

Management of Brain-Injured Patients by an Evidence-Based Medicine Protocol Improves Outcomes and Decreases Hospital Charges

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Objective: Traumatic brain injury (TBI) is the leading cause of death from blunt trauma, with an estimated cost to society of over \$40 billion annually. Evidence-based guidelines for TBI care have been widely discussed, but in-hospital treatment of these patients has been highly variable. The purpose of this study was to determine whether management of TBI patients according to a protocol based on the Brain Trauma Foundation (BTF) guidelines would reduce mortality, length of stay, charges, and disability.

Methods: In 1995, a protocol following the BTF guidelines was developed by members of the Level I trauma center's interdisciplinary neurotrauma task force. Inclusion criteria for the protocol were blunt head injury, age > 14 years, and Glasgow Coma Scale score ≤ 8. An extensive educational process was conducted to develop compliance among all disciplines for this new management strategy. A historical control group of patients eligible for the protocol was identified by retrospective analysis of trauma registry data for 1991 to 1994. Mortality, intensive care unit days, total hospital days, total charges, Rancho Los Amigos Scores, and Glasgow Outcome Scale scores were compared.

Results: Between 1991 and 2000, over 7,000 blunt TBI patients were managed by the Trauma Service. Of these, 830 met the inclusion criteria for the TBI protocol and lived > 48 hours. After implementation, initial analysis of the 1995–96 cohort indicated only 50% compliance with the protocol. By 1997, compliance had risen to 88%. Patients were therefore compared as three groups: before the protocol (1991–94, n = 219), during low compliance (1995–96, n = 188), and during high compliance (1997–2000, n = 423). Groups did not differ significantly on Injury Severity Score, head Abbreviated Injury Scale score, or age ($p > 0.05$). Admission Glasgow Coma Scale score was slightly higher in the 1991–94 cohort (4.0 vs. 3.5, $p = 0.001$). From 1991–94 to 1997–2000, intensive care unit stay was reduced by 1.8 days ($p = 0.021$) and total hospital stay was reduced by 5.4 days ($p < 0.001$). The charge reduction (calculated in 1997 dollars) per patient for the length of stay decrease was \$6,577 in 1995–96 and \$8,266 in 1997–2000 ($p = 0.002$). This represents a total reduction over 6 years of \$4.7 million in charges. In addition, the overall mortality rate showed a reduction of 4.0% from 1991–94

to 1997–2000 (17.8% vs. 13.8%), although this was not statistically significant. On the basis of the Glasgow Outcome Scale score, in 1997–2000, 61.5% of the patients had either a “good recovery” or only “moderate disability,” compared with 50.3% in 1995–96 and 43.3% in 1991–94 ($p < 0.001$). The Rancho Los Amigos Scores showed a similar trend, with 56.6% of the 1997–2000 patients having appropriate responses at 10 to 14 days, compared with only 44.0% of the 1995–96 patients and 43.9% of the 1991–94 patients ($p = 0.004$).

Conclusion: Adherence to a protocol based on the BTF guidelines can result in a significant decrease in hospital days and charges for TBI patients who live > 48 hours. In addition, mortality and outcome may be significantly affected. This analysis suggests that increased efforts to improve adherence to national guidelines may have a significant impact on head injury care outcomes and could dramatically reduce the substantial financial resources that are currently consumed in the acute care phases for this injury.

Key Words: Trauma, Neurotrauma, Brain injury, Brain Trauma Foundation, Protocol, Guidelines, Acute care, Evidence-based medicine, Health care expenditures.

J Trauma. 2004;56:492–500.

Traumatic brain injury (TBI) is a major cause of death and disability in both children and adults in the most productive years of their lives. It has been estimated that there are nearly 1.6 million traumatic head injuries every year

in the United States. Of these injuries, approximately 66.9% ($n = 1,070,000$) will receive emergency department or outpatient care, and approximately 16.9% ($n = 270,000$) will be admitted to the hospital for more complex care.^{1–3} Every year, approximately 52,000 people die as a result of TBI and another 70,000 to 90,000 persons will have permanent neurologic impairment from their injuries.^{4,5} Disability after TBI results in a considerable loss of both productive years and income potential, with an estimated cost to society of over \$40 billion annually.^{6,7} Traumatic brain injury is a major public health problem necessitating ongoing investigation in the areas of prevention, acute care, and rehabilitation.^{7,8}

Ongoing research has demonstrated that the initial traumatic event is merely the first insult sustained by the brain (primary injury). After the initial trauma, injury to the brain continues to evolve, and exacerbation of the primary injury

Submitted for publication February 12, 1999.

