Evidence-based Evaluation of Children with Blunt Head Trauma in the Emergency Department

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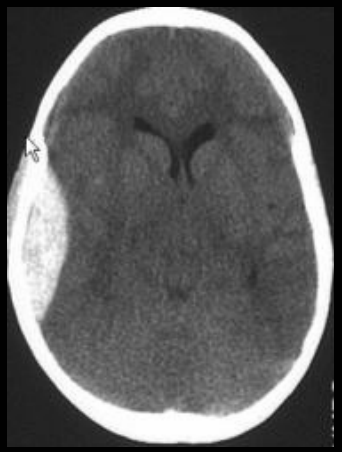
Jornadas Nacionales del Centenario de la Sociedad Argentina de Pediatria



Disclosure

- No financial relationships or conflict of interests

Today's Objectives

- Epidemiology of blunt head trauma (BHT) in children
- Evaluation in the ED (minor BHT)
- Indications for CT: the evidence and controversy
- Preverbal patients
- Pause: clinical decision rules
- UC Davis pilot study
- Multicenter studies, PECARN

Case

- 6 year-old falls 4 feet from a ladder
- No LOC
- On exam, GCS 15
- Small forehead hematoma, tender at site

What are you going to do?

Epidemiology of Pediatric Head Trauma

- Trauma the leading cause of death among children > 1 year
- Traumatic brain injury (TBI) the leading cause of death and disability due to trauma (> 70% of deaths)
- On an annual basis in the U.S., BHT in children results in:
  - 3,000 deaths
  - 50,000 hospitalizations
  - 650,000 ED visits (~50% evaluated with CT scans, and use of CT increasing over the past decade)

Centers for Disease Control 2010; NHAMCS 2006; Blackwell 2007

Variation in Care

- Some children with BHT present with overt signs

  little controversy in evaluation

- Most BHT patients present with few/subtle signs

  much controversy and substantial variation

The evidence for decision-making in evaluating children with minor BHT is limited…

Minor Head Trauma in Children

- ~97% of children with BHT evaluated in EDs, and 75% of those evaluated with CT, have “minor” BHT (GCS 14-15)
- ~50% of those with TBI on CT present with GCS 14-15

Dietrich 1993; Schunk 1996; Quayle 1997; Greenes 1999; Palchak 2003; Oman 2006

Controversy over CT for Minor BHT

<u>Arguments for liberal use of CT:</u>

- Preventable morbidity/mortality due to unrecognized TBIs
- Preverbal children difficult to eval.
- When indicated, benefit of CT greatly outweighs risk, *however…*

Controversy over CT for Minor BHT

Arguments against liberal use of CT:

- Of the large number of children evaluated with CT after BHT, fewer than 10% have TBI
- Drawbacks of CT include transport outside the ED, pharmacological sedation, costs
- Most important (theoretical) risk: *lethal malignancy risk from a single CT may be as high as 1:2500*

- *Pediatric BHT high priority for AAP, IOM, EMSC…*

CT Radiation Risks

- Helical CT scanners have enhanced diagnostic possibilities and reduced need for sedation

- Radiation exposure, however, not reduced with helical CT
- Radiation exposure of CT 300-600 times that of CXR

Brenner 2001, 2002; Hall 2002; http://www.cancer.gov; Brenner/Hall 2007; Smith-Bindman 2010

CT Radiation Risks

- *Estimates* (theoretical, not observed) of risks of lethal malignancies extrapolated from survivors of WWII atomic explosions:
  - 1 per 2500 head CT scans for 5 year-olds
  - 1 per 5000 for 10 year-olds
- Age and size-based radiation-reduction efforts ongoing ("*ALARA*" principle)
- CT radiation risks important from a public-health view
  - ~300,000 CTs for BHT, ~4 million pediatric CTs annually in U.S.

The ED Evaluation of Children with BHT

controversial factors

Blunt Head Trauma in Children
historical factors

History of LOC

- Most controversial historical finding
- Common in pediatric BHT
- Reliability of history? Accuracy of report of duration? Amnesia in pre-verbal children?

Blunt Head Trauma in Children
historical factors

History of LOC

- LOC common in patients with TBI, however…
- LOC absent in 20-30% of patients with TBI

Is LOC important after adjusting for mental status and other findings?

- In a few *multivariable* analyses, LOC not found to be an independent predictor of TBI

Davis 1994; Quayle 1997; Palchak 2003; Smits 2005; Oman 2006

Isolated **LOC**

When history of LOC ***without:***

Abnormal mental status, focal neurologic deficit, vomiting, headache, seizure, clinical signs of skull fracture, or scalp hematoma…

