and Education Trust Fund, Townsville, Australia; and supported by the Victorian Government's Infrastructure Support Program, Melbourne, Australia. FEB's time was part funded by a grant from the Royal Children's Hospital Foundation, Melbourne, Australia, a Melbourne Children's Clinician Scientist Fellowship, Melbourne, Australia; and an NHMRC Practitioner Fellowship, Canberra, Australia. SRD's time was part funded by the Health Research Council of New Zealand (HRC13/556).

Author Contributions

Franz E Babl: Conceived the study, obtained grant funding, designed the study, provided overall supervision, interpreted the data, wrote the initial draft of the paper, gave final approval to be published, and agreed to be accountable for all aspects of the work.

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Susan Donath: Designed the study, supervised the analysis of the data, contributed to the interpretation of the data, revised the paper critically, gave final approval to be published, and agreed to be accountable for all aspects of the work.

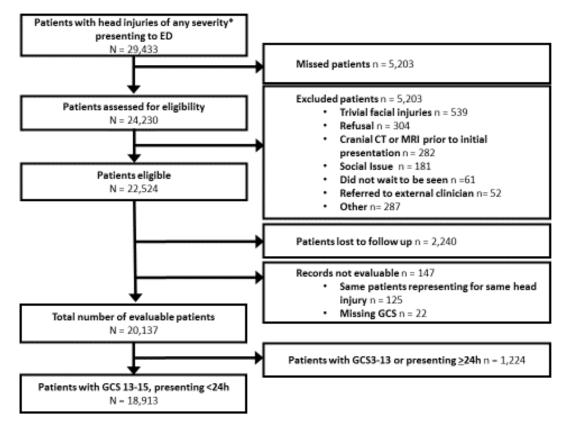
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Figure 1: Patients flow



GCS Glasgow Coma Scale CT computed tomography MRI magnetic resonance imaging ED emergency department

	Comparison cohort n=18913	
	n	%
Demographic characteristics		
Mean age (years) (SD)	5.7	4.6
Patients <2 years	5046	26.7
Males	12073	63.8
Clinician-assigned GCS score		
13	132	0.7
14	567	3.0
15	18214	96.3
Example symptoms and signs		
Known or suspected LOC	2468	13.1
History of amnesia	1591	8.4
History of vomiting	3094	16.4
Headache	3785	20.0
Witnessed disorientation	2425	12.8
Mechanism of injury		
Fall-related	13337	70.5
Motor-vehicle incident	745	3.9
Head hit by high-impact object or projectile	1228	6.5
Suspected NAI	81	0.4
Outcomes		
Cranial CT at any time	1691	8.9
Neurosurgery	24	0.1
Hospital admission	4164	22.0
Death	1	0.0
Clinically important traumatic brain injury*	160	0.9

Table 1: Demographics, injury characteristics, imaging and neurosurgery in children with mild headinjuries (GCS 13-15, presentation <24h)</td>

GCS Glasgow coma scale, NAI non accidental injury, LOC loss of consciousness, CT computed tomography

* clinically important traumatic brain injury (ciTBI) defined as per PECARN CDR death from traumatic brain injury, need for neurosurgery, intubation >24 hours for traumatic brain injury, hospital admission >2 nights for traumatic brain injury in association with traumatic brain injury on CT

