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

A Pandor, S Goodacre,* S Harnan, M Holmes, A Pickering, P Fitzgerald, A Rees and M Stevenson

School of Health and Related Research (ScHARR), University of Sheffield, Sheffield, UK

*Corresponding author

Executive summary

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Executive summary

Background

Head injury accounts for around 700,000 emergency department (ED) attendances each year in England and Wales; 90% of such head injuries are minor [Glasgow Coma Scale (GCS) score 13–15]. These patients have a small but important risk of serious intracranial injury (ICI) that requires early identification and neurosurgical treatment. Diagnostic assessment can either use a clinical decision rule or unstructured assessment of individual clinical features to identify those who are at risk of ICI and require computerised tomography (CT) scanning and/or hospital admission. Management involves a potential trade-off between underinvestigation, which risks missed opportunities to provide early effective treatment for ICI, and overinvestigation, which risks unnecessary radiation exposure and waste of NHS resources.

Objectives

The overall aim was to use secondary research methods to determine the most appropriate diagnostic management strategy for adults and children with minor (GCS 13–15) head injury in the NHS. More specifically, the objectives were to (1) undertake systematic reviews to determine the diagnostic accuracy of clinical decision rules and individual clinical characteristics for predicting ICI (including the need for neurosurgery) and evaluate the comparative effectiveness of different diagnostic management strategies for minor head injury (MHI); (2) undertake a cross-sectional survey and use routinely available data to describe current practice in the NHS; and (3) develop an economic model to estimate the cost-effectiveness of diagnostic strategies for MHI, identify the optimal strategy for managing MHI in the NHS, and identify the critical areas of uncertainty in the management of MHI.

Methods

Several electronic databases [including MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), EMBASE and the Cochrane Library] were searched from inception to April 2009 (updated searches to March 2010 were conducted on the MEDLINE databases only). Searches were supplemented by hand-searching relevant articles (including citation searching) and contacting experts in the field. For each of the systematic reviews the following studies were included: (1) cohort studies of patients with MHI in which a clinical decision rule or individual clinical characteristics (including biomarkers and skull radiography) were compared with a reference standard test for ICI or need for neurosurgical intervention and (2) controlled trials comparing alternative management strategies for MHI. Study quality was assessed using the Quality Assessment of Diagnostic Accuracy Studies tool (for the assessment of diagnostic accuracy) or criteria recommended by the Effective Practice and Organisation of Care Review Group (for the assessment of management practices). Where sufficient data existed in accuracy studies, we used meta-analysis to generate pooled estimates of sensitivity, specificity and likelihood ratios.

For the economic analysis we developed a decision-analysis model using Simul8 Professional software (Simul8 Corporation, Boston, MA, USA) to estimate the costs and quality-adjusted life-years (QALYs) accrued by each potential management strategy for MHI, including a

theoretical 'zero option' strategy of discharging all patients home without investigation. The model took a lifetime horizon and the perspective of the NHS. The benefits of early detection of ICI were modelled using literature reviews to estimate the proportion of patients with each Glasgow Outcome Score (GOS) after each strategy and then estimate subsequent QALYs accrued. Hospital costs were estimated for each strategy and each GOS category. Each CT scan performed attracted an additional cost and QALY loss due to radiation-induced malignancy. The analysis was conducted for patients aged 1, 10, 40 and 75 years. Initial analysis was deterministic, but probabilistic sensitivity analysis (PSA) was also performed. Secondary analyses were undertaken to explore the trade-off between sensitivity and specificity in diagnostic strategies, to determine the cost-effectiveness of hospital admission compared with discharge home for (1) patients with non-neurosurgical injuries on CT scan and (2) patients with a normal CT scan, and to explore the cost-effectiveness of strategies for adults when no responsible adult was available to observe the patient after discharge.

To describe current NHS practice we mailed a questionnaire survey to the lead clinician of all major acute hospital EDs in the UK and analysed routine ED data from Hospital Episode Statistics (HES). Where possible, we correlated survey responses with HES to determine whether service provision was associated with difference in the proportion of patients admitted.

Results

The literature searches identified 8003 citations. Of these, 93 full-text papers were included for the assessment of diagnostic accuracy and one for the assessment of management practices. The quality of studies and reporting was generally poor.

The Canadian CT Head Rule (CCHR) was the most widely validated adult rule, with a sensitivity of 99–100% and a specificity of 48–77% for neurosurgical injury using the high-risk criteria, and sensitivity of 99–100% and 80–100% for neurosurgical and any ICI, respectively, using the high- or medium-risk criteria, with corresponding specificities of 37–48% and 39–51%. Rules for children were less well validated. Several had high sensitivity and acceptable specificity in derivation cohorts, but the limited validation data suggested that specificity was poor.

In adults, the presence of depressed, basal or radiological skull fracture and post-traumatic seizure (PTS) each substantially increased the likelihood of ICI [point estimate for positive likelihood ratio (PLR) > 10]. Focal neurological deficit, persistent vomiting, decrease in GCS and previous neurosurgery markedly increased the likelihood (PLR 5–10). Fall from a height, coagulopathy, chronic alcohol use, age over 60 years, pedestrian motor vehicle accident (MVA), any seizure, undefined vomiting, amnesia, GCS < 14 and GCS < 15 moderately increased the likelihood (PLR 2–5). Loss of consciousness (LOC) or headache had little diagnostic value.