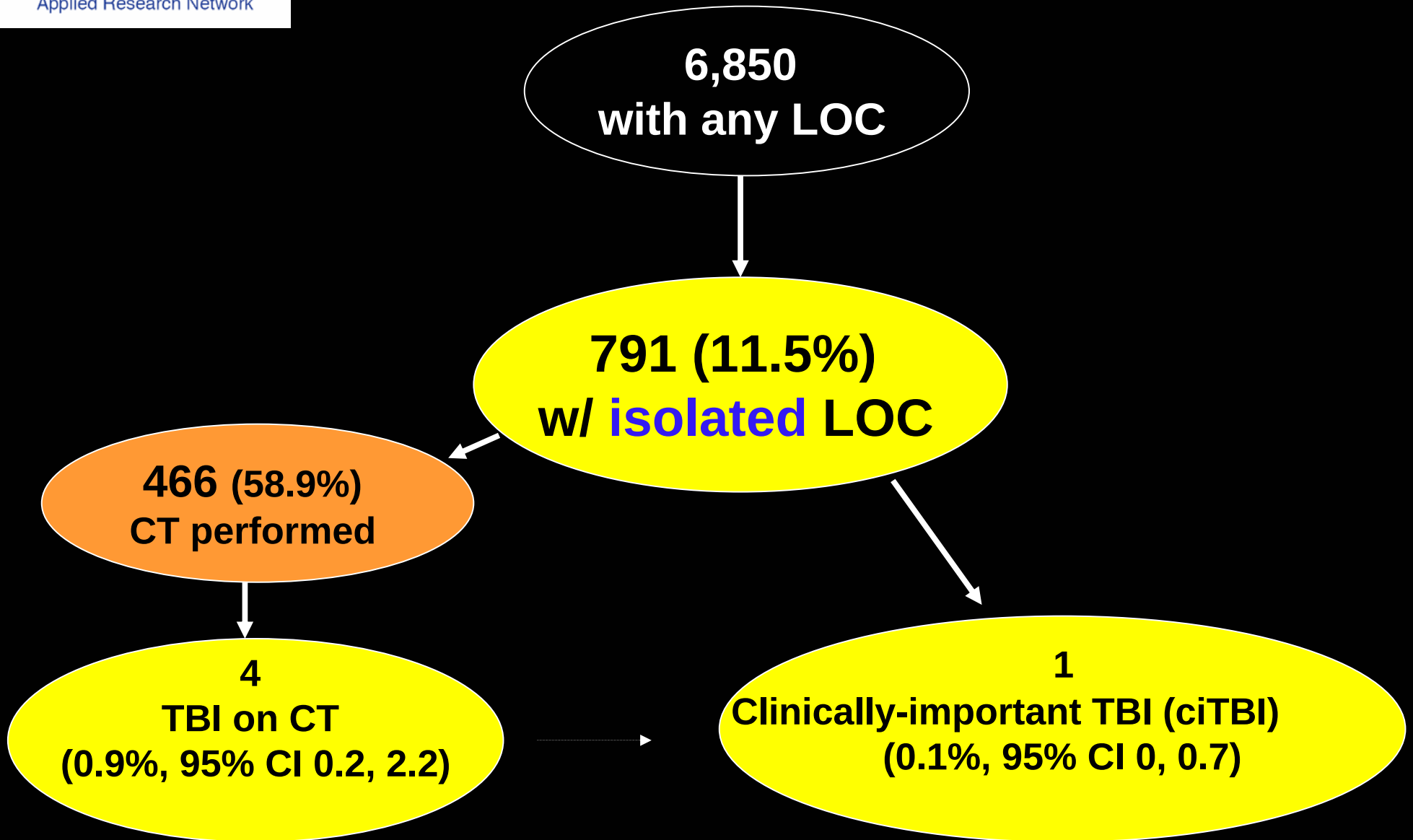
0/122 (+) CT (95% CI 0, 2.4%)

0/135 (+) Clin (95% CI 0, 2.2%)

Palchak 2004

PECARN 2008 *(enrolled 43,992)*

Isolated LOC



Blunt Head Trauma in Children
historical factors

Other possible predictors: vomiting and headache

- Frequently seen with TBI, however, frequently not "statistically significant" in (small) studies…
- In multivariate analyses, patients with TBI "missed" by the models frequently have vomiting and/or headache
- Larger studies using vomiting/headache as CT criteria missed no "important" TBIs *(Palchak 2003, Haydel 2003, Oman 2006, Dunning 2006)*
- Need large studies to investigate with necessary power

Blunt Head Trauma in Children

physical examination

Decreased level of consciousness

Eye Opening	
Spontaneous	4
To voice	3
To pain	2
None	1

Verbal Response	
Oriented (coos/smiles)	5
Confused (fussy/cries)	4
Inappropriate (screams)	3
Incomprehens. (grunts)	2
None	1

Motor Response	
Follows (spontaneous)	6
Localizes pain	5
Withdraws to pain	4
Decorticate posture	3
Decerebrate posture	2
None	1

- Definition of minor BHT varies (GCS $\geq$13? $\geq$14? 15?)

Blunt Head Trauma in Children
physical examination

Decreased level of consciousness

- Risk of TBI if GCS = 15 is ~2-3%
- Risk of TBI if GCS = 14 is ~7-8%
- Risk of TBI if GCS = 13 is ~25%
- GCS an important predictor in multivariable analyses

Quayle 1997, Palchak 2003, Haydel 2003, Smits 2005, Dunning 2006, Kuppermann 2009

Blunt Head Trauma in Children

physical examination

Clinical evidence of skull fracture

- ~20% of children with basilar skull fx and GCS=15 have TBI
- Signs of depressed skull fx highly associated with TBI
- In *multivariable* analyses, signs of basilar skull fx and signs/presence of *any* skull fx highly associated with TBI

Kadish 1995; Quayle 1997; Palchak 2003; Oman 2006, Dunning 2006

Gaps in Knowledge about Pediatric BHT
problematic issues with earlier studies

- Differing methodologies, variable definitions
- Inadequate power (wide confidence intervals)
- Lack of validation
- (Historical) lack of large multicenter study

Preverbal Children

Blunt Head Trauma in Children
infants (≤ 2 years) are different

- Mechanism typically is a fall
- The younger the infant, the greater the risk of TBI
- Head injury from abuse: 25-30% of infants ≤ 2 years hospitalized with BHT are abused and up to 10% of all infants evaluated in ED for head trauma
- High risk of abuse if “no history” of trauma
- Several biomarkers (neuron-specific enolase [NSE], myelin-basic protein [MBP], s100B) may be useful in identifying infants at risk for inflicted TBI

