

**Citation:** N. Kuppermann et. al. **Identification of children at very low risk of clinically-important brain injuries after head trauma: a prospective cohort study** *The Lancet*, Volume 374, Issue 9696, Pages 1160-1170

**CRITICAL REVIEW FORM FOR A CLINICAL PREDICTION RULE**

| GUIDE   | COMMENTS  |                       |                                      |                     |                      |            |            |                                      |                    |                       |                                      |                   |                   |                                      |                   |                   |                                      |                   |                   |                                    |                      |                       |                                    |                     |                      |                                    |                |                |                                    |                |                |                                    |                   |              |                                    |                  |                  |
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| <b>I. Is this a newly derived prediction rule? (Level IV)</b>   |   |                       |                                      |                     |                      |            |            |                                      |                    |                       |                                      |                   |                   |                                      |                   |                   |                                      |                   |                   |                                    |                      |                       |                                    |                     |                      |                                    |                |                |                                    |                |                |                                    |                   |              |                                    |                  |                  |
| 1. Were the outcomes and clinical predictors clearly defined and clinically sensible?   | Yes, they wanted to create and validate accurate, generalizable prediction rules for identifying children at very low risk of clinically important TBI  |                       |                                      |                     |                      |            |            |                                      |                    |                       |                                      |                   |                   |                                      |                   |                   |                                      |                   |                   |                                    |                      |                       |                                    |                     |                      |                                    |                |                |                                    |                |                |                                    |                   |              |                                    |                  |                  |
| 2. Were all-important predictors assessed in the derivation of the prediction guide?  | Yes. Authors looked at a broad range of mechanism of injury, history and symptoms, physical exam predictors variables and provided CI's around each of those listed. They included assessments by independent assessment in 5% of patients with kappa statistics @ 0.5 (moderate agreement)   |                       |                                      |                     |                      |            |            |                                      |                    |                       |                                      |                   |                   |                                      |                   |                   |                                      |                   |                   |                                    |                      |                       |                                    |                     |                      |                                    |                |                |                                    |                |                |                                    |                   |              |                                    |                  |                  |
| 3. Was validation restricted to the use of split samples, large retrospective databases, or by various statistical techniques?  | Validation was accomplished on the same population but separated by time.   |                       |                                      |                     |                      |            |            |                                      |                    |                       |                                      |                   |                   |                                      |                   |                   |                                      |                   |                   |                                    |                      |                       |                                    |                     |                      |                                    |                |                |                                    |                |                |                                    |                   |              |                                    |                  |                  |
| <b>II. Has the rule been validated? (Level II or III)</b>   |   |                       |                                      |                     |                      |            |            |                                      |                    |                       |                                      |                   |                   |                                      |                   |                   |                                      |                   |                   |                                    |                      |                       |                                    |                     |                      |                                    |                |                |                                    |                |                |                                    |                   |              |                                    |                  |                  |
| 1. Did validation include prospective studies on several different populations from that used to derive it (II), or was it restricted to only one population (III)?   | Validation included a diverse population evaluated prospectively and separated in time from the derivation population. That stated, the validation was performed on the same population across a broad representation of 25 hospitals however most were tertiary referral children's hospitals.   |                       |                                      |                     |                      |            |            |                                      |                    |                       |                                      |                   |                   |                                      |                   |                   |                                      |                   |                   |                                    |                      |                       |                                    |                     |                      |                                    |                |                |                                    |                |                |                                    |                   |              |                                    |                  |                  |
| 2. Was there appropriate blinding of those assessing the predictors and those assessing the outcome event?  | This is not clearly stated in the paper. The researchers assessing the predictors appear to be the same as those assessing the outcome. However, most of the data they collected was fairly objective. The radiologists evaluating the CTs were blinded to the assessment.  |                       |                                      |                     |                      |            |            |                                      |                    |                       |                                      |                   |                   |                                      |                   |                   |                                      |                   |                   |                                    |                      |                       |                                    |                     |                      |                                    |                |                |                                    |                |                |                                    |                   |              |                                    |                  |                  |
| 3. What were the sensitivity, specificity, positive and negative predictive values, likelihood ratios, relative risks or absolute outcome rates?  | The prediction rule in children < 2yrs (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%, 863–100.0)<br><br>In the validation group of children >2yrs, 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). |                       |                                      |                     |                      |            |            |                                      |                    |                       |                                      |                   |                   |                                      |                   |                   |                                      |                   |                   |                                    |                      |                       |                                    |                     |                      |                                    |                |                |                                    |                |                |                                    |                   |              |                                    |                  |                  |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">Derivation</th> <th style="text-align: center;">Validation</th> <th></th> <th style="text-align: center;">Derivation</th> <th style="text-align: center;">Validation</th> </tr> </thead> <tbody> <tr> <td>Prediction rule sensitivity (95% CI)</td> <td style="text-align: center;">98.6% (92.6–99.97)</td> <td style="text-align: center;">100.00% (86.3–100.00)</td> <td>Prediction rule sensitivity (95% CI)</td> <td style="text-align: center;">96.7% (93.4–98.7)</td> <td style="text-align: center;">96.8% (89.0–99.6)</td> </tr> <tr> <td>Prediction rule specificity (95% CI)</td> <td style="text-align: center;">53.7% (52.6–54.8)</td> <td style="text-align: center;">53.7% (51.6–55.8)</td> <td>Prediction rule specificity (95% CI)</td> <td style="text-align: center;">58.5% (57.9–59.1)</td> <td style="text-align: center;">59.8% (58.6–61.0)</td> </tr> <tr> <td>Negative predictive value (95% CI)</td> <td style="text-align: center;">99.9% (99.88–99.999)</td> <td style="text-align: center;">100.00% (99.7–100.00)</td> <td>Negative predictive value (95% CI)</td> <td style="text-align: center;">99.95% (99.9–99.98)</td> <td style="text-align: center;">99.95% (99.81–99.99)</td> </tr> <tr> <td>Positive predictive value (95% CI)</td> <td style="text-align: center;">1.8% (1.4–2.3)</td> <td style="text-align: center;">2.4% (1.6–3.5)</td> <td>Positive predictive value (95% CI)</td> <td style="text-align: center;">2.0% (1.7–2.2)</td> <td style="text-align: center;">2.3% (1.8–3.0)</td> </tr> <tr> <td>Negative likelihood ratio (95% CI)</td> <td style="text-align: center;">0.03 (0.001–0.14)</td> <td style="text-align: center;">0.0 (0–0.26)</td> <td>Negative likelihood ratio (95% CI)</td> <td style="text-align: center;">0.06 (0.03–0.11)</td> <td style="text-align: center;">0.05 (0.01–0.19)</td> </tr> </tbody> </table> |   |                       | Derivation                           | Validation          |                      | Derivation | Validation | Prediction rule sensitivity (95% CI) | 98.6% (92.6–99.97) | 100.00% (86.3–100.00) | Prediction rule sensitivity (95% CI) | 96.7% (93.4–98.7) | 96.8% (89.0–99.6) | Prediction rule specificity (95% CI) | 53.7% (52.6–54.8) | 53.7% (51.6–55.8) | Prediction rule specificity (95% CI) | 58.5% (57.9–59.1) | 59.8% (58.6–61.0) | Negative predictive value (95% CI) | 99.9% (99.88–99.999) | 100.00% (99.7–100.00) | Negative predictive value (95% CI) | 99.95% (99.9–99.98) | 99.95% (99.81–99.99) | Positive predictive value (95% CI) | 1.8% (1.4–2.3) | 2.4% (1.6–3.5) | Positive predictive value (95% CI) | 2.0% (1.7–2.2) | 2.3% (1.8–3.0) | Negative likelihood ratio (95% CI) | 0.03 (0.001–0.14) | 0.0 (0–0.26) | Negative likelihood ratio (95% CI) | 0.06 (0.03–0.11) | 0.05 (0.01–0.19) |
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III. Has an impact analysis demonstrated change in clinical behavior as a result of using the rule? (Level I)

