Resident Scholarly Project Expectations and Timeline Form

Meeting Date:

Resident: **Mentor:**

Research Project Title:

I. RESEARCH DESIGN AND METHODS

A. Design (Select all that apply)

- ☐ Case Report/Case series
- ☐ Observational Study with Existing Database(s)
- ☐ Prospective Qualitative Study
- ☐ Retrospective Experimental study
- ☐ Survey
- ☐ Chart Review
- ☐ Prospective Observational Study
- ☐ Quality Improvement Study
- ☐ Experimental Study

Brief Summary of Study Design

B. Research Objectives/Aims and Hypothesis (if applicable)

Primary Objective

Research Questions

Hypothesis(es)

C. Study Population
Population:

Inclusion criteria:

Exclusion criteria:

D. Intervention / Exposure of Interest

E. Comparison Group

F. Outcome(s) of Interest

Primary Outcomes

Secondary Outcomes

Exploratory Outcomes

Possible Confounding

G. Sample Size Calculation

Estimated Sample Size

Estimated Effect Size

Justification

H. Proposed Analyses to answer the research question:

I. Strategies to address possible confounding:

II. EXPECTATIONS

Mentor Expectations

Resident Expectations

Signatures:

Resident: **Mentor:**

III. PROJECTED TIMELINES

Please Initial		**Mentor**	**Resident**
Surveys will be completed by	_____	_____	_____
REB will be submitted by	_____	_____	_____
Work in Progress #1	_____	_____	_____
Small grant submitted by	_____	_____	_____
A database will be available by	_____	_____	_____
Database will be cleaned by	_____	_____	_____
Analyses completed by	_____	_____	_____
Work in Progress #2	_____	_____	_____
Abstract to local competition	_____	_____	_____
Local Competition	_____	_____	_____
External conference	_____	_____	_____
Document submitted to PD	_____ **DD/MM/YYYY**	_____	_____

Example of a Protocol

Vomiting as a predictor of intracranial injury after minor head injury

Research Project Protocol

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Supervisor: Dr. Terry Klassen

BACKGROUND & RATIONALE

Minor head injury is a very common reason for children to visit the Emergency Department. The use of CT scans to evaluate minor head injury and rule out intracranial injury in the ED is increasing(1), however with this comes increased exposure to ionized radiation and increased cost. In addition, the diagnosis of a rare number of intracranial hemorrhages continues to be delayed or missed(2).

Despite multiple proposed pediatric clinical decision making tools for determining whether or not a CT scan is necessary after a minor head injury, including CATCH (3), PECARN(4), and CHALICE(5), there is no current widely accepted evidence based guideline. Recurrent vomiting is currently included in the PECARN(4) and CHALICE(5) guidelines, however was not included in the original CATCH guidelines(3). With future research, the study aiming to validate the CATCH guidelines () identified that the addition of vomiting greater 3 times to the original guidelines increased the sensitivity of the tool to predict brain injury and need for neurosurgical intervention.

A meta-analysis of factors prediction of intracranial injury after pediatric minor head injury found that in general vomiting was not a significant predictor, however they were unable to isolate whether or not recurrent vomiting predicts intracranial injury.(6) In addition, a recent study using the PECARN data found that isolated vomiting did not predict clinically significant traumatic brain injury in their population (7). However, children presenting to the ED with minor head injury commonly have a history of vomiting(3), and vomiting one or more times has been associated with increased risk for skull fracture in children (8). It has also been suggested in the adult brain injury literature that vomiting is associated with increased risk of intracranial injury(9). Therefore, the clinical importance and predictive value of vomiting after minor head injury is still not well understood.

OBJECTIVES

Primary Objective

Does recurrent vomiting predict intracranial injury on CT head or need for neurosurgical intervention for children 0 to 16 years of age who present to the Emergency Department with minor head injury?

Secondary Questions

1. Does the number of episodes of vomiting after the head injury (1, 2, 3, 4, >4) change the predictive value of vomiting in identifying intracranial injury on CT?
2. Does the time after head injury of first episode of vomiting change the predictive value of vomiting in identifying intracranial injury on CT or need for neurosurgical intervention?
3. Does the duration of vomiting change the predictive value of vomiting in identifying intracranial injury on CT or need for neurosurgical intervention?
4. Does the age of the patient (<6months; 6months-24 months; > 24 months (10)) change the predictive value of vomiting in identifying intracranial injury?
5. Does isolated vomiting in the absence of other symptoms predict intracranial injury on Head CT or need for neurosurgical intervention?

6. Does recurrent vomiting predict intracranial injury on CT or need for neurosurgical intervention?

METHODS

Study Design

A secondary analysis will be conducted using data collected from the multicenter prospective cohort CATCH 2 study between April 2006 and December 2009. The full study design was described in the article published by Osmond et al(3), and a summary will be provided here. REB approval will be obtained.

Population

Data was collected on children 0 to 16 years old who consecutively presented to 9 different Canadian Emergency Departments with minor head injury after blunt head trauma. Minor head injury was defined as a Glasgow Coma Scale score of 13 to 15 after injury. Patients were included if they experienced at least one of loss of consciousness, amnesia, disorientation, persistent vomiting (≥2 episodes at least 15 minutes apart), or irritability. Patients were excluded if the injury was greater than 24 hours from ED presentation, had previously presented to the ED for the same injury, evidence of penetrating skull injury or obvious depressed fracture, acute focal neurologic deficits, global developmental delay, or injury secondary to child abuse.

Protocol

Trained staff physicians or supervised residents in the emergency department performed standardized history and physical exam assessments on a convenience sample of patients presenting to the ED with minor head injury, and completed the clinical data sheet prior to any imaging. If available, a second physician also performed the standardized assessment to measure interobserver reliability. The treating physician then decided whether to order a head CT scan based on clinical judgment.