Accepted for publication October 29, 2003.

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Presented in part at the Eastern Association for the Surgery of Trauma Twelfth Scientific Assembly, January 13–16, 1999, Orlando, Florida, and at Postgraduate Course 12: “Pre- and Postoperative Care: The Impact of Evidence Based Medicine on Surgical Practice,” Eighty-fifth Clinical Congress, American College of Surgeons, October 10–13, 1999, San Francisco, California.

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DOI: 10.1097/01.TA.0000115650.07193.66

can occur at any time after the initial event. This evolving damage is referred to as secondary injury. Secondary injury can prolong hospitalization, exacerbate disability, and increase mortality.^{6,8} The Brain Trauma Foundation (BTF), acknowledging that there was great potential for interventions to prevent or mitigate the secondary injury associated with TBI, examined the delivery of acute care for TBI in the United States. In early 1990, the BTF conducted a study of the state of TBI care that included 261 trauma centers in 45 states. Their conclusions suggested care varied not only between institutions but also between practitioners at the same institution. In addition, the care that was being delivered to TBI patients in hospitals was inconsistent at best and detrimental at worst, with many patients receiving treatments shown to be potentially harmful and outdated in the scientific literature.^{9,10} In an effort to promote best practice, and to optimize the care of the TBI patient, the BTF published the *Guidelines for the Management of Severe Head Injury* in 1995 in collaboration with the American Association of Neurologic Surgeons. These guidelines were designed for in-hospital care and were based on the best available scientific, evidence-based methodology.^{6,8} The core of the guidelines are 14 topics deemed critical to the care of TBI patients. Each topic includes recommendations based on the currently available data. These recommendations included standards (evidence that gives a high degree of clinical certainty), guidelines (evidence that gives moderate clinical certainty), and options (evidence that provides unclear clinical certainty) for the care of the TBI patient.

Because there is still no single best way to manage TBI patients, institutions must adapt the BTF guidelines to meet their individual circumstances while providing optimal care. Our institution manages over 500 head injuries annually, and the trauma service elected to determine whether a standardized best practice approach to TBI would improve the care of the head-injured patient. The purpose of this study was to determine whether evidence-based, guideline-driven care would result in improved outcomes as compared with management based solely on individual practitioner preferences. The hypothesis was that care delivered by an evidence-based protocol would reduce charges, disability, length of stay, and mortality.

PATIENTS AND METHODS

To develop the protocol, a multidisciplinary neurotrauma task force was formed with representatives from all of the associated medical, nursing, and ancillary specialties. Using the Brain Trauma Foundation guidelines as a template, the task force developed a set of standard orders and a pathway for the care of the severe TBI patient. Because the institution had no neurosurgery residents at the time of protocol initiation, neurosurgical participation in the management of TBI patients was often limited, particularly when the need for surgical intervention had been ruled out. Because almost all TBI patients had concomitant injuries requiring consultations from a trauma surgeon, it was agreed that the Trauma Service

would serve as the team leader for managing the TBI patient, with each patient also having a neurosurgeon as a principal consultant. It was felt that, in this way, the care would be most consistently delivered. An extensive educational process was conducted to develop compliance among all disciplines for this new management strategy. The protocol was implemented in late 1995. Inclusion criteria for the protocol were as follows: blunt head injury, age > 14 years, and Glasgow Coma Scale (GCS) score $\leq$ 8. The outline of the protocol appears in the Appendix.

Ongoing evaluation revealed that compliance with the protocol (as measured by the presence of TBI order sheets on the chart) was less than optimal. By the end of 1996, compliance was only at 50%. A second intensive education program was instituted, and by the end of 1998, compliance had risen to 88% for the 1997–98 cohort. In 2001, a comprehensive evaluation of the 6-year experience with the protocols was completed.

To compare the patients after the TBI protocol implementation to a comparable cohort, a historical control group of patients was identified by retrospective analysis of trauma registry data for 1991–94. Controls were patients who were treated at the study institution before the new protocol but who otherwise met protocol criteria (blunt head injury, age > 14 years, lived > 48 hours, and GCS score $\leq$ 8). Information was then abstracted for all the TBI patients (1991–2000) by means of trauma registry download and by individual chart review. Data were collected on mortality, intensive care unit (ICU) days, total hospital days, total charges, Rancho Los Amigos Scores (RLAS), Glasgow Outcome Scale (GOS) scores, and other related demographic and injury data.