**This is a new study and so no other studies have been applied to a wide variety of clinical settings nor have there been other studies to further validate the outcomes. There has also not been a study as yet to demonstrate impact analysis.**

### **Clinical bottom Line:**

This study presents us with a set of predictors that appear to be highly sensitive in the population being evaluated. The number of subjects was very large and notably diverse in its geographical distribution. There was a disproportionate number of tertiary referral Children's Hospital's with physicians having expertise in the assessment and management of pediatric patients. External validation among a broad range of community ED's would be useful. The authors note that peds EM specialists already have a high threshold to perform a CT on the pediatric brain and believe that applying the rule among non pediatric ED's would likely have a bigger impact on use of CT than in their centers. Further validation and impact assessment studies are likely to follow this well designed study. As there have been no prospective studies proving the impact of decreasing the radiation burden in children with minor head injuries, the value of a decision rule that assists in decreasing radiation exposure that can only be assumed.

### **Summary of Article**

- 600 000 emergency department visits every year
- Less than 10% of CT scans in children with minor head trauma show traumatic brain injuries
- This was a prospective cohort study of patients younger than 18 years with head trauma in 25 emergency departments of a pediatric research network.
- Enrolled the derivation population over 2004-2006, and the validation population over 6 months time
- Children were eligible if:
  - Within 24 h of head trauma
  - Not a trivial injury
  - No penetrating injury, neurologic d/o, GCS 14

Defined important TBI as:

death from TBI  
neurosurgery  
intubation for more than 24 h for TBI  
hospital admission of 2 nights or more associated with TBI  
Significant TBI on CT

Mechanism:

**Severe** (MVC with patient ejection, death of another passenger, or rollover; pedestrian or bicyclist without helmet struck by a motorized vehicle; falls of > 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)

