ARTICLE:
• Country: USA.
• Funding Sources: US Department of Health and Human Services

PURPOSE:
• Research Goal: To derive and validate prediction rules for ciTBI to identify children at very low risk of clinically important Traumatic Brain Injury (ciTBI) after blunt head trauma for whom CT might be unnecessary.

• Hypothesis: A subset of children with blunt head trauma may not require CT imaging.

DESIGN:
• Study Design: Prospective cohort derivation and subsequent internal validation.

• Dependent / outcome Variable(s): Clinically important Traumatic Brain Injury (ciTBI) and signs of Trauma Brain Injury (TBI) on CT.

• Independent / research Variable: 33 variable case report form.

SETTING / SUBJECTS:
• Research Setting: 25 emergency departments of the pediatric research network.

• Subjects:
  o Study population: patients younger than 18 years with head trauma.
    • Children <2 years old were analyzed separately due to greater sensitivity to radiation and variable historical and assessment characteristics inherent to this age group.
    • Children with GCS < 14 were analyzed separately.

  o Inclusion / Exclusion criteria:
    • Included: Children presenting within 24 hours of trauma.
Excluded: Children with trivial injury mechanisms defined by ground-level falls or walking or running into stationary objects, and no signs or symptoms of head trauma other than scalp abrasions and lacerations. Patients were also excluded if they had penetrating trauma, known brain tumors, pre-existing neurological disorders complicating assessment, or neuroimaging at an outside hospital before transfer.

- Number (control / intervention groups): 43904 of 57030 eligible patients were enrolled.
- Demographics:
  - Mean age 7.1 years
  - 10718 < 2 years
  - 97% had GCS 15.
  - CT scans performed in 35.3% of patients.
  - 81 % of patients were discharged.

- Attrition: Telephone calls (79%) as well as medical record reviews were performed for all discharged patients.
  - Follow up on discharged patients may have been missed if patient presented to a hospital not in the review area. Number unknown.
  - Eligible patients not enrolled were identified by ED record review, and these were analyzed separately to evaluate for enrollment bias.
  - Admitted patients were followed for 90 days through telephone interviews and records review.

METHODS:
- Interventions:
  - CT scans were obtained at the emergency department clinician's discretion with helical CT scanners, with radiographic slices separated by 10 mm or less. CT scans were interpreted by site faculty radiologists. A study pediatric radiologist, unaware of clinical data, made definitive interpretations of inconclusive CT scans.
- Instruments: 33 item standardized data collection form (panel 1).
- Data Collection: ED physicians and other trained study investigators completed data form prior to CT imaging results.
  - At each site, about 4% of patients had a separate, independent assessment done by another emergency department physician within 60 min of the first assessment to check inter-rater reliability. Quality-assurance practices included double and random triple data entry, and annual site monitoring visits.
• **Outcomes:**
  • *Clinically-important traumatic brain injury (ciTBI)* defined by any of the following descriptions:
    o Death from traumatic brain injury
    o Neurosurgical intervention for traumatic brain injury
    o Intracranial pressure monitoring
    o Elevation of depressed skull fracture
    o Ventriculostomy
    o Haematoma evacuation
    o Lobectomy
    o Tissue debridement
    o Dura repair
    o Intubation of more than 24 h for traumatic brain injury
    o Hospital admission of 2 nights or more for the traumatic brain injury in association with traumatic brain injury on CT
      • Hospital admission for traumatic brain injury defined by admission for persistent neurological symptoms or signs such as persistent alteration in mental status, recurrent emesis due to head injury, persistent severe headache, or ongoing seizure management
  • *Traumatic brain injury on CT* defined by any of the following descriptions:
    o Intracranial haemorrhage or contusion
    o Cerebral oedema
    o Traumatic infarction
    o Diffuse axonal injury
    o Shearing injury
    o Sigmoid sinus thrombosis
    o Midline shift of intracranial contents or signs of brain herniation
    o Diastasis of the skull
    o Pneumocephalus
    o Skull fracture depressed by at least the width of the table of the skull

**DATA ANALYSIS:**
• **Level of Data:** Categorical
• **Statistics Used:** Study was designed to maximize the sensitivity and negative predictive value.
  o Rule was devised using binary recursive partitioning.
  o Ten-fold cross validation was used to create prediction trees, and standard Gini splitting rules.
    • Missed ciTBI was given a 500:1 penalty for failure compared to misclassification of patients without ci TBI.
RESULTS:

• Brief answers to research questions: The analysis resulted in the decision rule outlined above. Algorithm A for <2 yrs, algorithm B for >2 yrs.
  o CT scans were obtained on 35.3% of patients (14,969).
  o 5.2% (780) had CT findings of TBI and 376 (0.9%) had ciTBI. 15.9% of patients with ciTBI underwent neurosurgery.
  o 96 patients not imaged on intial visit returned with related complaint. 5.2% of these had findings on CT.
  o Missed (not enrolled patients) had similar characteristics and outcomes as the study cohort.
  o In the validation group of patients <2 years, for ciTBI the prediction rule had a Sensitivity of 100% (25/25) and a negative prediction value of 100%.
  o For CT evidence of TBI, sensitivity was 100%, NPV was 100%.
In the validation group of patients over 2 years, for ciTBI sensitivity was 96.8% and NPV was 99.95%.

- 2 children with ci TBI were missed, neither of whom required neurosurgery. Both had significant mechanism of injury and large scalp hematoma.

- For CT evidence of TBI, sensitivity was 98.4% and NPV was 94%.

**Additional findings:**

- Based on these data, CT could be avoided in approximately 25% of patients <2 yrs and 20% of patients > 2 yrs. The rates of imaging in the study centers were lower than national averages, indicating that this may be even more useful in typical general emergency centers.

- Children with either clinical signs of skull fracture or altered mental status had >4% risk of ciTBI, while the other predictors related to <1% risk of ciTBI. Patients with these findings, therefore, represent those at highest risk for ciTBI and management and discussion with parents should be performed accordingly.

**Limitations?:**

- Some patients may have been missed by follow up.

- This study was conducted in large, mainly pediatric, academic hospitals. Patient characteristics and testing practices may be different in other settings.

- Study requires additional validation before it can be relied on clinically. However, validation of this size is difficult, and this may be the best we get.

**IMPLICATIONS FOR PRACTICE:**

- **Applicable to this clinical practice:** Absolutely.

- **Feasibility (cost, resources, etc):** Easily implemented.

- **Clinically Relevant:** Highly.

**LEVEL OF EVIDENCE / DECISION FOR USE:**

- Consider Replication

**Level of Evidence:**

- **Ia** Evidence obtained from meta-analysis of randomized controlled trials
- **Ib** Evidence obtained from at least one RCT
- **IIa** Evidence obtained from at least one well-designed controlled study without randomization
- **IIb** Evidence obtained from at least one other type of well-designed quasi-experimental study
- **III** Well-designed non-experimental studies
- **IV** Expert committee reports, opinions of experts