Management of brain-injured patients by an evidence-based medicine protocol improves outcomes and decreases hospital charges

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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
The study compared three cohorts of patients with traumatic brain injury (TBI):

the earliest group received care based on individual practitioner preference;

the next group received protocol-driven care with low compliance; and

the most recent group received high compliance protocol-driven care.

The protocol was based on the Brain Trauma Foundation (BTF) guidelines published in 1995 in collaboration with the American Association of Neurological Surgeons. These guidelines were designed for in-hospital care and were based on the best available scientific, evidence-based methodology. Two extensive educational processes were conducted to develop compliance among all disciplines for this new strategy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients managed by the Trauma Service between 1991 and 2000. Inclusion criteria for the protocol were blunt head injury, age older than 14 years, and a Glasgow Coma Scale (GCS) score of 8 or less. Patients were excluded if they did not have at least one head Abbreviated Injury Scale (AIS) score injury greater than 2. Any patient who had an AIS 6 injury, or who died in less than 48 hours after injury, was also excluded on the basis that they were so severely injured that a protocol (or lack thereof) would not have changed the outcome of the injury.

Setting
The setting was tertiary care (large Level I trauma centre). The economic study was carried out in Virginia, USA.

Dates to which data relate
The effectiveness evidence and resource use data related to 1991 to 2000. The price year was 1997.

Source of effectiveness data
The effectiveness data were derived from a single study.
Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used in the effectiveness study.

Study sample
Of 7,003 blunt TBI patients managed by the Trauma Service between 1991 and 2000, 830 (11.8%) met the inclusion criteria and were included in the study. The patients were analysed as three separate groups. The three cohorts were patients seen before the protocol (1991-94, n=219), patients seen during low compliance (1995-96, n=188), and patients seen during high compliance (1997-2000, n=423). Power calculations were not reported. The mean age of the sample was 34.7 years (range: 15 - 94), and males constituted 74.8% of the patients (n=621). The majority of patients screened (54.1%) were positive for alcohol (EtOH) use and 44.2% were legally intoxicated (EtOH > 80 mL/dL).

Study design
This was a single-centred, retrospective comparative study with a historical control. The patients were compared by year cohort, instead of comparing patients with and without TBI orders, as protocol patients tended to be more severely injured than non-protocol patients. Also, it was not possible to control for contamination of the intervention. No loss to follow-up was reported. It would appear that the patients were followed up until hospital discharge.

Analysis of effectiveness
The basis of the analysis was intention to treat. The primary health outcomes used were disability, mortality, and length of stay. There were no significant differences between the study groups in any of the demographic and clinical variables, except mean EtOH level and initial GCS score. All three groups differed significantly from each other in mean EtOH level (1991-94, EtOH = 119; 1995-96; EtOH = 176, 1997-2000, EtOH = 77; p <0.001). Patients in the 1991-94 cohort had a slightly higher initial GCS score than did patients in the other two groups (4.0 versus 3.5; p<0.001).

Effectiveness results
The overall mortality rate remained almost constant from 1991 to 1996 (17.8% versus 18.6%; p>0.10; mean 18.2%). However, in 1997-2000, there was a 4.5% reduction in the mortality rate to 13.7%. This was a statistically significant reduction compared with 1991-96, (p=0.047). There were also trend changes in the types of patients who died.

In the 1991-94 cohort, there was mortality for all levels of head injury whereas in the 1995-96 and 1997-2000 cohorts, the only deaths for isolated head injuries were among patients with AIS 5 injury. The 1997-2000 cohort exhibited lower mortality than the 1991-94 and 1995-96 groups at the AIS 5 level, 34.8% versus 42.7% (1991-94) and 36.6% (1995-96), respectively, although the trend was not statistically significant.

Disability outcomes were measured at hospital discharge using the Glasgow Outcome Scale score and Rancho Los Amigos Score. In the 1997-2000 cohort, 61.5% of the patients had either a good recovery or only a moderate disability on the Glasgow Outcome Scale. This was a significant improvement when compared with the 1995-96 cohort at 50.3% and the 1991-94 cohort at 43.3%, (p<0.001). The Rancho Los Amigos Score showed a similar trend, with 56.6% of the 1997-2000 patients having appropriate responses at discharge, compared with 44.0% of the 1995-96 patients and 43.9% of the 1991-94 patients, (p=0.004).

The mean length of stay in the intensive care unit (ICU) was 8.5 days (median stay 6 days; range: 1 - 62). From 1991-94 to 1997-2000, ICU days were reduced by 1.9 days (9.8 versus 7.9; p=0.021). The mean, total number of hospital days was 17.5 (median stay 12 days; range: 1 - 164. From 1991-94 to 1997-2000, the total hospital days were reduced by 5.4 days (21.2 versus 15.8; p=0.005).