	Initial CT scan	Initial CT scan or Length of Stay ≥4 hours
Clinically important traumatic	Positive Negative Yes 158 2	Positive Negative Yes 160 0
brain injury *	No 1421 17332	No 5723 13030
Sens (95% CI)	158/160 98.8% (95.6– 99.8)	160/160 100.0% (97.7-100.0)
Spec (95% CI)	17332/18753 92.4% (92.0 – 92.8)	13030/18753 69.5% (68.8-70.1)
PPV (95% CI)	158/1579 10.0% (8.6 – 11.6)	160/5882 2.7% (2.3-3.2)
NPV (95% CI)	17332/17334 100.0% (100 – 100.0)	13030/13030 100.0% (100 – 100.0)
	Positive Negative	Positive Negative
Neurosurgery***	Yes 24 0 No 1555 17334	Yes 24 0 No 5859 13030
Sens (95% CI)	24/24 100% (85.8 – 100)	24/24 100% (85.8 – 100)
Spec (95% CI)	17334/18889 91.8% (91.4 – 92.2)	13030/18889 69.0% (68.3-69.6)
PPV (95% CI)	24/1579 1.5% (1.0 – 2.3)	24/5883 0.4% (0.3-0.6)
NPV (95% CI)	17334/17334 100.0% (100.0 – 100.0)	13030/13030 100.0% (100.0 – 100.0)

Table 2: Diagnostic accuracy of clinician practice in patients with GCS 13-15 presenting within 24 hours of injury (n=18,913)

Sens= sensitivity; Spec= specificity; PPV= positive predictive value; NPV= negative predictive value; CI= confidence interval

* clinically important traumatic brain injury (ciTBI) defined as per PECARN CDR as death from traumatic brain injury, need for neurosurgery, intubation >24 hours for traumatic brain injury, hospital admission >2 nights for traumatic brain injury in association with traumatic brain injury on CT

** traumatic brain injury defined as per PECARN CDR as 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 at least the width of the table of the skull

*** neurosurgical intervention for traumatic brain injury defined as per PECARN CDR as intracranial pressure monitoring, elevation of depressed skull fracture, ventriculostomy, haematoma evacuation, lobectomy, tissue debridement, dura repair, other

Table 3: Diagnostic accuracy of clinician practice, PECARN, CATCH and CHALICE CDRs in patients with GCS 13-15 presenting within 24 hours of injury (n=18,913)

	Clinician	Clinician PECARN		САТСН	CHALICE
	Practice	< 2y	≥2y		
		n=5,046	n=13,867		
	Positive Negative	Positive Negative	Positive Negative	Positive Negative	Positive Negative
CiTBI *	Yes 158 2 No 1421 17332	Yes 42 0 No 2047 2957	Yes 117 1 No 6606 7143	Yes 147 13 No 5560 13193	Yes 148 12 No 4018 14735
Sens	158/160	42/42	117/118	147/160	148/160
(95% CI)	98.8% (95.6–99.6)	100.0% (91.6 -100.0)	99.2% (95.4 – 100.0)	91.9% (86.5-95.6)	92.5% (87.3-96.1)
Spec	17332/18753	2957/5004	7143/13749	13193/18753	14735/18753
(95% CI)	92.4% (92.0 – 92.8)	59.1% (57.7 – 60.5)	52.0% (51.1 – 52.8)	70.4% (69.7 – 71.0)	78.6% (78.0– 79.2)
PPV	157/1579	42/2089	117/6723	147/5707	148/4166
(95% CI)	10.0% (8.6-11.6)	2.0% (1.5 -2.7)	1.7% (1.4 – 2.1)	2.6% (2.2 - 3.0)	3.6% (3.0 - 4.2)
NPV	17332/17334	2957/2957	7143/7144	13193/13206	14735/14747
(95% CI)	100.0% (100.0 – 100.0)	100.0% (99.9 –100.0)	100.0% (99.9 – 100.0)	99.9% (99.8 – 99.9)	99.9% (99.9 – 100.0)

PECARN Pediatric Emergency Care Applied Research Network;

CATCH Canadian Assessment of Tomography for Childhood Head Injury;

CHALICE Children's Head Injury Algorithm for the Prediction of Important Clinical Events

Sens sensitivity Spec specificity PPV positive predictive value NPV negative predictive value CI confidence interval * ciTBI (clinically important traumatic brain injury) as defined per PECARN CDR as death from traumatic brain injury, need for neurosurgery, intubation >24 hours for traumatic brain injury, hospital admission >2 nights for traumatic brain injury in association with traumatic brain injury on CT