In children, the presence of depressed or basal skull fracture and focal neurological deficit substantially increased the likelihood of ICI (PLR > 10). Coagulopathy, PTS and previous neurosurgery markedly increased the likelihood (PLR 5–10). Visual symptoms, bicycle and pedestrian MVA, any seizure, LOC, vomiting, severe or persistent headache, amnesia, GCS < 14, GCS < 15, intoxication and radiological skull fracture all moderately increased the likelihood (PLR 2–5). Headache, scalp haematoma and scalp laceration had little diagnostic value.

The S100 calcium-binding protein B (S100B) was the only widely evaluated biomarker and had a pooled sensitivity of 96.8% [95% highest-density region (HDR) 93.8% to 98.6%] and specificity of 42.5% (95% HDR 31.0% to 54.2%).

The only controlled trial showed that early CT and discharge of patients with MHI is at least as effective as hospital admission (21.4% vs 24.2% not fully recovered at 3 months) and costs less (mean cost £314 vs £462 per patient). An additional two contemporaneous cohort studies and nine uncontrolled before/after studies evaluated the effect of changes in management and implementation of guidelines, but methodological weaknesses and lack of generalisability limited the conclusions that could be drawn.

The deterministic economic analysis showed that for all ages a strategy of selective CT use based on a clinical decision rule dominated both the 'CT all' and 'discharge all without investigation' strategies (i.e. accrued more QALYs at lower cost). Selective CT use was cheaper than discharging without investigation because of the substantial costs of care for patients with worse outcomes due to delayed treatment. It was more effective than CT for all because of the QALY loss through radiation-induced malignancy associated with additional CT scanning, although this was only true for highly sensitive strategies. The optimal strategies were the CCHR (medium- and high-risk criteria) for adults and the Children's Head Injury Algorithm for the Prediction of Important Clinical Events (CHALICE) rule for children, with other strategies being dominated or subject to extended dominance. PSA showed that these two strategies dominated all other strategies. However, deterministic scenario analyses showed that the CHALICE rule was dominated by other rules if validation cohort data were used instead of derivation cohort data, whereas the National X-Radiography Utilization Study II (NEXUS II) rule was the optimal rule for adults if different prevalence estimates were used for intracranial injuries.

Secondary deterministic analyses showed that the estimated sensitivity and specificity of the CCHR (99% and 47%, respectively) appeared to represent an appropriate trade-off of these two parameters. A rule with 100% sensitivity would only dominate the CCHR if specificity were ≥ 38%, whereas a rule with 70% specificity would dominate the CCHR only if sensitivity were ≥ 94%.

Other analyses showed that hospital admission for patients with non-neurosurgical injury on CT dominated discharge home, although hospital admission for clinically normal patients with a normal CT had an incremental cost-effectiveness ratio of £39M per QALY compared with discharge home with a responsible adult or £2.5M compared with discharge without a responsible adult. A selective CT strategy remained optimal for adults when there was no responsible adult available to observe the patient after discharge home.

The survey of NHS EDs showed that nearly all had unrestricted access to CT scanning (adults 96%, children 94.5%). Adults were usually admitted to an observation ward or clinical decision unit (61.4%), whereas children were usually admitted to an inpatient ward (86.7%). The median proportion of attendances admitted was higher for adults (18%) than for children (9%). There was no evidence of an association between the proportion admitted and the admission team, location or requirement for senior or specialist approval (all $p > 0.1$).

Conclusions

The CCHR is the most well-validated rule in adults and, when medium- and high-risk criteria are used, has high sensitivity and acceptable specificity. The CCHR and related National Institute for Health and Clinical Excellence guideline are based upon the clinical characteristics that our meta-analysis suggests are the most powerful predictors of ICI. The use of headache as an additional criterion for CT scanning (as used in some hospitals) was not supported by our meta-analysis.

The CCHR appears to be the most cost-effective strategy for managing MHI in adults. Improving upon the CCHR would require improved accuracy rather than a different trade-off between sensitivity and specificity as the current balance appears appropriate in terms of cost-effectiveness. The S100B biomarker might improve specificity and thus cost-effectiveness, but further research is required to determine how S100B performs alongside clinical decision rules.

Decision rules for children have not been widely validated so conclusions are less clear. Three rules have been validated in a different setting from the derivation cohort and one in the same setting. Specificity appears to be worse in validation cohorts. The CHALICE and NEXUS II rules appeared to be based on characteristics that our meta-analysis suggested were the most powerful predictors of ICI. All decision rule strategies were more cost-effective than 'CT all' or 'discharge all'. The CHALICE rule was the most cost-effective strategy when derivation data were used, but the NEXUS II rule was optimal where validation data were used.

Hospital admission for patients with non-neurosurgical injury on CT is cheaper and achieves better outcomes than discharge home, although data are currently lacking to clearly define which patients are most likely to benefit from hospital admission. Hospital admission of patients who are clinically well with a normal CT scan is not cost-effective.

The main research priorities are to (1) validate decision rules for children; (2) determine the prognosis and treatment benefit for non-neurosurgical injuries; (3) evaluate the use of S100B alongside a validated decision rule; (4) evaluate the diagnosis and outcomes of anticoagulated patients with MHI; and (5) 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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Publication

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NIHR Health Technology Assessment programme

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The research reported in this issue of the journal was commissioned by the HTA programme as project number 07/37/08. The contractual start date was in February 2009. The draft report began editorial review in June 2010 and was accepted for publication in October 2010. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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