Diagnostic management strategies for adults and children with minor head injury: a systematic review and an economic evaluation


CRD summary
This well-conducted review found that the Canadian Computed Tomography Head rule was the best validated rule in adults with high sensitivity and acceptable specificity for diagnosis of intracranial injury in patients with minor head injury. Decision rules for children needed further validation. These conclusions should be interpreted with some caution due to methodological limitations in the included studies.

Authors' objectives
To determine the diagnostic accuracy of clinical decision rules, individual clinical characteristics, skull radiography and biomarkers and the clinical effectiveness of diagnostic management strategies for minor head injury.

Searching
MEDLINE, EMBASE, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, Cochrane Database of Systematic Reviews, DARE, the HTA database, ReFeR, NIHR, INAHTA and Trip databases were searched to April 2009; the MEDLINE search was updated in March 2010. Full search strategies were reported and included a diagnostic filter. Reference lists of relevant studies were screened and citations searches of relevant studies were carried out. Internet searches were carried out using the Copernic Agent meta-search engine. Experts in the area were contacted for additional studies. There were no language restrictions for the search, but the review was restricted to studies in English.

Study selection
Diagnostic cohort studies that evaluated any test for the diagnosis of intracranial injury were eligible for inclusion. Intracranial injury was defined as any intracranial abnormality detected on computed tomography (CT) or magnetic resonance imaging (MRI) due to trauma. Studies needed to include at least 20 adults or children with minor head injury. The target conditions were the need for neurosurgical intervention and any intracranial injury. Reference standards used to define target conditions were CT scan, CT with follow-up for those with no CT scan and MRI scan. Studies had to report sufficient data to construct a 2x2 table of test performance. Studies that did not report sufficient methodological details to allow critical appraisal of study quality were excluded. Randomised controlled trials (RCTs), controlled trials and controlled before/after studies that assessed any diagnostic management or organisational change strategy for minor head injury in at least 20 adults and children with minor head injury were also eligible for inclusion. Primary outcomes of interest for these studies were hospital admissions, length of stay, time to neurosurgery and patient outcomes.

Included studies assessed a variety of different clinical prediction rules, individual clinical characteristics, radiographic findings and biomarkers. Studies were conducted in North America, the Middle East, Europe, Asia and Australasia. Median prevalence of neurosurgical injury ranged from 0.95% to 1.7%. Median prevalence of intracranial injury ranged from 6.5% to 9.4%. Ages ranged from infants to more than 70 years. Some studies enrolled only patients who had received a CT scan and some enrolled patients on the basis of clinical characteristics (such as amnesia or loss of consciousness at presentation). Studies included patients with Glasgow Coma Scale scores of 13 to 15, included patients with all Glasgow Coma Scale scores or did not provide information on Glasgow Coma Scale scores. Studies enrolled patients within 24 to 48 hours of injury. Where patients had no CT scan, follow-up was by telephone and/or review of hospital records. Some studies defined intracranial injury in terms of perception of clinical significance; others identified any common acute lesion. Definitions of surgical lesions varied; most included haematoma evacuation, elevation of depressed skull fracture and intracranial pressure monitoring.

Two reviewers independently screened the searches and assessed studies for inclusion. Disagreements were resolved through discussion.

Assessment of study quality
One reviewer assessed study quality using a modified version of the QUADAS tool. A second reviewer checked the
assessments. Disagreements were resolved through referral to a third reviewer. The items on disease progression bias and incorporate bias were omitted as all studies were considered to fulfil these items. Randomised controlled trials were assessed for methodological quality using Cochrane Effective Practice and Organisation of Care (EPOC) criteria.

**Data extraction**

One reviewer extracted data to populate 2x2 tables of test performance. These data were used to estimate sensitivity, specificity and positive and negative likelihood ratios (LR+ and LR-) together with 95% confidence intervals (CIs). The data extraction was checked by a second reviewer. Disagreements were resolved through referral to a third reviewer. Where studies reported multiple index tests, including different versions of a clinical decision rule, data were extracted for all tests. Data were analysed separately for adults and children.

**Methods of synthesis**

Where sufficient studies evaluated a single test or clinical prediction rule a meta-analysis was used to combined studies. Otherwise a narrative synthesis was presented and results illustrated with forest plots. For tests evaluated by at least three studies, summary estimates of sensitivity and specificity were estimated using the bivariate random-effects model. Where tests were evaluated in only two studies, the authors stated that a fixed-effect meta-analysis was conducted (but the stated method was a random-effects model). Summary LR+ and LR- were calculated (methods used were not reported). Heterogeneity was assessed using the Q statistic.

**Results of the review**

Ninety-four studies were included in the review: 93 diagnostic accuracy studies and one RCT. Study quality was variable. Patient spectrum was fulfilled by only two of the clinical decision rules studies and one of the individual characteristics studies. Less than 50% of studies fulfilled QUADAS items on reporting of uninterpretable results, avoidance of clinical review bias, blinding of index test and reference standard, avoidance of differential and partial verification bias and use of an appropriate reference standard. Biomarker studies were generally of better quality, but none fulfilled the patient spectrum, uninterpretable results or withdrawals criteria; other criteria were fulfilled by at least 70% of studies. The RCT was considered to have a moderate risk of bias.

**Clinical decision rules (adults):** Nineteen studies evaluated 25 decision rules. Eleven rules were evaluated in more than one data set and a further rule was evaluated within two cohorts in the same data set. Nine rules had two forms: one to identify patients at medium risk and one to identify patients at high risk.

