PROSPERO International prospective register of systematic reviews

Cervical spine clearance in the obtunded blunt trauma patient
Mayur Patel, Jeanette Capella, Joseph Cheng, Daniel Cullinane, Matthew Day, Margaret Delozier, Clinton Devin, Stephen Humble, Andrea Long, Lou Smith, Miya Smith, Randeep Jawa

Citation

Review question(s)
Should C-spine clearance be performed
- after a negative high-quality CT combined with adjunct imaging and/or further clinical follow-up
- or after a negative high-quality C-spine CT alone,
in order to reduce peri-clearance events in the obtunded adult blunt trauma patient?

Searches
Pubmed
Cochrane Central Register of Controlled Trials (CENTRAL)
EMBASE

Types of study to be included
There will be no restrictions on study design. We will exclude reviews, editorials, comments, letters, newspaper articles, guidelines, legal cases, congresses.

Condition or domain being studied
Cervical spine clearance is well-established for the alert patient with or without symptoms, however, it is unclear for the obtunded trauma patient whether primary screening with CT is sufficient or whether a second diagnostic adjunct is required.

Participants/ population
Inclusion: Adult (Age>=16) Blunt trauma patients undergoing cervical spine CT (thickness <3mm) who are obtunded (either GCS<14, unconscious, intubated, Altered Mental Status, unreliable exam, distracting injury, intoxication, not meeting NEXUS guidelines, able to move all extremities)
Exclusion: Age < 16, penetrating trauma, CT thickness unspecified or >=3mm, No comparator group (non-obtunded physical exam, MRI, Flexion-extension, dynamic fluoroscopy), Duplicate studies/populations, Alert patients

Intervention(s), exposure(s)
Inclusion: Imaging with cervical spine CT (thickness <3mm) and adjunct (physical exam, MRI, Flexion-extension, dynamic fluoroscopy)
Exclusion: Imaging with cervical spine CT (thickness >= 3mm), No adjunct imaging

Comparator(s)/ control
Inclusion: Imaging with cervical spine CT (thickness <3mm)

Outcome(s)
Primary outcomes
New neurologic change (paraplegia, quadriplegia).
Unstable injury treated operation.
Unstable injury treated with orthotic.
Secondary outcomes
Stable injury treated with operation
Stable injury treated with orthotic or operation
Post-clearance imaging
False negative CT imaging on re-review/re-read
Pressure ulcers
Time to C-collar clearance

**Data extraction, (selection and coding)**
SH will run the searches, collate the results and remove duplicates before transferring them to 4-person group screening (SH, MP, MD, MS). All sources will be managed using DistillerSR. Decisions on inclusion/exclusion of studies will be made independently by two authors using piloted criteria. Disagreements will be resolved with reference to a third experienced author.

We will extract the following data (where available) into a data extraction table:
- Author, year of study, year of publication, journal reference;
- Study design and timing of data collection (prospective/retrospective);
- Study population and participant characteristics (age, sex, setting - e.g. hospital, region, country, other details given);
- Trauma Type (% TBI, GCS, ISS);
- Definition of obtunded (Altered Mental Status, GCS<14, Unconscious, Intubated, unreliable exam, distracting injury, intoxication, not meeting NEXUS guidelines);
- Time to adjunct second diagnostic adjunct;
- CT characteristics (such as maximum slice thickness, multidetector rows, study quality);
- MRI strength and protocol characteristics;
- Number of negative CT studies;
- Number of positive adjunct imaging studies (resulting in outcomes of Unstable injury treated operation, Unstable injury treated with orthotic, stable injury treated with orthotic or operation, falsely read negative CT imaging);
- Events peri-clearance (new neurologic symptoms, pressure ulcers, time to c-collar clearance);
- Data from the 2x2 table will be extracted where presented, (i.e. true positives, false positives, true negatives and false negatives).

**Risk of bias (quality) assessment**
We will carry out quality assessment using a checklist approach to assess the quality of primary studies based on the QUADAS-2 instrument in line with advice given in Reitsma 2009. We will independently score each item as ‘Yes’, ‘No’ or ‘Unclear’ as recommended by the Cochrane Handbook for Diagnostic Test Accuracy Reviews (http://srdta.cochrane.org/). A categorization of 'unclear' will generally be considered a marker of poor quality, so care will be taken to account for the possibility that failing to report an item was reasonable given the circumstances in which the study was conducted. We will present results narratively in the text, and in an appropriate graphic representation of quality assessment (such as a table).

**Strategy for data synthesis**
Our initial approach to analysis is likely to be qualitative, with conclusions based on patterns of results. We will tabulate and comment on the number of uninterpretable results. We will carry out analysis and presentation of results in line with advice in Chapter 10 of the Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy. We will scrutinise carefully all the included studies for any further investigation of discrepant results between the index test and reference standards (False Positives (FP) and False Negatives (FN)), ideally based on independent clinical review of all available findings.

Quantitative meta-analysis may be appropriate where the quantity and nature of the included studies permit. If that is possible, the results will be the components of the 2x2 table, sensitivity and specificity and their 95% confidence interval (CI). These will be tabulated and presented graphically (forest plots and receiver operating characteristic (ROC) space). If meta-analysis is possible, our approach will be to calculate a summary ROC (sROC) curve using a hierarchical summary ROC (HSROC) model. We will also consider using a bivariate model depending on the data, but a priori uncertainty about thresholds, and the likelihood of implicit thresholds, suggest the HSROC model may be slightly preferable in the first instance. We will generate a summary of results table. If feasible and appropriate, translation of any summary results into natural frequencies and other metrics such as predictive values will be considered to facilitate improved understanding to readers.

**Analysis of subgroups or subsets**
Exploration of the following major types of subgroups are anticipated:
- Type of adjunct diagnostic
- Imaging characteristics (CT and/or MRI)
- Obtunded definition

**Dissemination plans**
The review will be presented at the 2014 EAST Annual Assembly and published in the Journal of Trauma and Acute Care Surgery.

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Anticipated or actual start date
22 August 2013

Anticipated completion date
01 February 2014

Funding sources/sponsors
Vanderbilt Physician Scientist Development Program

Conflicts of interest
Dr. Devin has resident grant and educational support from Depuy Spine and Stryker Spine.

Language
English

Country
United States of America

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Cervical Vertebrae; Humans; Spinal Injuries; Unconsciousness; Wounds, Nonpenetrating

Date of registration in PROSPERO
23 August 2013

Date of publication of this revision
27 August 2013

Stage of review at time of this submission

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