Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Six strategies for the management of patients with mild traumatic brain injury (TBI) were studied.

Strategy 1: cranial computed tomography (CT) scan for selected patient (Selective CT) and emergency department (ED) discharge for others. This strategy was based on the Canadian head rule in which CT scan was ordered for all patients with a Glasgow Coma Scale (GCS) score of 14 and only for those patients with a GCS score of 15 with at least one of the high-risk factors (suspected open, basilar or depressed skull fracture, multiple episodes of vomiting, age > 65 years).

Strategy 2: CT scan for all patients with mild TBI and ED discharge if normal (CT All).

Strategy 3: skull radiography for all patients with mild TBI, with discharge if no fracture (SXR Screen).

Strategy 4: prolonged (6 hours) ED observation and discharge if stable (Long ED).

Strategy 5: a 24-hour hospital admission of all patients with mild TBI for observation (Admit All).

Strategy 6: No treatment. Patients are discharged from the ED without further screening, and patients return if their missed lesions become sufficiently symptomatic.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis and cost-utility analysis.

Study population
The study population comprised a hypothetical cohort of patients presenting to the ED with an apparently minor closed head injury, which was defined as an admission GCS score of 14, or a score of 15 plus loss of consciousness (or amnesia of the event). The base-case analysis considered a 20-year-old patient.

Setting
The setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness data were derived from studies published between 1986 and 2005. No dates for the resource use data were explicitly reported. The price year was 2005.

Source of effectiveness data
The effectiveness evidence was derived from a synthesis of published studies.

Modelling
A decision tree model was constructed to assess the long-term costs and benefits of the alternative strategies in a hypothetical 20-year-old patient presenting to the ED with an apparently minor TBI, who might or might not have intracranial lesions. Depending on the accuracy of the diagnostic strategy, patients would undergo appropriate or unnecessary admission/discharge or further work-up. Intracranial lesions consisted of either intracranial haematomas, subarachnoid haemorrhage, cerebral oedema, or contusions (isolated skull fractures were excluded). Patients with lesions requiring surgery could be correctly diagnosed and receive prompt surgery (true positive for surgical lesions), or incorrectly diagnosed (false negative for surgical lesions) and receive delayed surgery. Outcomes of surgery were defined by five categories on the Glasgow Outcome Scale (GOS). GOS 1 corresponded to death, GOS 2 to vegetative state, GOS 3 to severe disability, GOS 4 to moderate disability, and GOS 5 to good outcome. Thus, the difference in outcomes between the six strategies under analysis would depend on the probability of correctly detecting a lesion and of correctly determining whether or not it required surgery. A graphical representation of the model was reported.

Outcomes assessed in the review
The outcomes estimated in the review were:

- the incidence of intracranial lesions among patients with mild TBI,
- the proportion of intracranial lesions that require surgery,
- the accuracy of the alternative strategies in determining the intracranial lesions and their need for surgery,
- life expectancy, and
- the utility weights associated with health conditions.

Study designs and other criteria for inclusion in the review
A review of the literature was undertaken to identify the primary studies. The review excluded case reports, non-English language publications, reviews without original data, and articles dealing with moderate or severe head injury and penetrating injuries. Also excluded were re-publications of previously reported data, letters, and animal studies. None of the studies included was a randomised, clinical trial. Most of the studies were retrospective and represented Level III evidence. Mortality data were obtained from US vital statistics.

Sources searched to identify primary studies
MEDLINE was searched from 1980 to December 2004 for relevant studies using the keyword "head injuries". The search was expanded to include the terms "mild", "minimal" and "minor".

Criteria used to ensure the validity of primary studies
Owing to the lack of clinical trials available in the literature, the authors were obliged to use a source of evidence with low internal validity.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
Fifty-one primary studies provided the clinical evidence.
Methods of combining primary studies
Estimates derived from the primary studies were pooled by calculating variance-weighed averages.

Investigation of differences between primary studies
Sources of evidence were tested to exclude heterogeneity.