Duhaime 1992; Hettler 2003; Berger 2006

Blunt Head Trauma in Infants ≤2 Years
clinical evaluation

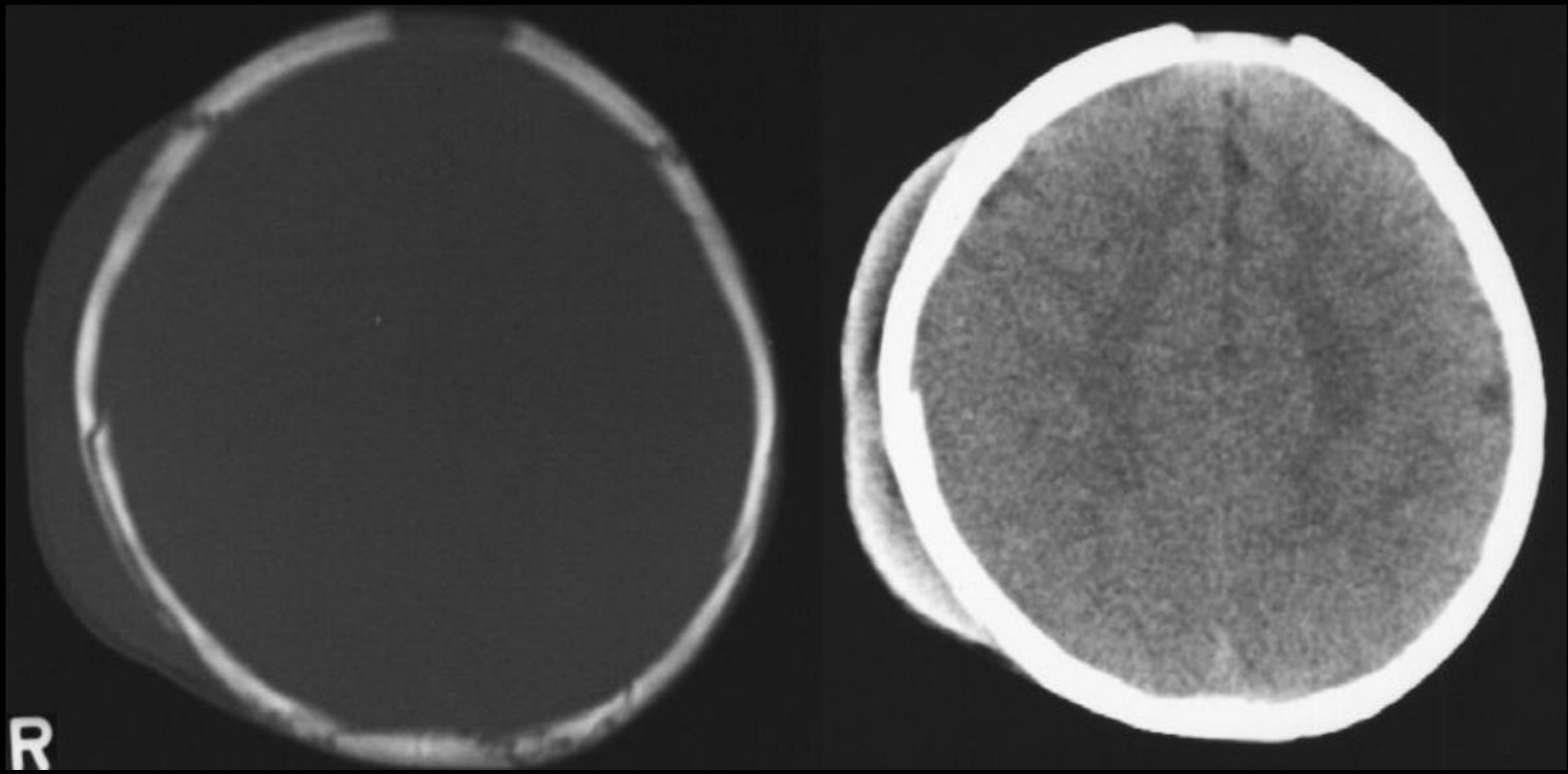
- Infants ≤2 years with TBI may have subtle signs
- ~50% of those with TBI are asymptomatic, however…
- Scalp hematomas present in:
  - >90% of otherwise asymptomatic infants with TBI
  - >95% of infants with skull fx

Shane 1997; Greenes 1997, 1999; Schutzman 2001

Blunt Head Trauma in Infants ≤2 Years: *scalp hematomas*

- *In this age range*, scalp hematoma is one of the most sensitive clinical predictors of TBI
- If scalp hematoma and SF present, ~30% TBI risk
- If scalp hematoma present w/o SF, <1% risk of TBI
- Large size and non-frontal location increase the risk

Greenes 1997, 1999, 2001; Schutzman 2001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More recent large prospective studies

Nexux II

methods

- Multicenter prospective study over 1 ½ years, of 13,728 adults and children with blunt head trauma of all severities who had CT scans performed
- Binary recursive partitioning identified eight important predictors of “significant intracranial injuries” on CT:
  - Evidence of significant skull fracture
  - Scalp hematoma
  - Neurological deficit
  - Altered level of alertness
  - Abnormal behavior
  - Coagulopathy
  - Persistent vomiting
  - Age 65 years or older

Mower 2005

Nexus II Pediatric Application

Results

When applied to the 1666 children:

Clinical Finding	+TBI	-TBI	Total
1 or more findings	136	1298	1434
None of 7 findings	2	230	232
Totals	**138**	**1528**	**1666**

Sens 98.6% (94.9, 99.8) Spec 15.1 (13.3, 16.9)

- *Did not include patients without CTs – limited follow-up*
- *Did not include 67 +CTs not deemed clinically important*
- *Use of criteria would have reduced CT by 14%*

Oman 2006

CHALICE Study

Methods

- Multicenter prospective study over 2 ½ years, of 22,772 children with blunt head trauma of all severities
- *Composite outcome*:
  - neurosurgery or “marked” abnormalities on CT
- CTs performed on only 3%
- Capture rate unclear *(selection bias?)*
- No (limited) follow-up of those discharged home:
  - review of national death registries
  - cross-check of participating hospitals for subsequent admissions and neurosurgeries

Dunning 2006

CHALICE Study

Results

- Binary recursive partitioning identified the following variables *(any positive suggests need for CT):*
  - *High-speed mechanism as pedestrian, bicyclist or occupant in MVC (> 40MPH)*
  - *Fall > 10 feet*
  - *High-speed injury from object/projectile*
  - *Suspicion of NAT*
  - *LOC > 5 min*
  - *Amnesia > 5 min*
  - *Abnormal drowsiness*
  - *≥ 3 episodes of emesis*
  - *Seizure*
  - *GCS < 14, or < 15 if age < 1 year*
  - *Suspicion of penetrating or depressed skull fx or tense fontanelle*
  - *Signs of basilar skull fx*
  - *Focal neurological deficit*
  - *Bruise, swelling or laceration > 5 cm if < 1 year old*

Dunning 2006

CHALICE Study

Results

- **281 “clinically significant injuries”, incl. 137 neurosurg**

- **For GCS 13-15 patients (99% of total), 168 outcomes:**
  - Sensitivity 97.6% (94.0-99.4%)
  - Specificity 87.3% (86.8-87.7%)
  - PPV 5.4% (4.7-6.3%)
  - NPV 99.9% (99.9-100%)

