Effective Health Care

Follow-up Head CT after complicated mild Traumatic Brain Injury

Results of Topic Selection Process & Next Steps

The nominator is interested in a new evidence review on Follow-up Head CT after Complicated Mild Traumatic Brain Injury (cmTBI) to inform clinical practice.

Because limited original research addresses key questions in the nomination, a new review is not feasible at this time. No further activity on this nomination will be undertaken by the Effective Health Care (EHC) Program.

Topic Brief

Topic Name: Follow-up Head CT after Complicated Mild Traumatic Brain Injury (cmTBI), number 0795.

Nomination Date: 06/22/2018

Topic Brief Date: 08/28/2018

Authors
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Conflict of Interest: None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

Summary

- Appropriateness and importance: The topic is both appropriate and important. Mild traumatic brain injury affects >500,000 people in the USA each year. The clinical dilemma is determining which patients with complicated mild TBI are at risk for deteriorating, and thus need further monitoring/repeat head CT.
- Duplication: A new review would not be duplicative of an existing product. No reviews address either of the Key Questions.
- Impact: A new systematic review has moderate impact potential.
- Feasibility: A new review may not be feasible. The evidence base is likely very small, and not of high quality.

Background

Traumatic brain injury (TBI) is a population problem because it occurs frequently, may lead to life-changing consequences, and incurs costly medical evaluation and treatment. Broadly, TBI is defined as an insult to the brain caused by external physical force that may produce an altered state of consciousness, and which may also impair cognitive abilities or physical functioning.

In the United States in 2010, there were about 2.5 million emergency department visits, hospitalizations, and deaths related to TBI. [1] What is more, rates of TBI-related ED visits have increased over the last decade. In the US, TBI severity is classified using the Glasgow Coma Scale (GCS), with scores of 13-15 considered mild, 9-12 as moderate, and 8 or less as severe. According to claims data, over 95% of TBI are considered mild. [2] About 10% of patients who have a mild traumatic brain injury (mTBI) also have an associated intracranial injury (usually discovered on imaging) and are deemed "complicated mTBI" (cmTBI). [3] About 500,000 patients per year fall into the cmTBI category.[1]

The prognosis for mTBI depends upon many clinical factors. The majority of those with mTBI recover fully without intervention. However, those with complicated mild TBI (cmTBI) are at increased risk of deterioration, especially if the abnormality is an intracranial hemorrhage. Two older systematic reviews estimated that about 2-4% of patients with cmTBI experience changes in clinical exam or CT scan which required prompt intervention. [4, 5] A 2018 metanalysis reported the following pooled risks for those with cmTBI: clinical deterioration 11.7% (95% confidence interval [CI]: 11.7%-15.8%), neurosurgical intervention 3.5% (95% CI: 2.2%-4.9%), and death 1.4% (95% CI: 0.8%-2.2%). [6]

Thus, clinicians are faced with the dilemma: which cmTBI patients require admission, observation, and follow-up head CT? A 2018 meta-regression of study characteristics and pooling of within-study estimates of risk factor effect found the following factors significantly affected the risk for adverse outcomes: age, initial Glasgow Coma Scale (GCS), type of injury, and anti-coagulation. [6]

The clinical dilemma is heightened because of secular practice changes. Since 2000, several guidelines recommend limiting the initial head CT to evaluate TBI. For example, the Canadian CT Head Rule recommends an initial head CT only for patients who meet one of these criteria: over 65 years; vomiting more than once, amnesia for >30 minutes, pedestrian struck, ejected from vehicle, fall >1 meter, suspected skull fracture, or whose GCS score is <15 at 2 hours after injury. [7] However, the use of head CT to evaluate patients with mTBI increased over the past decade in part because of defensive medicine and in part because of patient requests.[8] In addition, CT scan quality has improved dramatically, and can now detect small abnormalities that would previously have been missed.

Clinical management of patients with cmTBI differs within and between institutions, and optimal management remains controversial. Some authors argue that a repeat CT does not change management. In a 2014 systematic review, meta-analysis of a subgroup mild TBI patients (Glasgow Coma Scale score 13 to 15), estimated that the pooled proportion of patients with change in management following repeat CT across five prospective studies was 2.3% (95% CI 0.3-6.3) and across nine retrospective studies was 3.9% (95% CI 2.3-5.7). The evidence suggests that repeat CT in patients with cmTBI results in a change in management for only a minority of patients. [4]

However, this evidence has not been updated since 2012. Although we found two algorithms for identifying and stratifying cmTBI patients into groups that would benefit from follow-up CT scans,[9, 10] neither algorithm has been endorsed by major professional societies. [9, 10]

Nominator and Stakeholder Engagement: Scope and KQ were shared with the nominator, who reviewed and concurred.