Results of the review
The rate of intracranial lesion among patients with mild TBI was 0.132 (95% confidence interval, CI: 0.112 to 0.152).

The rate of intracranial lesion that will be surgical was 0.113 (95% CI: 0.084 to 0.142).

The rate of prolonged symptoms with nonsurgical lesion was 0.43 (95% CI: 0.33 to 0.52).

The rates of a false positive and a false negative for surgical lesion, and a false negative for nonsurgical lesion were as follows:
for Selective CT, 0.504 for a false positive and 0.017 for a false negative for surgical lesion, and 0.02 for a false negative for nonsurgical lesion;
for CT All, 0 for a false positive and 0.017 for a false negative for surgical lesion, and 0 for a false negative for nonsurgical lesion;
for SXR Screen, 0.05 for a false positive and 0.40 for a false negative for surgical lesion, and 0.61 for a false negative for nonsurgical lesion;
for Long ED, 0.25 for a false positive and 0.371 for a false negative for surgical lesion, and 0.25 for a false negative for nonsurgical lesion;
for Admit All, 0.879 for a false positive and 1 for a false negative for surgical lesion, and 0 (by definition) for a false negative for nonsurgical lesion; and
for no treatment, 0 for a false positive and 1 for a false negative for surgical lesion, and 1 (all by definition) for a false negative for nonsurgical lesion.

Outcomes following prompt or delayed surgery (GOS results) were also reported. For example, the probability of GOS 5 was 0.998 for prompt surgery and 0.67 for delayed surgery, while the probability of GOS 1 (death) was 0.0086 for prompt surgery and 0.1419 for delayed surgery.

The utility values were:
1.00 for GOS 1,
0.63 for GOS 2,
0.26 for GOS 3,
0.08 for GOS 4, and
0 for GOS 5.

Measure of benefits used in the economic analysis
The summary benefit measures used were the life-years (LYs) and quality-adjusted life-years (QALYs). These were estimated using the decision modelling approach. The QALYs were obtained by combining utility values and expected
survival derived from the literature. No details of the sources used to obtain utility weights were given. The benefits were discounted at an annual rate of 3%.

**Direct costs**
The cost analysis included only the direct medical costs associated with initial ED visit and screen, false-positive screen (CT plus admission), lesions, rehabilitation for GOS score of 4, and custodial care for more severely damaged patients. Thus, the perspective of the analysis appears to have been that of the payer. The unit costs were not presented separately from the quantities of resources used, the costs being reported as macro-categories. The estimation of costs and resource use was based on Medicare and Medicaid reimbursements. Discounting was relevant, owing to the long time horizon of the model, and an annual rate of 3% was used. The price year was 2005.

**Statistical analysis of costs**
Normal distributions were assigned to the costs in order to calculate CIs around the total costs.

**Indirect Costs**
The indirect costs were not included.

**Currency**
US dollars ($).

**Sensitivity analysis**
To assess the robustness of the results of the analysis to variations in the model inputs, a univariate sensitivity analysis was carried out for each model input using published CIs. The analysis was also replicated in hypothetical patients of older ages (40, 60 and 80 years). A Monte Carlo simulation was run to generate CIs around the estimates of costs and benefits. Probabilities were assigned beta distributions, while costs were considered as normally distributed.

**Estimated benefits used in the economic analysis**
In a hypothetical 20-year-old patient, the expected mean LYs were 58.6048 with Selective CT, 58.6048 with CT All, 58.4834 with SXT Screen, 58.4794 with Long ED, 58.4057 with no treatment, and 58.4057 with Admit All.

In a hypothetical 20-year-old patient, the expected mean QALYs were 28.854 with Selective CT, 28.854 with CT All, 28.7942 with SXT Screen, 28.7923 with Long ED, 28.756 with no treatment, and 28.756 with Admit All.

The advantage of CT strategies arose mainly from averting delayed surgeries.

**Cost results**
In a hypothetical 20-year-old patient, the expected costs were $1,668.49 with Selective CT, $1,888.09 with CT All, $2,201.00 with SXT Screen, $2,861.60 with Long ED, $3,143.95 with no treatment, and $4,923.96 with Admit All.

