Reduction in mortality from severe head injury following introduction of a protocol for intensive care management

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Background. To determine the effect of an intensive care management protocol on the intensive care unit (ICU) and hospital mortality of severely head-injured patients, we designed a longitudinal observational study of all patients admitted with a head injury between 1992 and 2000.

Methods. A computerized patient database was used to identify all patients with severe head injury admitted to the ICU at Frenchay Hospital, Bristol, UK: a tertiary referral centre for the clinical neurosciences. We compared the ICU and hospital mortality and length of stay in patients before and after implementation of a protocol for their ICU management in 1997.

Results. Implementation of the protocol was associated with a significant reduction in ICU mortality from 19.95% to 13.5% (odds ratio 0.47; 95% CI 0.29–0.75), and in hospital mortality from 24.55% to 20.8% (odds ratio 0.48; 95% CI 0.31–0.74). This was achieved despite a significant increase in the median APACHE II score (14 vs 18) of patients admitted after implementation of the protocol. The median ICU and hospital length of stay remained constant over the study period.

Conclusions. The introduction of an evidence-based protocol to guide the ICU management of patients with severe head injury has been associated with a significant reduction in both ICU and hospital mortality.

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Guidelines and protocols have been introduced into clinical practice as a means of reducing the variation in clinical management that may result in suboptimal outcomes and increased costs. Indeed, the implementation of clinical management protocols or guidelines can change practice and may improve outcome.1 In intensive care practice, protocols or guidelines for the management of sedation, weaning from mechanical ventilation and antibiotic selection have been associated with improved outcome.2 Recent surveys in the UK and in Europe have demonstrated a wide variation in the management of severely head-injured patients.3 4 Similar variation in practice also existed within our own intensive care unit (ICU), reflecting the preferences of individual neurosurgeons and intensivists. This prompted us to develop a local protocol for the ICU management of severe head injury (Fig. 1), adapting a protocol previously published by Souter and Andrews5 in which the maintenance of cerebral perfusion pressure is the primary goal. The protocol also considers the management of intracranial hypertension, and incorporates the consensus guidelines produced by the Brain Trauma Foundation and the European Brain Injury Consortium.6–8 A modified version of the protocol was introduced simultaneously for the management of children. The protocol was implemented in January 1997. An audit was subsequently performed and confirmed adherence to the protocol. The aim of this study was to determine the influence of the protocol on the ICU and hospital mortality of patients with head injuries.

Methods

The seven-bedded ICU at Frenchay Hospital, Bristol, provides a regional neurointensive care service for a population of approximately 2.5 million, as well as general intensive

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Footnotes:
2This article is accompanied by Editorial I.

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Fig 1 The Frenchay ICU head injury management protocols for (A) adults and (B) children. MAP, mean arterial pressure; CPP, cerebral perfusion pressure; ICP, intracranial pressure; CVP, central venous pressure; CT, computed tomography; $S_{po2}$, pulse oximetry; $S_{jo2}$, jugular venous oxygen saturation; TCD, transcranial Doppler; EEG, electroencephalogram.
care services for the local population. The ICU is supported by a five-bed high dependency unit (HDU) that opened in May 1997. A computerized patient database, established on the ICU in September 1992, was used to identify all patients with severe head injury admitted to the ICU between September 1992 and December 2000. These dates were selected to allow inclusion of all head-injured patients in our database. This cohort of patients was cross-checked against the hospital information system for completeness. The data examined included the admission diagnosis, admission source, Glasgow Coma Score (GCS) on admission, APACHE II score, length of stay in ICU, length of hospital stay and mortality. The length of hospital stay and outcome of patients discharged to referring hospitals was confirmed with these hospitals. A random sample of 10% of the case notes from each study year was examined to confirm the accuracy of the data. Patients were divided into two groups: those admitted before the introduction of the protocol in January 1997 (Group A), and those admitted afterwards (Group B).

Statistics

The ICU and hospital mortalities and lengths of stay were compared between the two groups. Binary outcomes (ICU and hospital mortality) were analysed using logistic regression. Length of stay was analysed using Cox regression. Lengths of stay for patients who died in ICU were treated as censored observations. All analyses were adjusted for age, GCS and APACHE II scores. The Wilcoxon rank sum test was used to compare the age, GCS and APACHE II scores of the patients in the two groups, and a χ²-test was used to test for differences in the sex distribution. All analyses were undertaken using 2001 Stata Statistical software (release 7.0; Statabase Corporation, College Station, TX, USA).