The Canadian CT Head Rule (CCHR) was validated in six studies. Using the high risk threshold it had a sensitivity of 99% to 100% and a specificity of 48% to 77% for neurosurgical injury; the high risk threshold was not evaluated for the detection of intracranial injury. Using the high or medium risk threshold sensitivity ranged from 99% to 100% for neurosurgical injury and from 80% to 100% for intracranial injury. Corresponding specificities ranged from 37% to 48% and 39% to 50%. Sensitivity for intracranial injury was lower in studies in which all patients had CT compared to those in which some patients received follow-up (80% to 86% compared to 98% to 100%).

The New Orleans Criteria (NOC) rule was validated in four studies. It had a sensitivity of 99% to 100% for neurosurgical lesion and 95% to 100% for intracranial lesions, but specificity was poor at 3% to 33% so that in most cohorts all patients would have undergone a CT scan.

National Institute for Health and Clinical Excellence (NICE) guidelines were based on CCHR and had a sensitivity of 88% to 98% for neurosurgical injury and 67% to 99% for any injury and specificity that ranged from 29% to 70% (three studies).

Other clinical prediction rules were evaluated in two studies or fewer; full results were reported.

**Clinical decision rules (children):** Fourteen studies evaluated 15 decision rules. Most rules were evaluated in two studies or fewer. The University of California-Davis (UCD) rule was evaluated in three studies. Sensitivity ranged from 91% to 100%. Specificity ranged from 12% to 43%.

**Individual clinical characteristics:** There were 42 studies in adults and 29 studies in children. No individual clinical or radiological characteristics were found to have sufficient accuracy to be able to rule in or rule out intracranial injury.
Depressed, basal or radiological skull fracture, post-traumatic seizure (adults only) and focal neurological deficit (children only) increased the likelihood of intracranial injury (LR+>10), but skull radiology has been largely replaced by CT scanning. Focal neurological deficit (adults only), persistent vomiting (adults only), decrease in Glasgow Coma Scale (adults only), coagulopathy (children only), post-traumatic seizure (children only), and previous neurosurgery were associated with an increased risk of intracranial injury (LR+ range 5 to 10).

Fall from a height (adults only), coagulopathy (adults only), chronic alcohol use (adults only), age more than 60 years, pedestrian motor vehicle accident, cycle motor vehicle accident (children only), any seizure, undefined vomiting, retrograde or anterograde amnesia, Glasgow Coma Scale less than 14 or 15 and severe or persistent headache (children only) were associated with a moderate increase in the risk of intracranial injury (LR+ 2 to 5). Loss of consciousness (adults only) and headache were of little value in diagnosing intracranial injury. Diagnosis of neurosurgical injury was assessed in only a small number of studies.

Biomarkers: There were 11 studies in adults and one study in children.

The protein S100 calcium binding protein-B biomarker was found to have excellent sensitivity with a pooled estimate of 97% (95% CI 94% to 99%) but specificity was less good (43%, 95% CI 31% to 54%) based on nine studies in adults. Estimates from the single study in children were similar with a sensitivity of 100% (95% CI 92% to 100%) and specificity of 42% (95% CI 38% to 43%).

Two studies assessed neuron-specific enolase (NSE) and suggested that it was a poor marker for predicting intracranial injury. A single study assessed various other biomarkers: adrenaline and dopamine were suggested as having good accuracy for ruling out head injury but the findings had not been validated.

Diagnostic management strategies: There was one RCT (2,062 participants). This study randomised patients aged at least six years with minor head injury to immediate CT or observation in hospital. At three months there was no significant difference between the treatment groups in terms of the proportion of patients who had recovered completely; mortality and severe loss of function were also similar between the groups. The authors concluded that use of CT in patients with minor head injury was feasible and led to similar outcomes compared to observation in hospital.

Cost information
The report included a full economic cost-effectiveness analysis that showed CT use dominated "CT all" or "discharge all" strategies. The optimal strategies were the CCHR for adults and CHALICE (Children's Head injury Algorithm for the prediction of Important Clinical Events) or NEXUS II (National Emergency X-Radiography Utilization Study II) rule (children). Hospital admission dominated discharge home for patients with non-neurosurgical injury, but cost £39 million per QALY (quality-adjusted life-year) for clinically normal patients with a normal CT.

Authors' conclusions
The CCHR was the most well validated rule in adults. When medium-risk and high-risk criteria were used it had high sensitivity and acceptable specificity.

CRD commentary
The review addressed several clear objectives. Inclusion criteria were appropriately defined. The literature search was extensive and included attempts to locate unpublished studies. The restriction to studies in English raised the possibility of language bias. Appropriate steps were taken to minimise bias and reviewer errors at all stages of the review process. Study quality was assessed using appropriate criteria and the results were reported clearly. Appropriate methods were used to pool data and assess heterogeneity.

The authors' conclusions are supported by the results of the review, but should be interpreted with some caution due to the methodological limitations of the included studies.

Implications of the review for practice and research
Practice: The authors stated that the CCHR and the related NICE guidelines were the most powerful predictors of intracranial injury. Use of headache as an additional criterion for CT scanning was not supported by the evidence.

Research: The authors stated that the five main research priorities were to validate decision rules for children,
determine the prognosis and treatment benefit for non-neurosurgical injuries, evaluate use of S100B alongside a valided decision rule, evaluate the diagnosis and outcomes of anti-coagulated patients with minor head injury and evaluate the implementation of guidelines, clinical decision rules and diagnostic strategies. Formal expected value of sample information analysis would be recommended to appraise the cost-effectiveness of future studies.

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