The groups were compared using analysis of variance for group-wise comparisons of three or more groups. Student's *t* test was performed for pair-wise related variable comparisons. Tukey's honest significant difference multiple comparison (post hoc) tests were performed for significant omnibus *F* tests. The level of significance was set at $p < 0.05$ for all comparisons unless a lower level was substituted for statistical stringency (this will be noted in the text).

Institutional review board approval for the study was obtained before initiation of data collection. The institutional review board determined this study to meet the criteria for exemption from written informed consent requirements and approved it as such.

RESULTS

Sample

Between 1991 and 2000, 7,003 blunt TBI patients were managed by the Trauma Service. Patients were initially screened to ensure they met TBI protocol criteria (blunt trauma, head injury, GCS score $\leq$ 8, age > 14 years). Because the purpose of the protocol was to evaluate severe head injury care, patients were eliminated if they did not have at least one head Abbreviated Injury Scale (AIS) score injury greater than 2. In addition, because certain injuries are con-

Table 1 Comparison of Groups by Year for TBI Patients

	1991–94 (n = 219)	1995–96 (n = 188)	1997–2000 (n = 423)	p Value
Demographics				
Age (mean)	33.8	33.9	35.6	NS
Alcohol level (mean)	119	176	77	<0.001
Gender (% male)	73.5	70.7	77.3	NS
Injury severity				
Initial GCS score (mean)	4.0	3.5	3.5	<0.001
Injury Severity Score (mean)	25.2	24.3	24.0	NS
Maximum head AIS score (mean)	4.0	3.9	3.8	NS
Mortality (% who died)	17.8	18.6 [*]	13.8 [†]	0.047
Length of stay and charges				
ICU days (mean)	9.7	8.4 [*]	7.9	0.021
Hospital days (mean)	21.2	16.7	15.8	0.001
Total charges (mean per patient)	\$36,6944	\$30,244	\$28,429	0.002
Disability scores				
Glasgow Outcome Scale (% w/good recovery or moderate disability)	43.3	50.3 [*]	61.5	<0.001
Rancho Los Amigos score (% appropriate at discharge)	43.9	44.0	56.6	0.004

All significant comparisons are for 1997–2000 and 1995–96 as compared to 1991–94.

^{*} Individual group did not differ significantly from 1991–94.

[†] 1997–2000 differs from 1991–94 and 1995–96.

sidered to have no reasonable chance for survival even with optimal care, patients were screened for severity of head injury to choose patients for whom the protocol had a realistic chance of making a difference. Any patients who had an AIS 6 injury or who died in less than 48 hours after injury were excluded as being so severely injured that a protocol (or lack thereof) would not have changed the outcome of the injury.

A total of 830 patients met the final inclusion criteria of age > 14 years, blunt injury, head AIS score > 2 and < 6, and survival > 48 hours. Because the interim analysis of the 1995–96 cohort had indicated only 50% compliance with the protocol, compared with the 1997–98 compliance rate of 88%, patients were analyzed as three separate groups. The three cohorts were patients seen before the protocol (1991–94, n = 219), during low compliance (1995–96, n = 188), and during high compliance (1997–2000, n = 423).

Patients were compared by year cohort as opposed to comparing patients with and without TBI orders for two reasons. First, protocol patients tended to be more severely injured than nonprotocol patients. The more severely injured patients were put on the protocol without hesitation, whereas the less severely injured tended to be the patients some physicians felt more “comfortable” with and opted against protocol-driven care. This enrollment inequity generally biased the nonprotocol group to the less severely injured, who by definition had better outcome measures. Second, year cohorts were chosen because we were unable to control for contamination of intervention. Because all the staff had been extensively educated in the new TBI care protocol, this would most likely affect the care given to even nonprotocol patients. The more conservative and rigorous approach of comparing year cohorts was therefore chosen for most comparisons.

Demographics

The mean age of the sample was 34.7 years (range, 15–94 years). The vast majority of patients were 55 years or younger (87.7%). Male patients constituted 74.8% of the patients (n = 621). Groups did not differ on age or gender ($p > 0.05$). The majority of patients screened (54.1%) were positive for alcohol (ETOH) use and 44.2% were legally intoxicated (ETOH > 80 mL/dL). There were no significant differences between the study groups on any of the demographic variables except mean alcohol level, where all three groups differed significantly from each other (1991–94, ETOH = 119; 1995–96, ETOH = 176; 1997–2000, ETOH = 77; $p < 0.001$) (Table 1). The most common causes of injury were motor vehicle crashes (75.4%) and falls (15.4%).