Results

A total of 843 head-injured patients were identified, accounting for approximately 20% of all admissions to the ICU. There were 391 (46.4%) patients in Group A, and 452 (53.6%) patients in Group B (Table 1). Data accuracy was confirmed, with only 1.5% of patient records containing minor inaccuracies. Patients in the two groups were similar with respect to sex, source of admission, GCS on admission and neurological surgical procedure before admission to ICU. The distribution in APACHE II score, GCS and age in each group is shown in Figure 2.

The age of the patients and their severity of illness as measured by APACHE II scores were significantly different between the two groups (Table 1). Patients in Group A had a median APACHE II score of 14 compared with a median score of 18 for patients in Group B. This difference in APACHE II score remained irrespective of whether patients had undergone secondary transport to Frenchay Hospital or had been admitted there directly (Table 1). Despite the higher APACHE II score, the ICU and hospital mortality of patients in Group B was significantly lower (Table 2). ICU mortality was reduced from 19.95% to 13.5% (odds ratio 0.47; 95% CI 0.29–0.75), and hospital mortality was reduced from 24.55% to 20.8% (odds ratio 0.48; 95% CI 0.31–0.74). The relative risk reductions were 32% and 15%, respectively. This reduction in mortality was due entirely to a reduction in the mortality of adult patients with head injuries. The mortality benefit was seen in patients with GCS≤8 as well as those with GCS>8 (Table 3). Mortality in children remained unchanged (Table 3). The reduction in ICU mortality for head-injured patients was not mirrored by a similar reduction in the unit mortality of the rest of the ICU population, nor was there any suggestion that the ICU mortality for head-injured patients was falling before the introduction of the protocol (Fig. 3). There was no change in either the ICU or hospital length of stay (hazard ratio 0.01; 95% CI 0.85–1.21; n=843).

Discussion

Use of clinical guidelines to effect change and improve the quality of care is often disappointing. Effective guidelines require more than the adoption of imported flowcharts or decision trees. They should be designed locally by a multi-disciplinary team to be user-friendly, evidence-based and relevant. The involvement of all relevant parties in the development of guidelines and protocols increases the likelihood that they will be followed and avoids the perception that they are there solely to dictate clinical practice. Adherence to specific protocols and the effect of a protocol on clinical outcome should be audited. Finally, guidelines should be updated regularly. All these points were observed in the development and implementation of our protocol. An audit of 56 consecutive cases admitted soon after 1997 confirmed 91.1% compliance with the protocol. It is possible that this high rate of compliance with the protocol coincided with its introduction and that subsequently compliance decreased gradually. The large number of patients involved in this study meant it was impossible to confirm adherence to

Table 1 Comparison of head-injured patients admitted to the ICU before the introduction of the protocol (Group A) with those admitted after its introduction (Group B). Values are expressed as median (inter quartile range) unless stated. *P<0.05

<table>
<thead>
<tr>
<th></th>
<th>Group A (n=391)</th>
<th>Group B (n=452)</th>
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<tbody>
<tr>
<td>Age (yr)</td>
<td>28 (15–45)</td>
<td>32 (18–51)**</td>
</tr>
<tr>
<td>Sex (n and % male)</td>
<td>291 (74.4%)</td>
<td>338 (74.8%)</td>
</tr>
<tr>
<td>Admission GCS</td>
<td>5 (3–8)</td>
<td>6 (3–9)</td>
</tr>
<tr>
<td>APACHE II score</td>
<td>14 (10–19)</td>
<td>18 (14–22)**</td>
</tr>
<tr>
<td>No. admitted following transfer from another hospital (% of total)</td>
<td>259 (66.2%)</td>
<td>292 (64.6%)</td>
</tr>
<tr>
<td>APACHE II scores of patients admitted directly to Frenchay Hospital</td>
<td>15 (10–20)</td>
<td>18 (13–22)**</td>
</tr>
<tr>
<td>APACHE II scores of transferred patients</td>
<td>14 (10–19)</td>
<td>19 (13–21)**</td>
</tr>
<tr>
<td>No. admitted following neurological procedure</td>
<td>184 (47.1%)</td>
<td>215 (47.6%)</td>
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</table>
the protocol in every case since 1997. But perhaps the
strength of the current study is that we have assessed the
impact of the protocol in everyday intensive care practice as
opposed to an artificial and rigorously controlled research
setting. Use of the protocol has other potential benefits that
we did not measure, such as improved communication
between clinicians and the education of junior staff. In addi-
tion, the impact of new therapeutic developments should be
assessed more easily in the future as they are added to this
standard package of care.