For the patients who underwent CT scan, a blinded radiologist interpreted the scan. If there was uncertainty about whether or not there was an acute intracranial injury, a second blinded radiologist and neurosurgeon also interpreted the scan. For the patients who did not undergo a CT scan, a blinded nurse conducted a structured telephone interview at 14 days post injury by a blinded nurse to follow up on symptoms and clinical condition. If the patient did not have symptoms, they were classified as a having no clinically important brain injury. If they did not meet these criteria, the patient returned for repeat clinical assessment and CT scan.

Data was collected on frequency and timing of episodes of vomiting. Recurrent vomiting was defined as 2 or more episodes of vomiting more than 15 minutes apart.

Outcome Measures

Primary outcome of intracranial injury was defined as evidence of acute brain lesion, closed depressed skull fracture, or pneumocephalus on CT scan. Basilar skull fractures and nondepressed skull fractures were excluded. Need for neurologic intervention was defined as either death secondary to the head injury within 7 days, or the need for treatment with craniotomy, skull fracture elevation, intracranial pressure monitoring, or intubation.

Sample Size

If the presence of intracranial injury on head CT is assumed as 5%(1) and a precision/absolute error of 2%, then sample size of 456 is needed to examine intracranial injury as an outcome. If the

need for neurosurgical intervention is assumed as 0.5%(11) and a precision/absolute error of 0.25%, then a sample size of 3058 will be needed to examine neurosurgical injury as an outcome.

Data Analysis

The participants will be split into two groups, recurrent vomiting and no recurrent vomiting. The demographic and clinical characteristics will be examined using descriptive statistics. Assuming the data is normally distributed, two-sample t-tests and chi-squared tests will be used to determine differences in characteristics, including recurrent vomiting. As well, multivariate logistic regression will be used to determine if frequency, timing, and duration of vomiting are associated with intracranial injury on CT and need for neurosurgical intervention, and will be reported as odds ratios with 95% confidence intervals. Analyses will also be repeated comparing isolated vomiting to no isolated vomiting, and stratified by age categories, to examine whether vomiting is an independent predictor of intracranial injury on CT scan.

Study Limitations

There are a number of potential limitations to this study. First, for ethical reasons of limiting unnecessary radiation, not all of the study participants underwent CT scan to determine presence or absence of intracranial injury. In addition, these children were followed up by phone interview to determine if clinically significant brain injury was present. Therefore, the number of children with intracranial injury may have been underestimated, as those who were asymptomatic may have had evidence of injury on CT scan. Also, it is unclear the clinical significance of small intracranial injury on CT scan. Further, patient report of symptoms, including frequency and timing of vomiting, are subject to recall bias. As well, vomiting is common in children outside of head injury, and therefore incidence of vomiting after minor head injury may be confounded by other causes of vomiting not controlled for.

REFERENCES

1. Klassen TP, Reed MH, Stiell IG, Nijssen-Jordan C, Tenenbein M, Joubert G, et al. Variation in Utilization of Computed Tomography Scanning for the Investigation of Minor Head Trauma in Children: A Canadian Experience. Acad Emerg Med. 2000 Jul 1;7(7):739–44.

2. Hamilton M, Mrazik M, Johnson DW. Incidence of Delayed Intracranial Hemorrhage in Children After Uncomplicated Minor Head Injuries. Pediatrics. 2010 Jul 1;126(1):e33–9.

3. Osmond MH, Klassen TP, Wells GA, Correll R, Jarvis A, Joubert G, et al. CATCH: a clinical decision rule for the use of computed tomography in children with minor head injury. Can Med Assoc J. 2010 Mar 9;182(4):341–8.

4. Kuppermann N, Holmes JF, Dayan PS, Hoyle JD, Atabaki SM, Holubkov R, et al. Identification of children at very low risk of clinically-important brain injuries after head trauma: a prospective cohort study. The Lancet. 2009 Oct 9;374(9696):1160–70.

5. Dunning J, Daly JP, Lomas J-P, Lecky F, Batchelor J, Mackway-Jones K. Derivation of the children's head injury algorithm for the prediction of important clinical events decision rule for head injury in children. Arch Dis Child. 2006 Nov;91(11):885.

6. Dunning J, Stratford-Smith P, Lecky F, Batchelor J, Hogg K, Browne J, et al. A meta-analysis of variables that predict significant intracranial injury in minor head trauma. J Neurotrauma. 2004 Jul;21(7):877–85.

7. Dayan PS, Holmes JF, Atabaki S, Hoyle Jr. J, Tunik MG, Lichenstein R, et al. Association of Traumatic Brain Injuries With Vomiting in Children With Blunt Head Trauma. Ann Emerg Med. 2014 Jun;63(6):657–65.

8. Nee PA, Hadfield JM, Yates DW, Faragher EB. Significance of vomiting after head injury. J Neurol Neurosurg Psychiatry. 1999 Apr 1;66(4):470–3.

9. Stiell IG, Wells GA, Vandemheen K, Clement C, Lesiuk H, Laupacis A, et al. The Canadian CT Head Rule for patients with minor head injury. The Lancet. 2001 May 5;357(9266):1391–6.

10. Burns ECM, Grool AM, Klassen TP, Correll R, Jarvis A, Joubert G, et al. Scalp Hematoma Characteristics Associated With Intracranial Injury in Pediatric Minor Head Injury. Acad Emerg Med. 2016 May 1;23(5):576–83.

11. Schnadower D, Vazquez H, Lee J, Dayan P, Roskind CG. Controversies in the evaluation and management of minor blunt head trauma in children. Curr Opin Pediatr. 2007 Jun;19(3):258–64.