Injury Severity

The mean admission GCS score for all patients was 3.6 (range, 3–8). The majority of patients (n = 657 [79.5%]) had a GCS score of 3 either on the scene or on arrival in the trauma bay. The patients in the 1991–94 cohort had a slightly higher initial GCS score than did patients in the 1995–96 or 1997–2000 cohort (4.0 vs. 3.5, $p < 0.001$) (Table 1).

The mean Injury Severity Score for all patients was 24.4, the median was 25, and the range was 4 to 75. The three groups did not differ significantly on Injury Severity Score ($p = 0.406$). The mean AIS score for the most severe head injury a patient incurred was 3.9 (range, 2–5). Groups did not differ significantly on mean head AIS score ($p = 0.223$) (Table 1). The largest proportion of patients had an AIS 5 head injury (n = 339 [40.8%]), with only a small number of patients incurring an AIS 2 head injury (n = 106 [12.8%]).

Table 2 Mortality Rates by Year and AIS Head Injury Score for All Patients, Isolated Head Injuries, and Multiple Trauma with Head Injury

Head AIS Score		1991–94		1995–96		1997–2000		Total 1991–2000	
		(n = 219)		(n = 188)		(n = 423)		(n = 830)	
		%	No.	%	No.	%	No.	%	No.
All patients	2	5.6	18	0	26	0	62	0.9	106
	3	3.1	65	0	55	0	122	0.8	242
	4	4.7	43	0	25	2.6	76	2.8	144
	5	36.6	93	42.7	82	35.0*	163	37.3	338
	Total	17.8	219	18.6	188	13.7	423	15.9	830
Isolated head injury		(n = 132)		(n = 105)		(n = 244)		(n = 481)	
		%	No.	%	No.	%	No.	%	No.
	2	10.0	10	0	11	0	40	1.6	61
	3	2.3	44	0	29	0	79	0.7	152
	4	3.9	26	0	13	0	45	1.2	84
Total	5	46.2	52	46.2	52	43.8	80	45.1	184
	Total	20.5	132	22.9	105	14.3	244	17.9	481
Multiple trauma with Head injury		(n = 87)		(n = 83)		(n = 179)		(n = 349)	
		%	No.	%	No.	%	No.	%	No.
	2	0	8	0	15	0	22	0.0	45
	3	4.75	21	0	26	0	43	1.1	90
	4	5.9	17	0	12	3.3	30	3.4	59
Total	5	24.4	41	36.7	30	26.2	84	27.7	155
	Total	13.8	87	13.3	83	12.8	179	13.2	349

* $p = 0.042$, 1997–2000 vs. 1991–94 and 1995–96.

The most common areas of injury other than the head were the extremities ($n = 360$ [43.4%]) and the chest ($n = 310$ [37.3%]). The majority of patients ($n = 481$ [58.0%]) had isolated head injuries with no injury $\geq$ AIS 2 to another body region (Table 2).

The overall mortality rate remained almost constant from 1991 to 1996 (17.8 vs. 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 (13.7 vs. 18.2, $p = 0.047$) (Table 1). Not only did mortality improve, there were also trend changes in the types of patients who died. In the 1991–94 cohort, although the numbers were small, there was mortality for all levels of head injury (AIS 2–5 injury), whereas in the 1995–96 and 1997–2000 cohorts, the only deaths for isolated head injuries were among patients with AIS 5 injury. There was one death with an AIS 4 injury in the multiple trauma group in the 1997–2000 cohort, but he died of complications related to advanced cirrhosis. The 1997–2000 cohort also exhibited lower mortality than the 1991–94 and 1995–96 groups at the AIS 5 level (34.8 vs. 42.7 and 36.6, respectively), although the trend was not statistically significant (Table 2).

Length of Stay

The vast majority of patients went from the resuscitation area directly to the ICU ($n = 758$ [91.3%]), with the remainder going to the operating room first and then to the ICU. The

mean ICU length of stay (LOS) was 8.5 days, with a median stay of 6 days and a range from 1 to 62 days. From 1991–94 to 1997–2000, ICU days were reduced by 1.9 days (9.8 vs. 7.9, $p = 0.021$). Mean total hospital days were 17.5, with a median stay of 12 days and a range of 1 to 164. From 1991–94 to 1997–2000, total hospital days were reduced by 5.4 days (21.2 vs. 15.8, $p = 0.005$).