- ***But for neurosurgery…***
  - Sensitivity 97.8% (93.7-99.6%)
  - Specificity 86.4 (86.0 – 86.9%)

Dunning 2006

Many questions remain…

perc
Pediatric Emergency Research Canada

CATCH Study

Methods

- Multicenter prospective study in 10 Canadian centers of patients with GCS 13-15
- Goal to derive a rule for CT use in symptomatic children after blunt head trauma
- Required symptoms of blunt head trauma to be enrolled: LOC, amnesia, ≥2 emeses, persistent irritability, etc.
- 3,866 children enrolled (64% capture rate)
  - 53% with CT
- 26-item data form
- *Outcomes*:
  - neurosurgery/intubation
  - abnormalities on CT – *proxy clinical follow-up if no CT*

Osmond 2010

CATCH Study

Results

- Positive CT in 159 (7.8%) of imaged patients
- Neurological intervention in 24 (0.6%) of enrolled patients
- One rule for all ages
- Binary recursive partitioning identified the following:

<u>High risk variables (need for neurological intervention)</u>

1. GCS< 15 two hours after injury
2. Suspected open or depressed skull fracture
3. History of worsening headache
4. Persistent irritability on exam (if younger than 2 years)

<u>Medium risk variables (brain injury on CT)</u>

5. Any signs of basilar skull fracture
6. Large, boggy scalp hematoma
7. Dangerous mechanism of injury

Osmond 2010

CATCH Study

Results

- **Neurological intervention (n=24):**
  - Sensitivity 100% (86.2 - 100.0%)
  - Specificity 70.2% (68.8 - 71.6%)

- **Brain injury on CT (n=159, includes those not scanned):**
  - Sensitivity 98.1% (94.6 - 99.4%)
  - Specificity 50.1% (48.5 - 51.7%)

- Validation finished – to be published

Osmond 2010

UC Davis Study

methods

- Prospective study over three years, 2043 children younger than 18 with non-trivial head trauma
- Cranial CTs at the discretion of treating physician
- Clinical data recorded before CT
- Two physicians evaluated 5% of patients
- Discharged patients: follow up telephone call
- Admitted patients: review of medical record

Palchak 2003

Outcome Variable Definitions

1. TBI visible by CT *(n=98)*

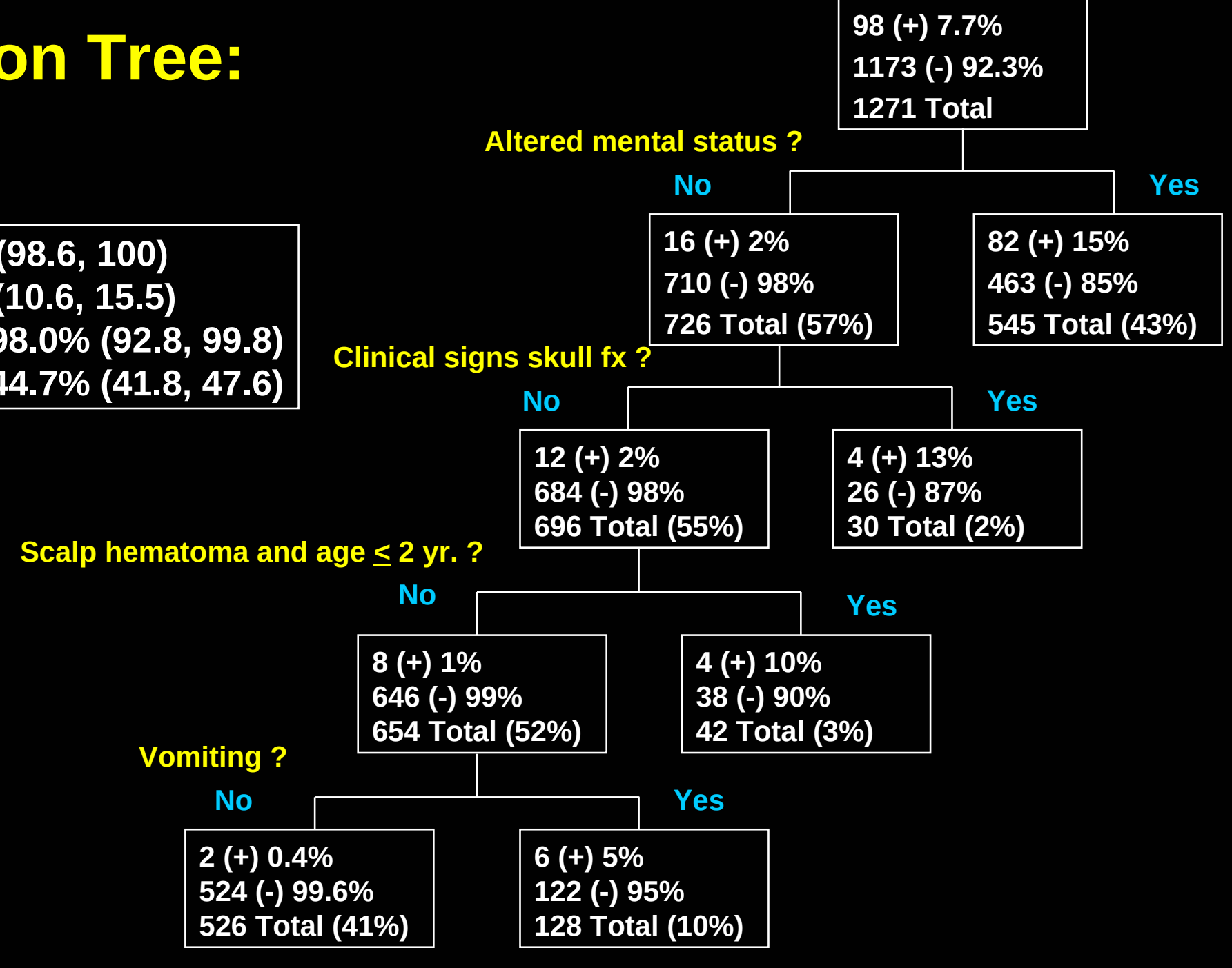
- Intracranial hematoma, contusion, or cerebral edema

