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**Performance of Two Head Injury Decision Rules Evaluated on an External
Cohort of 18,913 Children**

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Abbreviations: Emergency Department (ED); computed tomography (CT); Glasgow Coma Scale (GCS); clinically important traumatic brain injury (ciTBI); Pediatric Emergency Care Applied Research Network (PECARN); Israeli Decision Algorithm for Identifying Traumatic Brain Injury in Children (IDITBIC); positive predictive values (PPV); negative predictive value (NPV); positive likelihood ratio (PLR); negative likelihood ratio (NLR); receiver operating characteristic (ROC); area under curve (AUC)

Author Contributions:

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Abstract

Background: The Pediatric Emergency Care Applied Research Network (PECARN) decision rule demonstrates high sensitivity for identifying children at low risk for clinically important traumatic brain injury (ciTBI). As with the PECARN rule, the Israeli Decision Algorithm for Identifying TBI in Children (IDITBIC) recommends proceeding directly to computed tomography (CT) in children with Glasgow Coma Score (GCS) <15 . The aim was to assess the diagnostic accuracy of two clinical rules that assign children with GCS <15 at presentation directly to CT.

Materials and methods: Accuracy analysis for detecting ciTBI was performed on a multicenter cohort of children used in the Australasian Pediatric Head Injury Rules Study.

Results: The external cohort included 18913 children, 1691 (8.9%) had CT scan; 160 had ciTBI, and 24 (0.13%) had neurosurgery. Applying IDITBIC and PECARN rules would have missed 11 and 1 ciTBI patients; respectively. All patients with missed injuries were classified as such based on a hospital stay of >2 days. None of these patients died, needed neurosurgery, or required ventilatory support. In children aged <2 years, sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of IDITBIC and PECARN rule were [95.2%, 79.5%, 3.8%, and 99.9%] and [100.0%, 59.1%, 2.0%, and 100.0%]; respectively. In children ≥ 2 years, sensitivity, specificity, PPV and NPV of IDITBIC and PECARN rule were [92.4%, 75.3%, 3.1%, and 99.9%] and [99.2%, 52.9%, 1.7%, and 100.0%]; respectively.

Conclusions: The two decision rules demonstrated high accuracy in identifying ciTBI. As a screening tool, the PECARN rule outperformed IDITBIC. The findings suggest that clinicians should strongly consider directing children with GCS <15 at presentation to CT scan.

Keywords: Head injury, children, accuracy, decision rule, computed tomography

Background

Minor head trauma is one of the most common reasons for visits to the emergency department (ED). The challenge for the ED physician is to identify those with severe brain injury who require urgent cranial computed tomography (CT) to identify injuries requiring neurosurgery or admission for observation.⁽¹⁻³⁾ In children, utilization of clinical decision rules is important to avoid unnecessary CT scans, given the increased risk of malignancy associated with ionizing radiation from CT scans.⁽⁴⁾ Data from large-scale studies revealed that clinical decision rules can effectively guide clinicians who treat pediatric minor head injury. Several clinical decision rules for children have been developed including the Pediatric Emergency Care Applied Research Network (PECARN) rule, the Children's Head Injury Algorithm for the Prediction of Important Clinical Events rule (CHALICE), and the Canadian Assessment of Tomography for Childhood Head Injury (CATCH) rule.⁽⁵⁻⁷⁾ These clinical decision rules have been validated and compared against each other in a single-center study and in a large, well-powered, multicenter study.^(8,9) These studies revealed that the PECARN rule, designed to identify children at low risk for significant brain injury, demonstrated the highest sensitivity for identifying patients with clinically important traumatic brain injury (ciTBI). As with the PECARN rule, the Israeli Decision Algorithm for Identifying Traumatic Brain Injury in Children (IDITBIC), recommends proceeding directly to CT scan in children with Glasgow Coma Scale (GCS) of less than 15 (Figure 1, Table 1).⁽¹⁰⁻¹²⁾

The objective of the study was to assess the diagnostic accuracy of two clinical rules that assign patients with GCS<15 at presentation directly to CT.

Materials and methods

Study design and population

We performed accuracy assessments of the IDITBIC and the PECARN rule on an external data set, a large cohort of children used in the Australasian Pediatric Head Injury Rules Study (APHIRST).^(9,13) APHIRST was a prospective multicenter observational study in ten pediatric EDs in Australia and New Zealand. The APHIRST database includes patients less than 18 years of age who presented to EDs between April 11, 2011, and Nov 30, 2014 with head injuries of any severity (except trivial facial injury) to one of 10 study sites in the Paediatric Research in Emergency Departments International Collaborative (PREDICT).⁽¹⁴⁾

APHIRST was registered prospectively with the Australian New Zealand Clinical Trials Registry (ACTRN12614000463673). An informed verbal consent was obtained from parents, guardians, or older adolescents (as per local ethics requirements) apart from instances of life-threatening or fatal injuries where participating ethics committees granted a waiver of consent. Amendment approval for the current study was obtained by the Royal Children's Hospital Melbourne ethics committee.