Charges for patients were calculated in 1997 dollars and represent the charges for a hospital room, critical care, nursing services, direct expenses, indirect fees, and general hospital charges. It does not include physician billings, diagnostic services medications, or other professional fees. 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. The mean reduction per patient was \$6,577 from 1991–94 to 1995–96 and \$8,266 from 1991–94 to 1997–2000 ($p = 0.002$). Multiplying the charge reduction by the number of patients per group, this represents a total charge reduction over 6 years of \$4.7 million.

Disability

The discharge dispositions were remarkably homogeneous. Of the 696 patients who lived, most were discharged to rehabilitation or other inpatient follow-up management ($n = 339$ [48.7%]), although a significant number went home with outpatient follow-up treatment ($n = 316$ [45.3%]). The re-

Table 3 Comparison of TBI and Non-TBI (Other) ICU Patients by Year Groups

	1991–94 (TBI: n = 219) (Other: n = 354)	1995–96 (TBI: n = 188) (Other: n = 181)	1997–2000 (TBI: n = 423) (Other: n = 525)	p Value
ICU days (mean)				
TBI	9.7	8.4	7.9	0.020
Other	5.8	6.8	9.3	<0.001
Hospital days (mean)				
TBI	21.2	16.7	15.8	0.001
Other	14.5	14.9	14.7	NS
Total charges (mean per patient)				
TBI	\$36,694	\$30,244	\$28,428	0.002
Other	\$23,560	\$25,711*	\$30,090	0.011
Mortality (% who died)				
TBI	17.8	18.6 [†]	13.8 [†]	0.047
Other	6.2	8.8	5.9	NS

All significant three-group comparisons are for both other groups as compared to 1991–94.

* Individual group does not differ significantly from 1991–94.

[†] 1997–2000 differs from 1991–94 and 1995–96.

mainder were transferred to a long-term care facility (n = 41 [5.9%]).

Outcomes were measured using the GOS score and the RLAS. The GOS is a five-level scale for grading outcome from head injury. Its five levels are Death, Vegetative State, Severe Disability, Moderate Disability, and Good Recovery. The RLAS is an eight-level scale measuring cognitive functioning. Possible scores range from 1 (completely unresponsive) to 8 (purposeful and appropriate responses). Both GOS score and RLAS were measured at hospital discharge.

The years of highest compliance to the protocol (1997–2000) also demonstrated some of the best outcomes. In the 1997–2000 cohort, 61.5% of the patients had either a good recovery or only moderate disability. 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 RLAS 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 ($p = 0.004$).

Non-TBI Comparisons

The 1990s brought many changes to the way trauma care was delivered in hospitals. To ensure that the trends seen in the TBI patients were a result of the protocol implementation and were not merely reflective of overall changes in care delivery over the decade, the same variables were examined comparing the TBI patients to a similar trauma population of non-head-injured patients. The TBI patients (n = 830) were compared with a non-TBI sample of patients (n = 1,060) who otherwise met the same inclusion criteria (age > 14 years, ICU patient, blunt injury, survival > 48 hours, and maximum head AIS score ≤ 1).

On all measures, the non-TBI group generally demonstrated the opposite trend from the TBI group. Each of the year groupings showed an increase over the past years in all

of the measured variables rather than a decrease. The ICU LOS increased by 1.4 days (from 5.8 to 9.3), and total charges increased by \$7,590 (from \$23,560 to \$30,090), Hospital days stayed nearly the same (14.5 vs. 14.7), as did mortality (6.2% vs. 5.9%), with neither comparison being statistically significant (Table 3). These data demonstrate that the reduction in the ICU LOS, hospital LOS, charges, and mortality seen in the TBI population after protocol implementation was not likely to be attributable to system-wide improvements in the delivery of care or other universal factors or trends.

DISCUSSION

Brain injury is the largest single cause of death in the acute phases of care of trauma patients. The in-hospital care of patients with TBI is characterized by frequent morbidity, high mortality, prolonged stays, and large fiscal expenditures. Each year, more than 50,000 Americans die after traumatic brain injuries, and an estimated 80,000 Americans survive a hospitalization for traumatic brain injury but are discharged with TBI-related disabilities.¹¹ It is estimated that there are 5.3 million Americans living with a TBI-related disability. One study estimated that the annual economic burden of TBI in the United States was approximately \$37.8 billion in 1985.¹² This estimate included \$4.5 billion in direct expenditures for hospital care, extended care, and other medical care and services; \$20.6 billion in injury-related work loss and disability; and \$12.7 billion in lost income from premature death. These estimates cannot begin to quantify the intangible costs to the families and friends of those who die or are permanently disabled from brain injury. Most patients surviving severe TBI are admitted to rehabilitation and/or require long-term or permanent care. The costs of long-term care are borne predominantly by government and third-party insurers.