The relatively high cost of a CT scan was more than outweighed by a reduction in treatment costs.

**Synthesis of costs and benefits**
Incremental cost-effectiveness and cost-utility ratios were not calculated as the Selective CT strategy was both more effective and less expensive than any other alternative strategy, and was therefore the dominant strategy.

The probabilistic analysis showed that the QALYs associated with the Selective CT strategy and the CT All strategy were significantly higher than the QALYs related to the remaining strategies (the CIs did not overlap), while there was
no statistically significant difference in the costs.

The analysis suggested that, for values of willingness-to-pay between $50,000 and $100,000 per QALY, the probability of the Selective CT strategy being cost-effective ranged from 68 to 90%.

The deterministic sensitivity analysis showed that the base-case results were quite stable to variations in both the clinical and economic inputs. Both QALYs and expected costs were quite sensitive to the probability that prompt surgery for haematomas resulted in good outcomes. However, the Selective CT strategy remained the preferred option in all scenarios, even when older patients were considered (although differences among strategies were smaller with increasing age).

**Authors' conclusions**

Both the Selective CT strategy and the CT All strategy were clinically superior to the other options for the management of patients with mild traumatic brain injury (TBI). The two strategies were no more costly than other approaches, thus the liberal use of computed tomography (CT) scanning in mild TBI appears to be justifiable on cost-effectiveness grounds.

**CRD COMMENTARY - Selection of comparators**

The authors provided a clear justification for their choice of the comparators, which were appropriately selected and described in detail. The no-treatment option was included only for comparative purposes as it is not recommended by any authorities. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**

The effectiveness evidence came from a synthesis of published studies. The authors reported information on the methods and conduct of a systematic review of the literature. Details of the type of studies included and the number of patients were given. Unfortunately, the quality of evidence was low given the lack of published clinical trials and that most of the studies were retrospective. The primary estimates were combined using variance-weighted averages, and the issue of heterogeneity amongst the primary studies was addressed by standard tests. The uncertainty surrounding the clinical estimates was extensively investigated in the sensitivity analysis.

**Validity of estimate of measure of benefit**

QALYs and LYs were the most appropriate benefit measures because they capture the impact of the intervention on two important dimensions of health (quality of life and survival). Both measures can be compared with the benefits of other health care interventions. Discounting was applied, as recommended in published guidelines. Limited information on the utility adjustments used to calculate the QALYs was provided, but the impact of changing utility values was tested in the sensitivity analysis.

**Validity of estimate of costs**

The analysis of the costs appears to have been carried out from the perspective of the third-party payer in that the costs were derived from Medicare and Medicare payers in the USA. However, the authors noted that these reimbursement rates might not reflect the true health care costs. It was also pointed out that the inclusion of indirect costs and other categories of costs not captured in the analysis (hidden costs of head injuries) would further strengthen the results of the base-case analysis. Information on the unit costs and quantities of resources used was limited and a breakdown of the cost items was not presented. This could limit the possibility of replicating the analysis in other settings. The sources of the data were explicitly reported. Statistical analyses of the costs were performed in the sensitivity analysis, and cost estimates were also varied in the sensitivity analysis. The price year was reported, which will facilitate reflation exercises in other time periods.

**Other issues**
The authors did not compare their findings with those from other studies. The issue of the generalisability of the study results to other settings was implicitly addressed by the use of extensive sensitivity analyses. However, the authors stated that the relative cost of the different strategies is likely to vary between settings and that it could be difficult to transfer their findings to other contexts. The study referred to patients with mild TBI presenting to the ED, and this was reflected in the authors’ conclusions. The results of the base-case analysis were presented clearly, whereas those of the sensitivity analysis were presented selectively.

Implications of the study
The study results support the use of CT scanning in the management of patients with mild TBI. However, the authors highlighted that the availability of ready access to CT scan and the relative cost of the procedure might affect the conclusions of the analysis.

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MeSH
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