Study definitions

IDITBIC - The Israeli Decision Algorithm for Identifying Traumatic Brain Injury in Children

In Israel, in order to standardize the diagnostic approach across all EDs accepting children, the Ministry of Health issued in 2014 a consensus policy statement concerning pediatric minor head injury in the ED.⁽¹⁰⁾ This policy statement was developed by a task force of experts in pediatric emergency medicine, pediatric neurosurgery, pediatric trauma, and pediatric neurology. The statement includes a decision algorithm which indicates when to

perform CT scan in these patients, and is intended to serve as a reference for ED physicians (Figure 1, Table 1).⁽¹⁰⁾ Patients with GCS of 15 are stratified into three risk categories for TBI; a high-risk category which includes symptoms or signs considered as highly suggestive for TBI, intermediate-risk category which includes symptoms or signs considered as moderately suggestive for TBI, and low-risk category without symptoms or signs suggestive for TBI (Figure 1, Table 1).

ciTBI

The primary outcome of this study was ciTBI, defined as death from TBI, neurosurgical intervention for TBI (intracranial pressure monitoring, elevation of depressed skull fracture, ventriculostomy, hematoma evacuation, lobectomy, tissue debridement, dura repair), intubation of more than 24 h for TBI or hospital admission of 2 nights or more for the TBI in association with traumatic brain injury on CT.^(5,8,9) TBI-on-CT was defined as 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, or skull fracture depressed by at least the width of the table of the skull.^(5,8,9)

Statistical analysis

The primary analysis of this study was the diagnostic accuracy of PECARN and IDITBIC in detecting ciTBI using the predictor variables of the algorithm, as applied to the APHIRST data set. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were used to assess the diagnostic accuracy of in detecting ciTBI.

Algorithm-specific predictor variables were applied to calculate the number of patients (within cohorts using the specified inclusion and exclusion criteria) which fulfilled the relevant outcome measures. Percentages with 95% confidence intervals were used to describe

sensitivity, specificity, NPV, and PPV for each age group, as well as negative likelihood ratios (NLR) and positive likelihood ratios (PLR). Receiver operating curves (ROC) were configured as well as area under curve (AUC) and the corresponding 95% confidence interval values. A chi-square test was used to compare the risk for neurosurgery between patients with GCS of 13-14 and patients with GCS of 15.

Results

The APHIRST database included 18,913 children with a GCS score of 13–15 who presented within 24 hours of injury. The mean age was 5.7 years, and 12,078 (63.8%) were males. One thousand six hundred and ninety one (8.9%) underwent cranial CT scan, and 4,164 (22%) were admitted to the hospital. There were 160 (0.85%) patients who had ciTBI, 24 (0.13%) who needed neurosurgery and 251 (1.3%) who had TBI-on-CT. One patient died.

Missed ciTBI cases

Applying the IDITBIC would have missed eleven ciTBI patients. All the missed patients were classified as such based on the admission to hospital >2 nights for TBI, with no patients dying or requiring any specific intervention; neurosurgery, or intubation due to the head injury (Table 2). Applying the PECARN rule would have missed one ciTBI patient. This patient was in the age range of 2 years or older, did not require neurosurgery or intubation but was admitted for more than two nights.

ciTBI cases that needed neurosurgery

Of the 18,913 cases, 9/699 (1.3%) with GCS 13-14, and 15/18,214 (0.08%) with GCS 15 needed neurosurgery. Patients with GCS 13-14 had a higher risk for neurosurgery than patients with GCS 15 ($p < 0.0001$), Figure 3).

Comparison of IDITBIC and PECARN rule

Accuracy analysis of IDITBIC and PECARN rule for identifying ciTBI and TBI on CT is presented in Table 3.

For ciTBI in the <2 years age range, sensitivity, specificity, PPV and NPV of the IDITBIC and PECARN rule were [95.2%, 79.5%, 3.8%, and 99.9%] and [100.0%, 59.1%, 2.0%, and 100.0%]; respectively.

For ciTBI in the ≥ 2 years age range, sensitivity, specificity, PPV and NPV of the IDITBIC and PECARN rule were [92.4%, 75.3%, 3.1%, and 99.9%] and [99.2%, 52.9%, 1.7%, and 100.0%]; respectively.

ROC curves for the analysis of IDITBIC and PECARN rule performances are presented in Figure 2. AUC (95% CI) values of the IDITBIC and the PECARN rule for the <2 years age range, and the ≥ 2 years age range were 0.88 (0.85-0.90) and 0.77 (0.76-0.78) and 0.83 (0.80-0.86) and 0.72 (0.71-0.73) respectively.