Fig 2  Percentage distribution of (A) APACHE II score, (B) GCS and (C) age in Group A and Group B patients.
ICU protocol reduces head injury mortality

Although there is no Class 1 evidence to support many of the specific interventions used in the management of head injuries, it is generally agreed that the aim of intensive care for these patients is to prevent, identify and treat the causes of secondary brain injury. The introduction of a protocol to manage severe head injuries based on the best available evidence supporting this aim was associated with a significant reduction in both ICU and hospital mortality. This was achieved without increasing the patients’ length of stay in the ICU and despite a higher median age and APACHE II score in Group B patients. As the mortality on the wards after discharge from the ICU remained unchanged (Table 2), it is clear that, as might be expected, the major impact of the protocol was within the ICU itself.

Although the GCS and neurosurgical interventions of the two groups were similar, we would have expected the higher age and APACHE II score of group B patients to be associated with a higher mortality rate. The difference in age, while statistically significant, is unlikely to be clinically significant. We are unable to explain the differences in APACHE II scores between the groups. The difference almost certainly lies in the acute physiology scores of the two groups, and may reflect changes in referral and admission patterns during the study period. The act of transferring a patient from another hospital may result in deterioration in the physiological variables contributing to the APACHE II score on admission to our unit. However, there was neither a difference in the proportion of patients transferred before or after the implementation of the protocol (Table 1), nor a difference in the APACHE II scores of patients who underwent transfer when compared with those who did not.

This study, although retrospective, examined a large number of patients, but in the absence of randomization factors the protocol may be responsible for the observed improvement in outcome. These may include improvements in pre-ICU care, general intensive care management or high-dependency care after the ICU. The significant increase in the admission APACHE II score in Group B (Table 1) suggests that an improvement in pre-ICU care was not a major contributing factor. General intensive care management is likely to have improved over time, making it possible that other organizational changes within the ICU may have contributed to the change in ICU mortality. These would include increased numbers of ICU beds, an increase in medical and nursing staffing levels, and improved training in intensive care medicine. If these were major contributory factors, one would expect the mortality in patients with other diagnoses to have been reduced by a similar proportion to that observed in patients with head injuries. This was not the case, as the ICU mortality for patients without head injury did not change significantly (Fig. 3). Finally, while the opening of an HDU may affect the ICU length of stay and the hospital mortality, it should not influence the ICU mortality. Because the ICU length of stay was unchanged (Table 2) and the improvement in hospital mortality was primarily attributable to a reduction in ICU mortality, not post-ICU mortality, we can only conclude that the contribution of the HDU was not a significant factor.

Several other factors will have influenced the outcome measures chosen, particularly length of stay and hospital mortality. Workload pressure affects length of stay on both the ICU and in hospital, and care on the neurosurgical wards impacts upon hospital mortality. However, it is reassuring that the survival benefit observed extends beyond the ICU. In addition, the reduction in hospital mortality implies that the decrease in ICU mortality is not simply a result of transferring patients with a very poor prognosis to the ward. If post-ICU mortality could be further reduced, then the impact of the protocol on hospital mortality would be even greater. It is recognized that 20–30% of intensive care patients who die will do so on the wards after discharge from the ICU, and that some of these deaths may be avoidable. We were disappointed to find that the opening of the HDU did not affect this post-ICU discharge mortality. This may reflect the use of the HDU primarily as an overflow ICU rather than as a proper stepdown facility or a unit for the care of elective surgical patients. The introduction of Outreach teams as recommended in Comprehensive Critical Care may address this issue in the future.