2. TBI needing acute intervention *(n=105)*

- Neurosurgical procedure
- Hospitalization $\geq$ 2 nights for head injury
- Use of anti-convulsant medication > 7 days
- Persistent neurological deficit

Decision Tree: + CT

NPV 99.6% (98.6, 100)
PPV 12.9% (10.6, 15.5)
Sensitivity 98.0% (92.8, 99.8)
Specificity 44.7% (41.8, 47.6)



Missed + CT Patients

1 12 year old boy, auto-pedestrian

- GCS 15, scalp hematoma
- Small extra-axial hematoma on CT, initially missed
- Evaluated in the ED and discharged to home
- Called back to ED next day, doing well

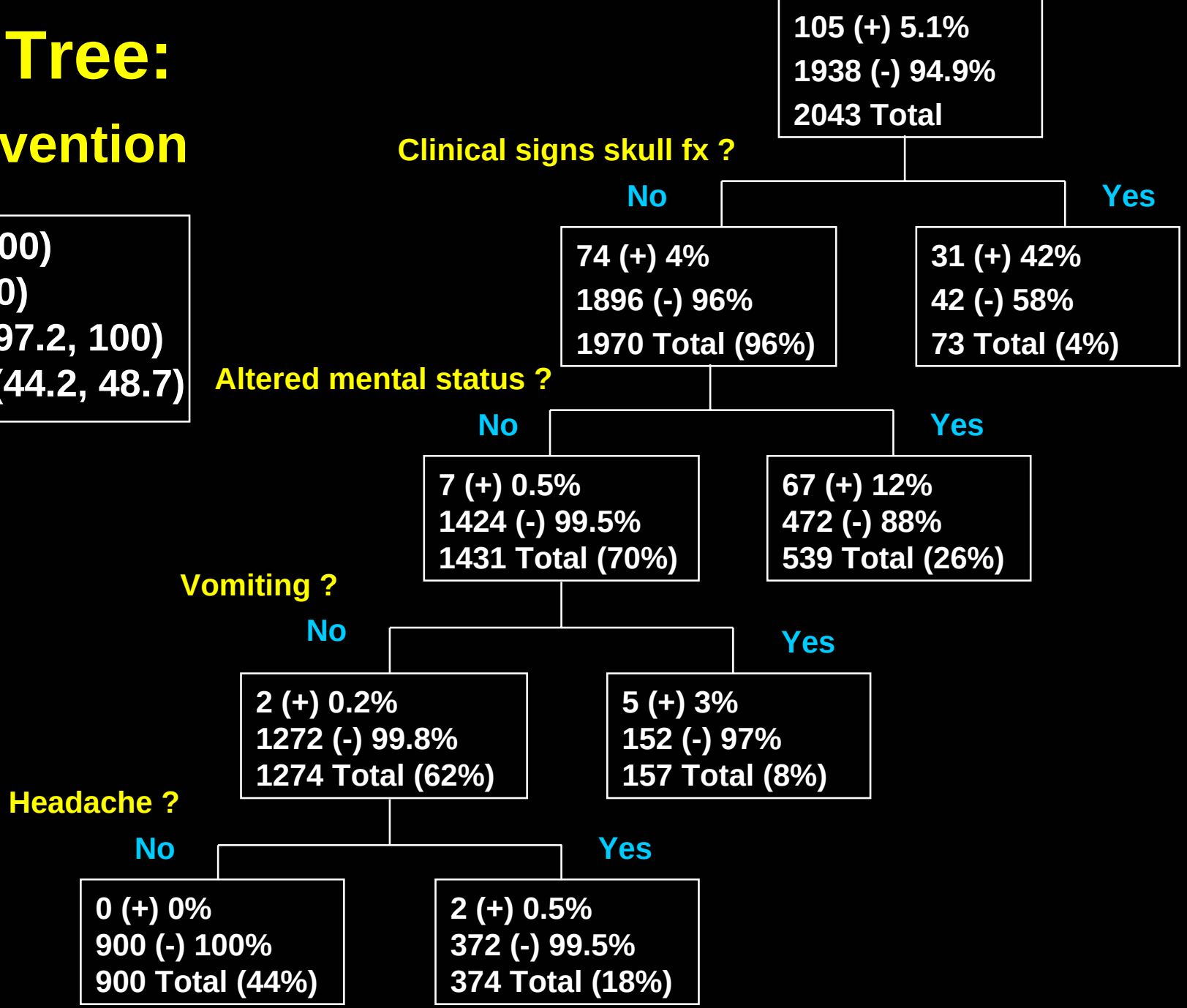
2 13 year old boy, fell off bicycle

- GCS 15, headache, scalp/facial wounds
- Small subarachnoid hemorrhage on CT
- Hospitalized for one night

Decision Tree:

Acute intervention

NPV 100% (99.7, 100)
PPV 9.2% (7.6, 11.0)
Sensitivity 100% (97.2, 100)
Specificity 46.4% (44.2, 48.7)



Combined rule performance

When decision trees combined:

TBI visible by CT

Altered mental status
Clinical signs of skull fracture
Vomiting
Scalp hematoma (≤ 2 years)

TBI needing acute intervention

Altered mental status
Clinical signs of skull fracture
Vomiting
Headache

+ CT

NPV 303/304 (**99.7%;** 98.2, 100)
Sensitivity 97/98 (**99%;** 94.4, 100)

Acute Intervention

NPV 827/827 (**100%;** 99.6, 100)
Sensitivity 105/105 (**100%;** 97.2, 100)

Altered mental status
Clinical signs of skull fracture
Vomiting
Headache
Scalp hematoma (≤ 2 years)

Study limitations

- Not everyone had CT
- Only one study site
- Needs external validation
- Preverbal patients
- Needs large multicenter study *(tighten the CI, enhance generalizability)*

Pediatric Emergency Care Applied Research Network (PECARN)

Supported in full by Project #U03 MC00001-01 from the Maternal and Child Health Bureau, Health Resources and Services Administration, Department of Health and Human Services

What is PECARN?