The purpose of this study was to determine whether implementation of evidence-based, guideline-driven care at a

large Level I trauma center with a substantial volume of neurotrauma would result in improved outcomes as compared with management based solely on individual practitioner preferences. The specific hypotheses tested were that care delivered by an evidence-based protocol would reduce charges, disability, length of stay, and mortality. Our study demonstrated that a care protocol derived from guidelines developed by the Brain Trauma Foundation leads to improved outcomes for patients with severe blunt brain injury. In particular, the gradual adoption of the protocol was accompanied by an incremental improvement in mortality, whereas ICU and hospital lengths of stay decreased. There was a significant decrease in charges for care 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.

Care of TBI patients has traditionally been the primary responsibility of neurosurgeons. The majority of studies published on TBI outcomes in the United States are reported by neurosurgeons, and care is usually rendered on neurosurgical services.^{10,13–24} Our practice setting provided an opportunity for the Trauma Service to assume a lead role in nonoperative brain injury management. The Trauma Service managed the patient's care following the protocol, with Trauma Service physicians (general surgeons and general surgery residents) writing orders, providing care in the critical care units and wards, and coordinating multispecialty care delivery and discharge planning. Neurosurgery consultations were obtained on every case, and neurosurgical specialists were always readily available. In this study, the use of a protocol decreased variance in care delivery and empowered bedside providers to institute management in a timely manner as the patient's condition changed. The traditional delays in contacting physicians and obtaining orders were ameliorated.

We designed our protocol, clinical pathway, and standard orders using the guidelines of the Brain Trauma Foundation.^{8,9} We developed our protocol and standard orders based on the evidence presented in the BTF guidelines and our own clinical experience in a manner that would ensure broad and consistent adherence to the guidelines while allowing some individual physician preferences in areas where there was little established evidence. Despite the initial consensus building and the flexibility of the protocols, during the implementation phase (1995–96), the physicians followed the guidelines only approximately 50% of the time. It was our impression that many neurosurgeons and some attending trauma surgeons were not convinced of the efficacy of the protocol. The Neurosurgery Section and the Trauma Service leadership offered a repetition of educational seminars, repeatedly citing the evidence and allowing debate. Gradually, as our initial results began to show improved outcomes, many skeptical participants agreed to adhere to the protocol. By 1997, our compliance rate exceeded 85%. The importance of an educational program to build consensus and drive this process cannot be overemphasized. We feel that this multi-

disciplinary collaborative effort over several years demonstrates the efficacy of consensus-based protocol managed care in a complex patient population. The central role of the Trauma Service in organizing and implementing this project and delivering patient care supports the need for a committed, well-organized, and continuously available team of trauma surgeons and allied health care professionals directing care for the seriously injured.

Two recently published studies support the conclusions of our study.^{25,26} Palmer et al. studied a cohort of 93 patients between 1994 and 1999 at a community hospital in California.²⁵ Thirty-seven patients were treated before the implementation of a TBI protocol on the basis of BTF guidelines, and 56 patients were treated after protocol implementation. There was at least a threefold increase in the odds of a good outcome (as opposed to death or a bad outcome) after protocol implementation for patients with GCS scores ≤ 8 . The authors reported no change in ICU or hospital length of stay and an increase of approximately \$97,000 per patient in hospital charges. Spain et al. demonstrated decreased resource use and lower length of stay after implementation of a clinical pathway for TBI.²⁶

The most prominent improvement in outcome was the significant decrease in mortality from approximately 18% to 13.7%. Because the severity of injury at presentation was unchanged over the course of the study, we assume that the reduction in hospital mortality was the result of amelioration of secondary injury effects by more prompt and appropriate therapy. This is supported by the finding that mortality in those patients with AIS 3 and AIS 4 injuries was essentially eliminated as protocol compliance exceeded 85%. Because these patients are likely to have more survivable injuries, the protocol may have effectively limited the numbers of potentially preventable deaths in this patient population. It is our impression that patients on the TBI protocol who experience clinical deterioration in the ICU (e.g., increased intracranial pressure, decreased systemic blood pressure, hypoxemia) receive immediate therapy based on the protocol. Nonprotocol patients who experience similar deterioration must await the completion of the traditional ICU communication cycle between the nurse and the physician and are subject to variation in therapeutic responses. This may be especially relevant in settings where relatively junior or inexperienced practitioners provide the initial therapeutic decision making. Our experience has been that the TBI protocol has not interfered with the education of residents, students, or nurses as some had feared. Instead, the emphasis on evidence-based medicine guidelines has promoted a more scientifically based understanding of these complex problems and provided intensive learning experiences for all concerned.