The key questions for this nomination are:

KQ1: In patients with a cmTBI who are neurologically stable, how effective is a routine follow-up head CT to change outcomes, compared to no routine CT?

KQ2: In patients with a cmTBI who are neurologically stable, what are the adverse effects associated with routine follow-up head CT?

To define the inclusion criteria for the key questions we specify the population, interventions, comparators, outcomes, timing, and setting (PICOTS) of interest (Table 1).

Table 1. PICOTS

Population	• Adults (≥ age 18) • Documented cmTBI (Glasgow Coma Scale (GCS) score of 13-15, and a head CT positive for intracranial blood or a skull fracture) • Without neurosurgical intervention
Interventions	Neurological exam plus Routine/automatic follow-up CT scan within 24 hours of initial head CT scan
Comparators	Neurological exam alone without routine/automatic follow-up CT scan
Outcomes	
KQ1:	<u>Primary:</u> Any change in management • any neurosurgical intervention (e.g.,craniotomy, intracranial pressure (ICP) monitoring) • change in IPC monitoring or drug therapy • admission to a higher level of care <u>Secondary:</u> Neurological deterioration Progression of lesion on CT Death
KQ2:	• Adverse effects of intervention: Longer hospital stay
Setting	Inpatient/ ED

Abbreviations: CT-computed tomography; cm-complicated mild; TBI-traumatic brain injury; ED-Emergency Department

Methods

We assessed nomination #0795, Follow-up Head CT after Complicated Mild Traumatic Brain Injury (cmTBI) for priority for a systematic review or other AHRQ EHC report with a hierarchical process using established selection criteria. Assessment of each criteria determined the need to evaluate the next one. See Appendix A for detailed description of the criteria.

1. Determine the *appropriateness* of the nominated topic for inclusion in the EHC program.
2. Establish the overall *importance* of a potential topic as representing a health or healthcare issue in the United States.
3. Determine the *desirability of new evidence review* by examining whether a new systematic review or other AHRQ product would be duplicative.
4. Assess the *potential impact* a new systematic review or other AHRQ product.
5. Assess whether the *current state of the evidence* allows for a systematic review or other AHRQ product (feasibility).
6. Determine the *potential value* of a new systematic review or other AHRQ product.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

Desirability of New Review/Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last three years on the key questions of the nomination. See Appendix B for sources searched.

Impact of a New Evidence Review

The impact of a new evidence review was qualitatively assessed by analyzing the current standard of care, the existence of potential knowledge gaps, and practice variation. We considered whether it was possible for this review to influence the current state of practice through various dissemination pathways (practice recommendation, clinical guidelines, etc.).

Feasibility of New Evidence Review

We conducted a literature search in PubMed from July 2013 to July 2018. We supplemented this with a “similar articles” search using the most relevant articles from the PubMed search. See Appendix B for the PubMed search strategy and links to the ClinicalTrials.gov search.

We reviewed all identified titles and abstracts for inclusion and classified identified studies by key question and study design to assess the size and scope of a potential evidence review.

Results

See Appendix A for detailed assessments of all EPC selection criteria.

Appropriateness and Importance

This is an appropriate and important topic. The nominator requests a systematic review on comparative effectiveness. The topic is important because mild traumatic brain injury affects >500,000 people in the USA each year. Clinical deterioration that requires neurosurgical intervention is rare but serious. The clinical dilemma is determining which patients with complicated mild TBI are at risk to deteriorate, and thus need further monitoring/repeat head CT (indicated CT). Routine follow up CT scans may be a waste of health care resources, causing both unnecessary radiation exposure and increased hospital length of stay.

Desirability of New Review/Duplication

A new evidence review would not be duplicative of an existing evidence review. We found one systematic review published in the last three years. A 2018 metanalysis by Marincowitz et al included 49 primary studies (no RCTs) and one systematic review. [6] Their population definition matched ours, however they included some pediatric patients (age 12-17). Their outcomes were the same as KQ1. However, their main goal was to estimate the risk of outcomes and to identify the predictors of deterioration. They did not use a comparator, and did not assess harms.

See Table 2, Duplication column.