- A collaborative research group of hospital EDs organized into nodes and coordinated by a Steering Committee
- The infrastructure supported by funding from the MCHB
- PECARN works with the EMSC/MCHB/HRSA:
  - multi-center randomized trials
  - observational studies
  - other issues related to emergency medical services for children
- Highlighted in 2006 IOM reports on the future of EMSC

Ongoing PECARN Research Development

- Patient safety and error reduction
- Quality of PEM care
- **Evaluation of head trauma**
- C-Spine immobilization
- Steroids in acute bronchiolitis
- The burden of mental illness and psychiatric emergencies in PED
- RCT of fluids for DKA
- Magnesium for sickle cell pain
- Therapeutic hypothermia in pediatric cardiopulmonary arrest
- Diagnostic categorization of illnesses and injuries in the PED
- Management of status epilepticus
- Evaluation of abdominal trauma
- Progesterone for severe TBI
- Knowledge translation of TBI rules
- RNA transcription biosignatures to diagnose febrile infants

PECARN
Pediatric Emergency Care Applied Research Network

Childhood Head Trauma:
A Neuroimaging Decision Rule

PECARN
Pediatric Emergency Care
Applied Research Network

Supported by grant R40MC02461-01-00 from EMSC/MCHB/HRSA

The PECARN Head Injury Study

Goal: to derive a clinical decision rule to accurately identify children at near zero risk of clinically important traumatic brain injury after blunt trauma with high accuracy and wide generalizability

Methods

- ***Design:***
  - Prospective multicenter study over 28 mo. (6/04 – 9/06) in 25 sites in PECARN

- ***Inclusion Criteria:***
  - Age < 18 years with head trauma evaluated in ED

- ***Exclusion Criteria:***
  - Ground-level mechanisms and no symptoms or signs of TBI
  - Penetrating trauma
  - Injury > 24 hours old
  - Pre-existing neurological disease impeding assessment
  - Transfer with neuroimaging already performed

Outcome Definition

Clinically-important TBI (ciTBI)

- Death from TBI
- Neurosurgical procedure
- Intubation for $\geq$ 24 hours for head injury
- Positive CT in association with hospitalization $\geq$ 2 nights

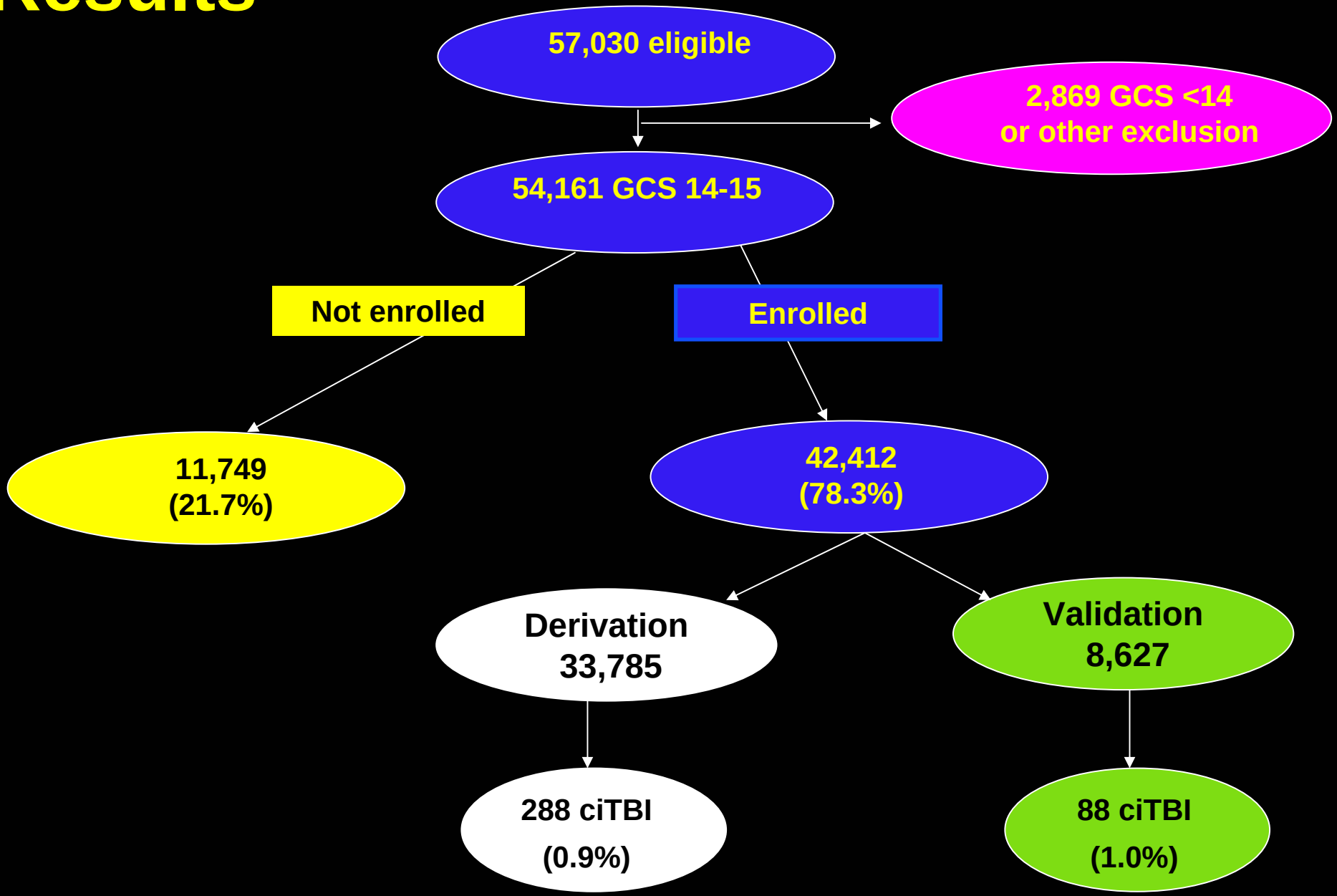
Variables Considered

- Age in years
- 3-level mechanism severity
  - High risk
    - MVC - ejection, rollover, death
    - Ped or unhelmeted bicyclist struck by motorized vehicle
    - Fall > 5 feet (> 3 feet if < 2 years)
    - High impact / projectile
- Amnesia
- LOC (duration)
- Seizure
- Acting normal per parent
- Headache (severity, location)
- Emesis (number, timing)
- GCS (14 vs. 15)
- Other mental status
  - Agitated
  - Sleepy
  - Slow to respond
  - Repetitive
- Palpable skull fx signs
- Basilar skull fx signs
- Bulging fontanelle
- Scalp hematoma (location, size, quality)
- Focal neurological deficit
- Other system injuries
- Evidence of intoxication