An important limitation of this study is the use of historical controls. Because of this limitation, it is not possible to exclude bias, random variation, or other uncontrolled variables from affecting the results of the study. In addition, it should be noted that it is difficult to confirm the accuracy of

the initial GCS score recorded because the patients may have been sedated or intubated or had other interventions to make their GCS score inaccurate. To remedy this and the other limitations of our retrospective design, we call for a large multicenter study of the outcomes of TBI care in the United States.

The implementation of an evidence-based medicine protocol for TBI care at our institution resulted in significant improvements in mortality, ICU and hospital lengths of stay, and hospital charges. As the state of knowledge in neurotrauma improves, we anticipate continued refinements and modifications to the TBI protocol. These data suggest that even with our current understanding of TBI, the broad adoption of guideline-driven care could lead to dramatic improvements in outcomes while significantly decreasing resource use and the charges for care.

REFERENCES

- Bullock R, Chestnut RM, Clifton G, et al. Guidelines for the management of severe head injury. *J Neurotrauma*. 1996;13:638–817.
- Sosin DM, Snizek JE, Thurman DJ. Incidence of mild and moderate brain injury in the United States, 1991. *Brain Inj*. 1996; 10:47–54.
- Centers for Disease Control and Prevention. Traumatic brain injury: Colorado, Missouri, Oklahoma, and Utah, 1990–1993. *MMWR Morb Mortal Wkly Rep*. 1997;46:8–11.
- Sosin DM, Snizek JE, Waxweiler RJ. Trends in death associated with traumatic brain injury, 1979 through 1992: success and failure. *JAMA*. 1995;273:1778–1780.
- U.S. Department of Health and Human Services. *Interagency Head Injury Task Force Report*. Washington, DC: U.S. Department of Health and Human Services; 1989.
- Guidelines for the Management of Severe Head Injury*. New York: Aitken Brain Trauma Foundation; 1995.
- National Academy of Sciences/National Research Council. *Accidental Death and Disability: The Neglected Disease of Modern Society*. Washington, DC: National Academy of Sciences; 1966.
- Brain Trauma Foundation Guidelines. Available at: <http://www.braintrauma.org>. Accessed August 26, 2000.
- Kolata G. Flawed treatment of head injuries found. *The New York Times: Health*. October 16, 1991:C14.
- Ghajar J, Hariri RJ, Narayan RK, et al. Survey of critical care management of comatose, head-injured patients in the United States. *Crit Care Med*. 1995;23:560–567.
- Traumatic Brain Injury in the United States: A Report to Congress*. Washington, DC: Division of Acute Care, Rehabilitation Research, and Disability Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; December 1999.
- Max W, MacKenzie EJ, Rice DP. Head injuries: costs and consequences. *J Head Trauma Rehabil*. 1991;6:76–91.
- Jaggi JL, Obrist WD, Gennarelli TA, et al. Relationship of early cerebral blood flow and metabolism to outcome in acute head injury. *J Neurosurg*. 1990;72:176–182.
- Colohan AR, Alves WM, Gross CR, et al. Head injury mortality in two centers with different emergency medical services and intensive care. *J Neurosurg*. 1989;71:202–207.
- Smith HP, Kelly DL, McWhorter JM, et al. *J Neurosurg*. 1986; 65:820–824.
- Saul TG, Ducker TB. Effect of intracranial pressure monitoring and aggressive treatment on mortality in severe head injury. *J Neurosurg*. 1982;56:498–503.
- Bowers SA, Marshall LF. Outcome in 200 cases of severe head injury treated in San Diego County: a prospective analysis. *Neurosurgery*. 1980;6:237–242.
- Becker DP, Miller JD, Ward JD, et al. The outcome from severe head injury with early diagnosis and intensive management. *J Neurosurg*. 1977;47:491–502.
- Miller JD, Becker DP, Ward JD, et al. Significance of intracranial hypertension in severe head injury. *J Neurosurg*. 1977;47:503–576.
- Muizelaar JP, Marmarou A, Ward JD, et al. Adverse effects of prolonged hyperventilation in patients with severe head injury: a randomized clinical trial. *J Neurosurg*. 1991;75:731–739.
- Marion D, Obrist WD, Penrod LE, et al. Treatment of cerebral ischemia improves outcome following severe traumatic brain injury. Presented at: 61st Annual Meeting of the American Association of Neurological Surgeons, April 24–29, 1993; Boston, Massachusetts.
- Narayan RK, Kishore PR, Becker DP, et al. Intracranial pressure: to monitor or not to monitor? A review of our experience with head injury. *J Neurosurg*. 1982;56:650–659.
- Rosner MJ, Daughton S. Cerebral perfusion pressure management in head injury. *J Trauma*. 1990;30:933–941.
- Ghajar JB, Hariri R, Patterson RH, et al. Improved outcome from traumatic coma using only ventricular CSF drainage for ICP control. *Adv Neurosurg*. 1993;21:173–177.
- Palmer S, Bader MK, Qureshi A, et al. The impact on outcomes in a community hospital setting of using the AANS traumatic brain injury guidelines. *J Trauma*. 2001;50:657–664.
- Spain DA, McIlvoy LH, Fix SF, et al. Effect of a clinical pathway for severe traumatic brain injury on resource utilization. *J Trauma*. 1998;45:101–105.