Impact of a New Evidence Review

A new systematic review may have some level of impact. There is practice variability and a lack of current guidance.

Estimates of current practice are difficult to find. Although most authors describe follow up CT as routine care, we found estimates ranging from 32% to 91%, The practice seems to differ both by year and location. [11, 12 13 14]

Major professional groups such as the Congress of Neurological Surgeons (CNS), the American Association of Neurological surgeons (AANS), the CDC and the American College of Emergency Physicians (ACEP) have only endorsed guidelines that address when to perform an initial head CT. [15] None of these organizations have developed clinical guidelines to assist clinicians in determining which patients with mTBI should undergo routine follow-up head CT.

Feasibility of a New Evidence Review

A new evidence review may not be feasible. A search of PubMed yielded only 74 studies; after abstract review, only 11 could potentially be used to answer KQ1, and two of these addressed KQ2. A "similar articles" search using the most promising articles yielded only one new reference (KQ1). We could find no randomized controlled trials. The quality of the studies we identified is unclear. The comparator group (number of subjects without a routine follow up head CT) is much smaller than the intervention group (routine head CT). See Table 2, Feasibility column.

Table 2. Key Questions and Results for Duplication and Feasibility

Key Question	Duplication (07/2015-07/2018)	Feasibility (07/2013-07/2018)
KQ 1: change in outcomes due to routine head CT	Total number of identified systematic reviews: None	Size/scope of review Relevant Studies Identified: 9 • RCT: none • Observational: • Prospective: 5 [13, 16-19] • Retrospective: 7 [20-26] Clinicaltrials.gov • Recruiting: 0 • Active: 0 • Complete: 0

Key Question	Duplication (07/2015-07/2018)	Feasibility (07/2013-07/2018)
KQ 2: harms of routine head CT	Total number of identified systematic reviews: None •	Size/scope of review Relevant Studies Identified: 2 RCT: none Observational: 2[20, 23] Clinicaltrials.gov • None

Abbreviations: AHRQ=Agency for Healthcare Research and Quality; KQ=Key Question

Summary of Findings

- Appropriateness and importance: The topic is both appropriate and important. Mild traumatic brain injury affects >500,000 people in the USA each year. The clinical dilemma is determining which patients with complicated mild TBI are at risk for deteriorating, and thus need further monitoring/repeat head CT.
- Duplication: A new review would not be duplicative of an existing product. No reviews address either of the Key Questions.
- Impact: A new systematic review has moderate impact potential.
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Appendix A. Selection Criteria Assessment

Selection Criteria	Assessment
1. Appropriateness	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the U.S.?	Yes
1b. Is the nomination a request for a systematic review?	Yes
1c. Is the focus on effectiveness or comparative effectiveness?	Yes
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes
2. Importance	
2a. Represents a significant disease burden; large proportion of the population	Yes. TBI affects 2.5 million people per year, and is increasing in the USA
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the US population or for a vulnerable population	Yes. TBI may lead to life-changing consequences, and incurs costly medical evaluation and treatment
2c. Represents important uncertainty for decision makers	Yes. The clinical dilemma is determining which patients with complicated mild TBI are at risk for deteriorating, and thus need further monitoring/repeat head CT.
2d. Incorporates issues around both clinical benefits and potential clinical harms	Yes
2e. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	Yes. Inpatient admissions and CT scans are costly.
3. Desirability of a New Evidence Review/Duplication	
3. Would not be redundant (i.e., the proposed topic is not already covered by available or soon-to-be available high-quality systematic review by AHRQ or others)	Yes. A 2018 SR and metanalysis does not address KQ1. Harms specific to repeat CT scan itself (KQ2) were not reported. Prior SRs (2014 and earlier) are incomplete and outdated.
4. Impact of a New Evidence Review	

Selection Criteria	Assessment
4a. Is the standard of care unclear (guidelines not available or guidelines inconsistent, indicating an information gap that may be addressed by a new evidence review)?	Two algorithms to guide clinical care have been published, but are not endorsed by professional societies such as CNS and ACNS. For example, The authors of the BIG guidelines demonstrated that, in a single institution, implementing their guidance in 2012 resulted decreased utilization with no decrease in outcomes. The use of routine repeat head CT decreased from 91% in 2009 to 54% in 2014; the rate of neurosurgical consultation, the length of stay, and hospital costs also decreased significantly in the same time period. Mortality and neurosurgical intervention rates were unchanged. [13] Current guidelines by the CNS, AANS and ACEP address only the initial evaluation, and not follow up head CT.
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	The practice differs both by year and location. In single center US studies, authors reported that routine follow up head CT was performed in over 60% of cmTBI patients in 2003 and 2010, and in over 90% of patients in 2009. [11, 12] [13] In an Australian study, routine follow up head CT was performed in only 32% of subjects. [14]
5. Primary Research	
5. Effectively utilizes existing research and knowledge by considering: - Adequacy (type and volume) of research for conducting a systematic review - Newly available evidence (particularly for updates or new technologies)	The evidence base is small, and of uncertain quality. There are few subjects in the comparator arms.

