Isolated Loss of Consciousness in Children With Minor Blunt Head Injury

Summary by Dr. Kirstin Weerdenberg-Yeh

Topic	Resuscitation
Citation of Paper:	Lee, Lois K., et al. "Isolated loss of consciousness in children with minor blunt head trauma." *JAMA pediatrics* 168.9 (2014): 837-843. LINK: 10.1001/jamapediatrics.2014.361
Are the results valid?	**1. Was there a clearly defined, focused research question? What was the study question?** Yes, there was a clearly defined, focused research question: "What is the risk of ciTBIs in children with isolated loss of consciousness (LOC)?" **2. How was the exposed cohort selected? Was there a well-defined selection procedure for inclusion into the cohort? What proportion of eligible subjects was actually included?** The exposed cohort was selected from the group of children who presented with a GCS of 14 or 15 within 24 hours of a blunt head injury. The examining physician had indicated that there was a suspected or actual history of LOC on a structured data collection form. There was a well-defined selection procedure, which included history of LOC if there was any period of unconsciousness reported after the traumatic event. As this was a planned subanalysis of a large prospective observational cohort study, the investigators enrolled 42 412 children from the parent study, excluded 1 719 children due to missing information about LOC, and finally included 6 286 (15.4%) children with a history of LOC. **3. How was the non-exposed cohort selected? Was this cohort drawn from the same source population as the exposed cohort? Was there a well-defined selection procedure for inclusion into the cohort? What proportion of eligible subjects was actually included?** The non-exposed cohort was selected from the same group of children as the exposed cohort, but for this group, the examining physician indicated that there was no known history of LOC. There was a well-defined selection procedure for inclusion, which was when there was no history of LOC. Again, in this planned sub analysis of a large prospective observational cohort study, of the eligible children, 34 407 (84.6%) children did not have a history of LOC. **4. How were the main exposures ascertained? Were the exposures clear, specific and measureable? Any likelihood of exposure misclassification?** The main exposure of LOC was ascertained by the physician on history. The exposure was clear, specific and measurable, as it had to either be present, suspected, not present, or unknown. The exposure could have been misclassified if the patient had amnesia after the traumatic event or if it was unwitnessed, and the patient or parent was unaware of a history of LOC. **5. Was the cohort free of the disease (outcome) at the start of follow up? Were only people at risk of the outcome included?** This detail was discussed in the parent paper. **6. Was the duration of follow up adequate (i.e. long enough for main outcomes to occur)?** This detail was discussed in the parent paper. **7. Was follow-up complete? Were efforts made to limit the loss to follow-up? What was the rate of attrition and was loss to follow-up similar in the exposed and non-exposed cohorts?** This detail was discussed in the parent paper. **8. What were the primary and secondary outcomes of the study? How well were the outcomes measured? Was the outcome clear, specific and measurable? Were surrogate outcomes used?** The main outcomes were ciTBI and TBI on CT. ciTBI was defined as (1) death from intracranial injury, (2) any neurosurgical intervention, (3) intubation longer than 24 hours for head injury, or (4) hospitalization for 2 nights or longer owing to head injury. TBI on CT included any traumatic intracranial injury and skull fractures depressed at least the width of the table of the skull. There was no secondary outcome measured. The outcomes were measured well, and were clear, specific and measurable. No surrogate outcomes were used.

Are the results valid? (Continued)	**9. Were outcomes measured similarly in exposed and non-exposed cohorts? Was outcome ascertainment influenced by knowledge of the exposure status (i.e. lack of blinding)?** Yes, outcomes were measured similarly in exposed and non-exposed cohorts, and outcome ascertainment was not influenced by knowledge of the exposure status. **10. How comparable were the exposed and non-exposed cohorts? Have the authors identified all potentially important cofounders? Is there information on how the potential confounders are distributed between groups? What confounders were adjusted for and was the adjustment adequate? Is residual confounding a concern?** The exposed cohort with a history of LOC had more CT scans done, but otherwise it was comparable to the non-exposed cohort without a history of LOC. There were no potential confounders in this study.
Biases	**1. Potential for selection bias?** None. **2. Potential for information bias?** None. **3. Potential for confounding?** None. **4. Was there a clear rationale for the sample size estimation?** This was discussed in the parent paper. **5. Are the analytic strategies clearly described? Were the data analytic methods appropriate for the research question and study design?** Yes, the analytic strategies were clearly described. The authors defined isolated LOC in 2 ways: (1) PECARN-isolated LOC – isolated LOC with no other PECARN ciTBI age-specific clinical predictors and (2) expanded-isolated LOC – isolated LOC with no other PECARN age-specific clinical predictors and no other clinical factors identified in other pediatric studies of TBI (excluding mechanism of injury). They divided the study cohort into children younger than 2 years and older than 2 years, as per the PECARN ciTBI rules. The investigators used appropriate data analytic methods for the research question and study design, as they calculated rates and risk.
What are the study results?	**1. How strong was the association between the exposure and outcome (e.g. rate ratio or hazard ratio or odds ratio)?** For PECARN-isolated LOC, the rate of TBI on CT was 1.9% (95% CI, 1.4-2.6; 38 of 1993) and the rate of ciTBI was 0.5% (95% CI, 0.2-0.8; 13 of 2780). For expanded-isolated LOC, the rate of TBI on CT was 0.9% (95% CI, 0.2-2.7; 3 of 326) and the rate of ciTBI was 0.2% (95% CI, 0.0-1.0; 1 of 576). Risk ratio for ciTBI in isolated LOC compared with LOC with additional age-specific PECARN predictors: Children aged <2 years: 0.13 (95% CI, 0.005-0.72). Children aged ≥2 years: 0.10 (95% CI, 0.06-0.19). **2. How precise was the estimate of the association (i.e. confidence intervals)?** The estimate of the risk ratio for ciTBI was precise for children aged ≥2 years as the confidence interval was small. This was not, however, the case for children aged <2 years, where there was a large confidence interval.
Can you apply the results to patient care?	**1. Were the study participants similar to the patient in your practice? Does your patient match the study inclusion criteria?** Yes, many of the patients I see in practice match this study population. **2. Were all clinically important outcomes considered?** Yes. **3. Do the results of this study fit with other available evidence?** This evaluation of isolated LOC has not previously been investigated.
In Summary	**What are the major strengths of this study?** • Large population of children from multiple Pediatric Emergency Departments making it more generalizable. • Prospective nature of the study reduces the possibility that results are biased by selecting subjects for the comparison group who may be more or less likely to have ciTBI or TBI on CT. • Provides useful data on risk of ciTBI in the setting of isolated LOC. • Highlights the importance of determining whether LOC occurred with or without other ciTBI risk factors when deciding on CT use, given the incremental increase for ciTBI with the addition of 1 PECARN predictor in conjunction with history of LOC, and its very strong influence on imaging decisions. **What are the major limitations of this study?** • Not all children had cranial CT imaging completed, meaning that the gold standard comparator was missing in some cases. • Some children were missing data on the presence or absence of LOC or whether it was actually isolated; the authors were unable to determine the isolated LOC status in all enrolled children. • Possibility of varying interpretations of history of LOC recorded on data collection forms by different clinicians. • Relatively small sample size of children aged <2 years with isolated LOC, as well as a large confidence interval around the risk ratio for this age group, meaning we should be wary about applying this rule to this age group. **Are there any major ethical concerns with this study?** • None

Evidence Bites