NLRs (95% CI) and PLRs (95% CI) for IDITBIC and PECARN rule were [0.1 (0.0-0.2) and 4.6 (4.3-5.1)] and 0.01 (0.0-0.1) and 2.4 (2.4-2.5); respectively for the <2 years age range, and 0.1 (0.1-0.2) and 3.7 (3.5-4.0) and 0.01 (0.0-0.1) and 2.1 (2.0-2.1) respectively for the ≥ 2 years age range.

Discussion

The present study used the multicenter APHIRST data to assess the accuracy of the PECARN rule and IDITBIC in identifying children with ciTBI; two decision rules that assign patients with GCS<15 at presentation directly to CT. We found that 11/160 (6.9%) ciTBI cases were missed by IDITBIC, and 1/160 (0.6%) ciTBI case was missed by the PECARN rule. These children were classified as ciTBI only because they were hospitalized for more than two

nights due to the TBI; the two clinical decision rules did not miss any patient who died, needed neurosurgical intervention, or was intubated due to the head injury. The high point sensitivities and NPVs of IDITBIC and the PECARN rule suggest their validity as screening tools for ciTBI in this cohort.

Accuracy analysis revealed higher sensitivity of the PECARN rule for identifying ciTBI in each age range. NPVs were very high (≥ 99.9) for both instruments (Table 3). These results demonstrate the superiority of the PECARN rule over IDITBIC as a screening tool for ciTBI. Likelihood ratios can be used to incorporate research evidence into clinical decision making. ⁽¹⁵⁻¹⁷⁾ In our study the NLR of IDITBIC, which is the probability of a ciTBI among children *who did not meet the risk criteria* was substantially low for both infants (0.1) and children (0.1). The NLR of the PECARN rule which is the probability of a ciTBI among children *meeting the low risk criteria* is even lower: 0.01 for infants and 0.01 for children. These results further support the superiority of the PECARN rule over IDITBIC as a screening tool. Our analysis reveals higher specificities and higher AUC values for the ROC curves of the IDITBIC compared with PECARN rule for both age groups. These findings suggest that IDITBIC has a higher discrimination performance and is better at correctly classifying patients into those who need CT scan and those who do not need CT scan.

An important finding of our study is the significantly higher risk for neurosurgery in patients with GCS 13-14 than in patients with GCS 15. This finding, along with the high-accuracy performances of the two decision rules, suggests that in children with GCS < 15 at presentation, CT scan should be strongly considered. Our results are supported by a previous meta-analysis that reported a relative risk of 5.5 for significant intracranial injury in children with minor head injury who have a GCS less than 15. ⁽¹⁸⁾

Our study has several limitations. Firstly, IDITBIC was designed to identify children at high risk for ciTBI (need cranial CT scans), as opposed to the PECARN rule which was designed

to identify children at low risk for ciTBI (do not need cranial CT scans). Secondly, we decided not to assess the CATCH and CHALICE because these clinical decision rules do not recommend proceeding directly to CT scan in children with GCS<15 at presentation. ^(6,7) CATCH recommends CT scan only in patients where GCS < 15 was present at two hours after injury, and for the CHALICE additional conditions need to be fulfilled. Thirdly, the dataset was from Australian and New Zealand EDs, which may differ from American EDs and Israeli EDs for which these clinical decision rules were developed. Nevertheless, using this extensive, preexisting data set provides a unique opportunity to assess locally developed guidelines for head injury imaging in children. ⁽¹⁹⁾

Conclusions

The clinical decision rules demonstrated high accuracy in identifying ciTBI. As a screening tool, the PECARN rule outperformed IDITBIC. The findings suggest that clinicians should strongly consider directing children with GCS<15 at presentation to CT scan.

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Legend to Figure 1

The Israeli Decision Algorithm for Identifying Traumatic Brain Injury in Children (IDITBIC)

Legend to Figure 2

Receiver operator curves for the detection of ciTBI by the Israeli Decision Algorithm for Identifying Traumatic Brain Injury in Children (IDITBIC) and the Pediatric Emergency Care Applied Research Network (PECARN) rule (n=18,913)

Legend to Figure 3

Distribution of the percentage of ciTBI patients according to Glasgow Coma Scale (GCS) level (n=18,913)

Legend to Table 1

Inclusion and exclusion criteria and predictor variables of IDITBIC and the PECARN rule.

Legend to Table 2

Demographics, mechanism of injury, and symptoms at presentation of ciTBI patients that were missed by the Israeli Decision Algorithm for Identifying Traumatic Brain Injury in Children (IDITBIC)

Legend to Table 3

A comparative analysis according to age range of the Israeli Decision Algorithm for Identifying Traumatic Brain Injury in Children (IDITBIC) and the Pediatric Emergency Care Applied Research Network (PECARN) rule (n=18,913)