A study by Patel and colleagues reported that overall there was no reduction in mortality and no general

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Outcomes before (Group A) and after (Group B) introduction of the management protocol (NS, not significant)</th>
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<tbody>
<tr>
<td></td>
<td>Group A (n=391)</td>
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<tr>
<td>ICU deaths</td>
<td>78 (19.95%)</td>
</tr>
<tr>
<td>Hospital deaths</td>
<td>96 (24.55%)</td>
</tr>
<tr>
<td>Deaths after ICU discharge</td>
<td>18 (4.6%)</td>
</tr>
<tr>
<td>Median ICU length of stay (days)</td>
<td>3 (1–40)</td>
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<tr>
<td>Median hospital length of stay (days)</td>
<td>10 (1–351)</td>
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<tr>
<th>Table 3</th>
<th>Subgroup analysis: ICU and hospital mortality and adjusted odds ratios (Group B/Group A) for the whole study population, adults, children aged &lt;16 yr and patients with GCS ≤8</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Group A</td>
</tr>
<tr>
<td>Overall study population: Group A, n=391; Group B, n=452</td>
<td>ICU deaths</td>
</tr>
<tr>
<td></td>
<td>Hospital deaths</td>
</tr>
<tr>
<td>Adults aged &gt;16 yr: Group A, n=291; Group B, n=360</td>
<td>ICU deaths</td>
</tr>
<tr>
<td></td>
<td>Hospital deaths</td>
</tr>
<tr>
<td>Children aged ≤16 yr: Group A, n=100; Group B, n=91</td>
<td>ICU deaths</td>
</tr>
<tr>
<td></td>
<td>Hospital deaths</td>
</tr>
<tr>
<td>Patients with a GCS ≤8: Group A, n=316; Group B, n=353</td>
<td>ICU deaths</td>
</tr>
<tr>
<td></td>
<td>Hospital deaths</td>
</tr>
</tbody>
</table>
improvement in outcome after the introduction of a head-injury management protocol, but observed significantly less morbidity in patients with severe head injuries (GCS <8) and in those with a raised intracranial pressure but no surgically remediable cause. At first sight, our results may appear to be better than those of Patel and colleagues. However, as our study was much larger than theirs (843 vs 285 patients), it is possible that their study lacked the power to identify a difference in hospital mortality. Furthermore, their baseline hospital mortality before the introduction of their protocol was lower than ours (22.7% vs 24.5%), yet the similarity between the mortalities in the two ICUs after the introduction of the protocol is remarkable (20.2% vs. 20.8%). Any reduction in mortality in their study would require many more patients to reach statistical significance. The effect of the protocol on their ICU mortality was not reported, which is unfortunate as the protocol is most likely to have the largest effect within the ICU, as demonstrated in our study.

Unfortunately, we do not have data on the long-term neurological function for our patients and cannot comment on this aspect of outcome. It is tempting to speculate that the combination of our results with those of Patel and colleagues may suggest that protocol-driven care may reduce mortality and morbidity in this population of patients. Patel and colleagues argue that the improvement they observed was due to the application of ICP/CPP-guided therapy within a specialist neurocritical care setting. The reduction in mortality that we observed was significant in patients with both severe (GCS <8) and less severe (GCS >8) head injuries, and in patients requiring neurosurgical intervention as well as those managed medically. Whilst it is possible that the improvements we noted may also be achieved by the application of protocol-driven care in a non-specialist ICU, we would agree with Patel and colleagues that there may be a case for managing all severely head-injured patients in specialist units. The comparative data from all types of ICU, provided by the Intensive Care National Audit and Research Centre (ICNARC), although open to many interpretations, adds weight to this argument (Table 4).

The mortality of children receiving intensive care is gratifyingly low, and prohibitively large studies may be necessary to show changes in mortality. In this study, the mortality rate in children with head injuries remained unchanged after the introduction of the protocol. The ICU and hospital mortality in children was half that observed in adults (Table 3), and because the number of children admitted was much smaller, it is likely that much larger numbers would need to be included to detect a difference in mortality, if one exists. It is also possible that the outcome of children would only be improved by the application of protocol-driven care within a tertiary paediatric ICU.

Head injury remains a leading cause of death among young adults in the industrialized world, and survival with moderate or severe disability is more common than expected, even after a mild head injury. This study suggests that implementation of a protocol has resulted in a relative reduction in ICU mortality of almost 30% at this hospital. We would recommend that implementation of locally agreed guidelines, based on the available published evidence, facilitates the use of best practice and results in improved patient care.

Acknowledgements

We would like to thank the Research and Development Support Unit at North Bristol Trust for statistical advice. The ICNARC data derive from the national comparative audit of patient outcomes (CMPD) co-ordinated by ICNARC. These analyses are based on data for 75 621 admissions to 102 adult ICUs based in NHS hospitals in England, Wales and Northern Ireland. For more information on the quality of these data, please contact ICNARC.

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ICU protocol reduces head injury mortality


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