Variable Modification for Children < 2 Years

- Headache and amnesia not evaluated
- Age dichotomization at < 3 months
- Any scalp trauma considered

Results


57,030 eligible
2,869 GCS <14
or other exclusion
54,161 GCS 14-15
Not enrolled
Enrolled
11,749
(21.7%)
42,412
(78.3%)
Derivation
33,785
Validation
8,627
288 ciTBI
(0.9%)
88 ciTBI
(1.0%)

PECARN Prediction Rules

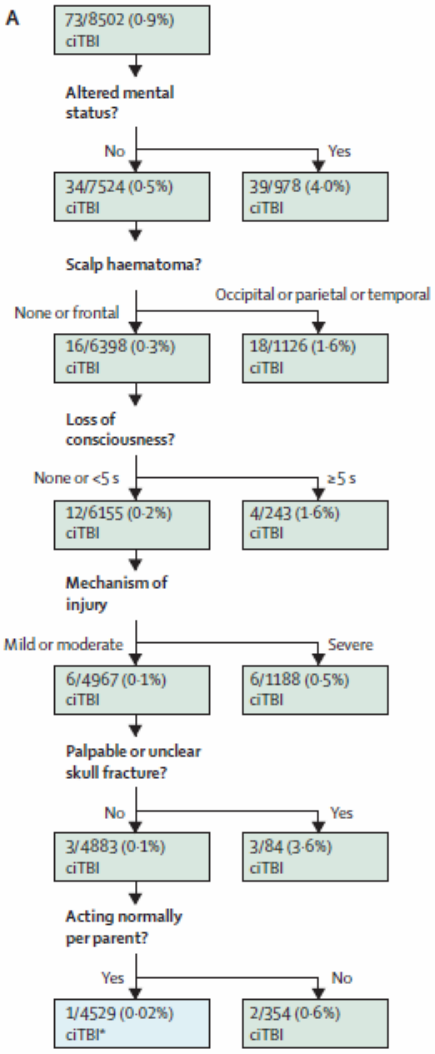
Age younger than 2 years

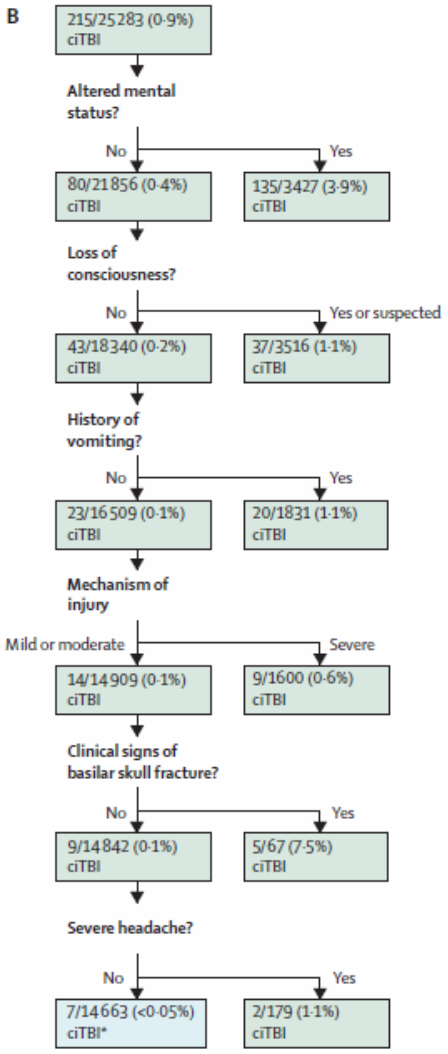
- GCS < 15 or abnormal mental status
- Tempero/parietal/occipital scalp hematoma
- LOC > 5 seconds
- Severe mechanism of injury
- Palpable/suspected skull fracture
- Acting abnormal per parent

PECARN Prediction Rules

Age 2 years and older

- GCS < 15 or abnormal mental status
- LOC
- History of emesis
- Severe mechanism of injury
- Signs of basilar skull fracture
- Severe headache





	Derivation			Validation		
	ciTBI	No ciTBI	Total	ciTBI	No ciTBI	Total
Any predictor present	72	3901	3973	25	1015	1040
No predictor present	1	4528	4529	0	1176	1176
Total	**73**	**8429**	**8502**	**25**	**2191**	**2216**

	Derivation	Validation
Prediction rule sensitivity (95% CI)	98·6% (92·6–99·97)	100·00% (86·3–100·00)
Prediction rule specificity (95% CI)	53·7% (52·6–54·8)	53·7% (51·6–55·8)
Negative predictive value (95% CI)	99·9% (99·88–99·999)	100·00% (99·7–100·00)
Positive predictive value (95% CI)	1·8% (1·4–2·3)	2·4% (1·6–3·5)
Negative likelihood ratio (95% CI)	0·03 (0·001–0·14)	0·0 (0–0·26)

	Derivation			Validation		
	ciTBI	No ciTBI	Total	ciTBI	No ciTBI	Total
Any predictor present	208	10412	10620	61	2550	2611
No predictor present	7	14656	14663	2	3798	3800
Total	**215**	**25068**	**25283**	**63**	**6348**	**6411**

	Derivation	Validation
Prediction rule sensitivity (95% CI)	96·7% (93·4–98·7)	96·8% (89·0–99·6)
Prediction rule specificity (95% CI)	58·5% (57·9–59·1)	59·8% (58·6–61·0)
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Positive predictive value (95% CI)	2·0% (1·7–2·2)	2·3% (1·8–3·0)
Negative likelihood ratio (95% CI)	0·06 (0·03–0·11)	0·05 (0·01–0·19)