Abbreviations: AHRQ=Agency for Healthcare Research and Quality; KQ=Key Question

Appendix B. Search for Evidence Reviews (Duplication) and Feasibility

Primary Sources	Results
AHRQ: Evidence reports and technology assessments, USPSTF recommendations https://www.effectivehealthcare.ahrq.gov/ https://www.ahrq.gov/research/findings/ta/index.html https://www.uspreventiveservicestaskforce.org/ https://www.ahrq.gov/research/findings/evidence-based-reports/search.html	 0 0 0 0 0
VA Products: PBM, and HSR&D (ESP) publications, and VA/DoD EBCPG Program https://www.hsrd.research.va.gov/publications/esp/ https://www.healthquality.va.gov/	0
Cochrane Systematic Reviews and Protocols http://www.cochranelibrary.com/	0
PubMed https://www.ncbi.nlm.nih.gov/pubmed/	4 related [4-6, 27, 28]
PubMed Health http://www.ncbi.nlm.nih.gov/pubmedhealth/	
HTA (CRD database): Health Technology Assessments http://www.crd.york.ac.uk/crdweb/	
PROSPERO Database (international prospective register of systematic reviews and protocols) http://www.crd.york.ac.uk/prospero/	0 (3 related)
CADTH (Canadian Agency for Drugs and Technologies in Health) https://www.cadth.ca/	
DoPHER (Database of promoting health effectiveness reviews) http://eppi.ioe.ac.uk/webdatabases4/Intro.aspx?ID=9	
ECRI institute https://www.ecri.org/Pages/default.aspx	
Systematic reviews Journal: protocols (SR and scoping reviews) and systematic reviews https://systematicreviewsjournal.biomedcentral.com/	0
PsycINFO (Ovid)	
Secondary Sources checked on an as needed basis	
Campbell Collaboration http://www.campbellcollaboration.org/	
McMaster Health System Evidence https://www.healthsystemsevidence.org/	
Robert Wood Johnson http://www.rwjf.org/	
UBC Centre for Health Services and Policy Research http://chspr.ubc.ca/	
WHO Health Evidence Network http://www.euro.who.int/en/data-and-evidence/evidence-informed-policy-making/health-evidence-network-hen	0
CINAHL (EBSCO)	
Joanna Briggs Institute http://joannabriggs.org/	

Duplication Search Details

- **Pub Med**
  - TBI
  - “traumatic brain injury”
  - ((complicated) AND mild) AND TBI
  - Similar articles for Stippler [5, 29]
  - Similar articles for Marincowitz (2018)[6]

- **Cochrane:**
  - TBI
  - Concussion
  - brain

- **Prospero:**
  - TBI
  - brain
  - brain injury

Feasibility Search Details

- **Pub Med**
  - search string

Search (((((((traumatic brain injury[Title/Abstract]) OR Brain Injuries/*diagnostic imaging/surgery) OR Head Injuries, Closed/*diagnostic imaging/surgery) AND "last 5 years"[PDat] AND Humans[Mesh] AND English[lang] AND adult[MeSH])) AND mild[Title/Abstract]) AND "last 5 years"[PDat] AND Humans[Mesh] AND English[lang] AND adult[MeSH])) AND *Tomography, X-Ray Computed[MeSH Terms] Filters: published in the last 5 years; Humans; English; Adult: 19+ years

  - search results: 74 (9 met some criteria)
  - Similar articles search:
    - used four most likely articles from PubMed [17, 19, 20, 23]
    - Results: 83 similar articles; most duplicates of PubMed search; One new article [16] was found, and a similar article search from this yielded no new articles.

- **Clinical trials.gov:**
  - search string

Mild Traumatic Brain Injury AND imaging | Traumatic Brain Injury | Adult, Older Adult
Also searched for Brain Concussion, Trauma, Wounds and more.

  - search results: 51. None had CT scan as intervention