Results

- Enrolled 43,000 children, 10,700 were <2 years.
- CT scans obtained in 15,000 patients and 780 had TBI on CT and 376 had ciTBI
- Of the CT's obtained in children <2yrs in the derivation and validation groups 668 (25.4%) and 167 (24.1%) CTs were obtained in children with none of the clinical predictors
- In children >2yrs, 1992 (21.1%) and 446 (20.1%) were in children with none of the six predictors
- This amounts to about 3273 (21.8%) CT's done that were potentially unnecessary

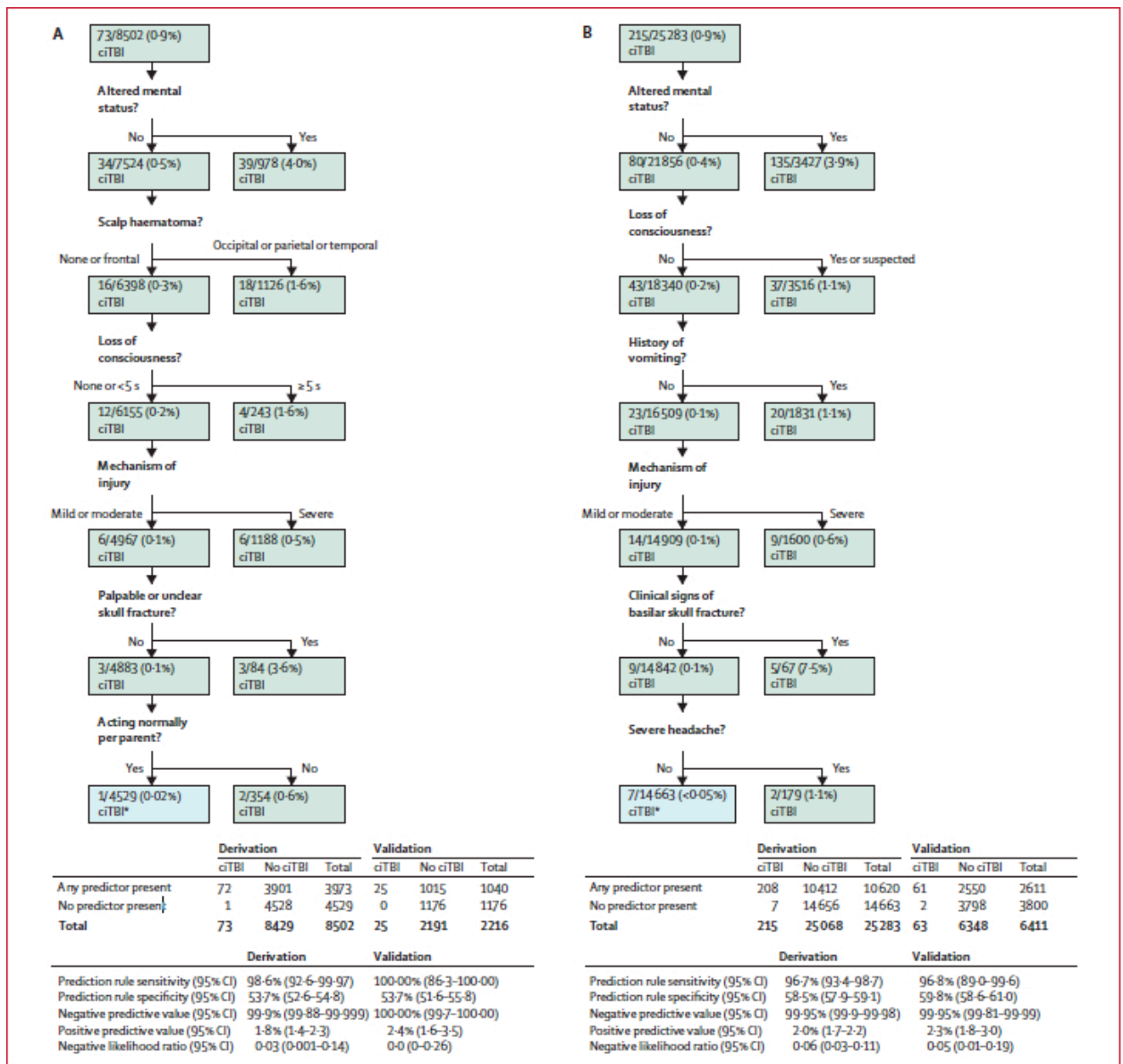


Figure 2: Prediction tree for ciTBI in children younger than 2 years (A) and in those aged 2 years and older (B) in the derivation group. ciTBI—clinically-important traumatic brain injury. \* This box indicates children at very low risk of ciTBI in whom CT scans could be obviated.

#### Weaknesses

- Did not reveal the outcome of the children missed, or the extent of their injuries
- Not validated in adult ED

#### Other tidbits

- <3mos is high risk
- Even patients with certain isolated findings (ie, with no other findings suggestive of traumatic brain injury), such as isolated LOC, isolated headache, isolated vomiting, and certain types of isolated scalp hematomas in infants older than 3 months, have a risk of ciTBI **substantially lower than 1%**.
- AMS and signs of basilar skull fx = CT
- <2yrs does not incorporate vomiting as part of rule
- Vomiting is not defined by number or timing