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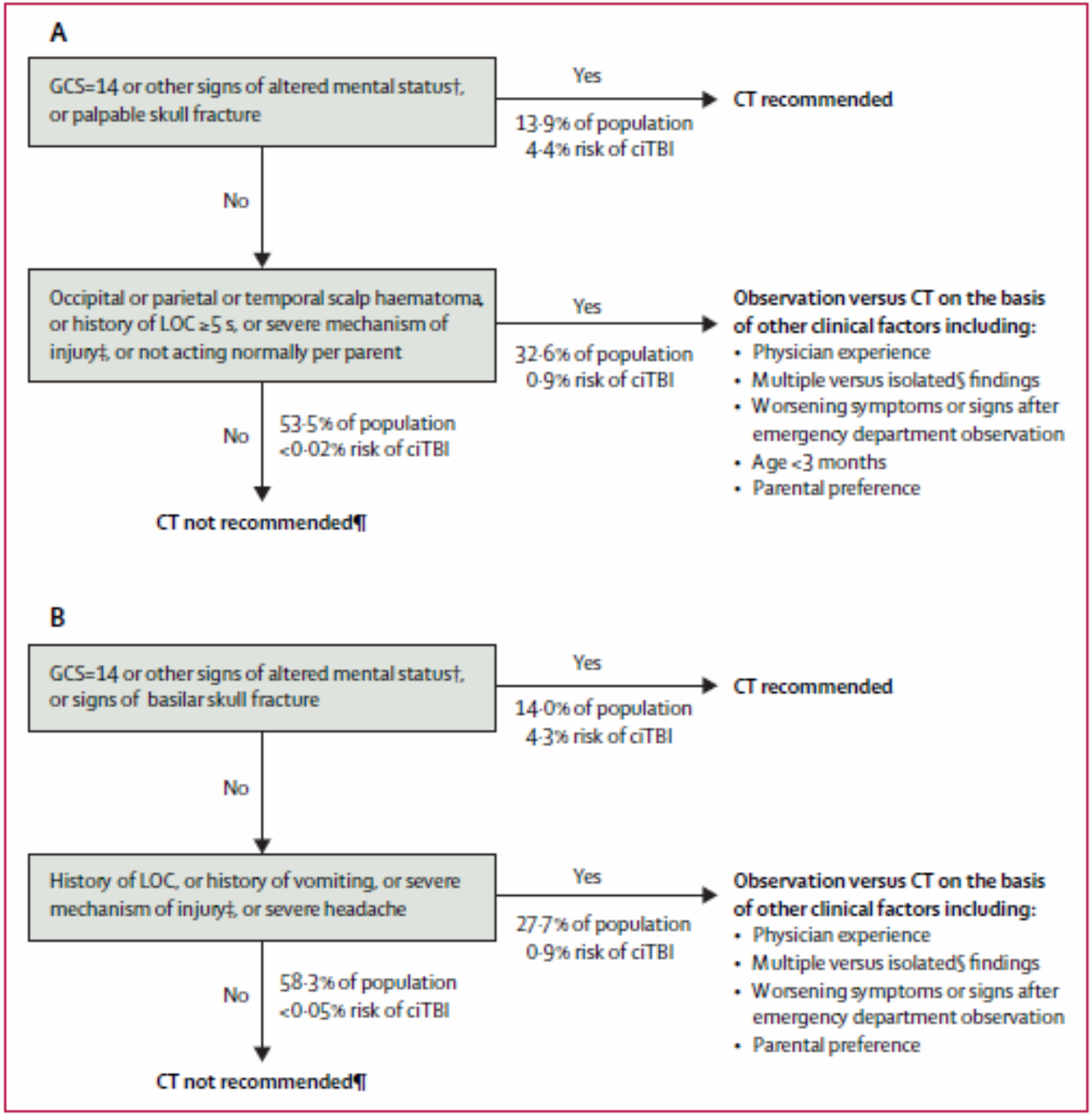
A
GCS=14 or other signs of altered mental status†, or palpable skull fracture
Yes
13·9% of population
4·4% risk of ciTBI
CT recommended
No
Occipital or parietal or temporal scalp haematoma, or history of LOC ≥5 s, or severe mechanism of injury‡, or not acting normally per parent
Yes
32·6% of population
0·9% risk of ciTBI
Observation versus CT on the basis of other clinical factors including:
• Physician experience
• Multiple versus isolated§ findings
• Worsening symptoms or signs after emergency department observation
• Age <3 months
• Parental preference
No
53·5% of population
<0·02% risk of ciTBI
CT not recommended¶
B
GCS=14 or other signs of altered mental status†, or signs of basilar skull fracture
Yes
14·0% of population
4·3% risk of ciTBI
CT recommended
No
History of LOC, or history of vomiting, or severe mechanism of injury‡, or severe headache
Yes
27·7% of population
0·9% risk of ciTBI
Observation versus CT on the basis of other clinical factors including:
• Physician experience
• Multiple versus isolated§ findings
• Worsening symptoms or signs after emergency department observation
• Parental preference
No
58·3% of population
<0·05% risk of ciTBI
CT not recommended¶

Case

- 6 year-old falls 4 feet from a ladder
- No LOC
- On exam, GCS 15
- Small forehead hematoma, tender at site

What are you going to do?

Pediatric Blunt Head Trauma

summary

- The study of pediatric head trauma is important
- Pressing issues include indications for emergency CT
  - Benefits: early identification of TBI
  - Drawbacks: radiation-induced malignancies
- Current data re: indications for CT in children are limited
- Definitive decision rule requires large, multicenter study
  - *Then need to translate the research into practice!*
- Multicenter networks can help improve the foundation of evidence for CT use after pediatric BHT

Selected References

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Differences between CATCH and PECARN rules

- Focus on who to CT
- Derivation only
- One rule for all ages
- Only symptomatic patients
- Included GCS 13-15
- Predictive variables (multiple emesis)
- Outcome definitions
  1. CT and proxy
  2. Neurosurgery/Intubation

- Focus on who not to CT
- Derivation and validation
- Different rules for verbal and pre-verbal
- All patients with head trauma, except trivial mechanisms
- Included GCS 14-15
- Predictive variables (any emesis)
- Outcome – clinically-important TBI

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PECARN
Pediatric Emergency Care Applied Research Network