Clinical conclusions
The implementation of the protocol for TBI care resulted in significant improvements in mortality, length of stay and disability outcomes. The most prominent improvement in outcomes was a significant decrease in mortality from...
approximately 18% to 13.7%. Because the severity of injury at presentation was unchanged during the course of the study, the authors assumed that the reduction in hospital mortality was the result of amelioration of secondary injury effects by more prompt and appropriate therapy, as guided by the implementation of the protocol.

Measure of benefits used in the economic analysis
No summary measure of benefit was used in the economic evaluation. The authors carried out a cost-consequences analysis.

Direct costs
Charges to the patients were used. These included hospital room, critical care, nursing services, direct expenses, indirect fees and general hospital charges. The study did not include physician billings, diagnostic services medications, or other professional fees. Discounting was not undertaken, which was appropriate as the time horizon was less than two years. The quantities and the costs were not analysed separately. The quantities and the costs were estimated from actual data and the source was hospital charges. The price year was 1997.

Statistical analysis of costs
The costs were treated stochastically and compared through an analysis of variance for group-wise comparisons.

Indirect Costs
The indirect costs were not reported.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The mean total charges overall were $30,995 per patient.

For 1991-94, the mean charges per patient were $36,694.

The charges fell in 1995-96 to $30,117 and again in 1997-2000 to $28,428 per patient.

The mean reduction per patient was $6,577 from 1991-94 to 1995-1996 and $8,266 from 1991-94 to 1997-2000, (p=0.002).

The total charge reduction over 6 years was $4.7 million.

Synthesis of costs and benefits
The costs and benefits were not combined as the study was, in effect, a cost-consequences analysis.
Authors' conclusions
The gradual adoption of the protocol was accompanied by an incremental improvement in mortality, whereas lengths of stay in the intensive care unit (ICU) and hospital decreased. There was a significant decrease in charges which was consistent with the hypothesis that the elimination of variance in care using evidence-based guidelines results in more efficient use of resources and lower costs and charges.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used. It reflected standard practice in the authors’ setting before the implementation of protocol-driven care. You should judge whether this is relevant in your setting, or whether other comparators from other therapeutic options could also have been relevant.

Validity of estimate of measure of effectiveness
The estimate of effectiveness was based on a retrospective analysis, which may be prone to bias and might limit the validity of the comparison between groups. The authors acknowledged that an important limitation of the study was the use of a historical control, which may increase the risk of bias, random variation and other uncontrolled variables affecting the results of the study. Also, there may be concerns about sample size and power calculations, which were not reported and should be taken into account when considering the results. Blinding of the outcome assessment, which could reduce potential bias, was not reported.

Validity of estimate of measure of benefit
No summary measure of benefit was derived. The reader is therefore referred to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The cost analysis seems to have been performed from a hospital perspective. Charges were used as a proxy. However, charges do not reflect true opportunity costs (due to profit margin) and (in the absence of a cost-to-charge ratio) may limit the generalisability of the results beyond the authors’ clinical setting. Some costs were excluded from the analysis. However, it is unclear whether these exclusions would have affected the authors' conclusions. Since there was little detail on the costs estimation, some costs may have been omitted from the analysis and their omission might have affected the authors’ conclusions.

The costs and the quantities were not reported separately, thus making it difficult to extrapolate the analysis to other settings. A statistical analysis of the costs was carried out. Discounting was not undertaken, which was appropriate as the time period was less than one year. The price year was reported, which will aid any future refiation exercises.

Other issues
The authors compared their findings with those from other studies showing similar conclusions. The issue of generalisability was partially addressed by the authors (see the 'Implications' section below). The authors did not present their results selectively and their conclusions reflected the scope of the analysis. However, as reported already, the cost information was not sufficiently complete to be sure of the authors' conclusions. The authors reported two critical limitation. First, the use of historical controls (as mentioned already). Second, the difficulty of confirming the accuracy of the initial GCS score recorded because the patients might have been sedated or intubated, or had another intervention which may have made their GCS score inaccurate.

Implications of the study
The emphasis on evidence-based medicine guidelines has promoted a more scientifically based understanding of complex problems and provided an intensive learning experience for all concerned. This may be especially relevant in settings where relatively junior or inexperienced practitioners provide the initial therapeutic decision-making. To overcome the limitations of this observational study, the authors recommend a large multi-centre study of the
outcomes of TBI care in the USA.

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**Other publications of related interest**


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**MeSH**
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