APPENDIX

Traumatic Brain Injury Protocol
Inova Regional Trauma Center
Inova Fairfax Hospital
Falls Church, Virginia

Inclusion Criteria: blunt head injury and age >14 and Glasgow Coma Score ≤8

Exclusion Criteria: patients without at least one AIS head injury greater than 2, AIS 6 injury died less than 48 hours after injury

Clinical protocol:

- Admit to Trauma Neuro ICU
- Standard ICU order set and TBI protocol orders
- Place ICP monitor, ventriculostomy preferred
- Administer prophylactic diltiazem intravenously
- Intubate and mechanically ventilate patient. Target pCO₂ approximately 35, “prophylactic” hyperventilation discouraged. Lidocaine suction protocol
- Place arterial line and pulmonary artery catheter
- Optimize head position for lowest ICP
- Aggressively maintain normothermia
- Use analgesia/sedation as needed (morphine and lorazepam preferred)
- Manage blood pressure and ICP to maintain CPP ≥ 70 mmHg and ICP ≤ 20 mm Hg. If CPP goal not met OR ICP > 20 mmHg, provide the following sequentially:

- drain ventriculostomy
- increase analgesia/sedation
- infuse crystalloid to ensure intravascular volume is adequate
- administer neuromuscular blocking agent
- infuse mannitol as intravenous bolus 0.5-1 mg/kg, monitor serum osmolality and repeat every 4-6 hours as long as osmolality < 320

ICU nursing staff will implement protocol and notify trauma and neurosurgery services of persistently abnormal values as well as major changes in status

- 11) If patient has persistent intracranial hypertension and inadequate CPP, notify trauma and neurosurgery attending for initiation of pentobarbital coma. Consult neurology for dosing and continuous bedside EEG monitoring for burst suppression

DISCUSSION

Dr. Akella Chendrasekhar (Des Moines, Iowa): The management of severe closed head injury is an area of significant importance in any trauma service. A consensus statement using evidence-based medicine on guidelines for the management of severe closed head injury was published by the Brain Trauma Foundation in 1995. These guidelines were in response to a series of articles that came out in both the lay press and the medical press regarding a lack of consistent treatment for severe closed head injury.

Dr. Trask and colleagues have undertaken the daunting task of evaluating the Brain Trauma Foundation guidelines for efficacy. They have chosen to look at mortality, patient length of stay, and hospital costs as outcome criteria for evaluation of these guidelines. The patient population evaluated were severe closed head injury patients and patients who had anatomic AIS scores > 2 for head injury and blunt mechanism injury.

In the results of the 498 patients that met inclusion criteria for this study, 219 were in their group I (1991-94), which didn't have any protocolized approach; 188 were in group II (1995-96), where they met 50% compliance; and 93 were in group III, where they met 85% compliance.

The ICU days showed a significant reduction between groups I and III and with the high compliance having a much shorter length of stay. Statistical significance was 0.02. This consequently resulted in a drop in cost as far as these patients were concerned.

I congratulate the authors on undertaking this daunting task. I have several questions for the authors and several comments for this distinguished body.

In your revised article, you provide a standard deviation and error of the means, but it was unclear which population this referred to. With the standard deviations for each of your study areas, such as ICU length of stay, the variation was so great that it was equivalent to your mean values in both the hospital length of stay and the ICU length of stay. Are your conclusions really valid if your variation is so great?

You stated that your compliance was improving and went from 50% to 85% by the third group. Compliance was simply measured by writing the initial orders and then you said further monitoring was performed. What type of monitoring was performed?

The difference between the two groups was approximately 2 ICU days per patient. This was statistically significant. However, could this not be an effect attributable to deliberate attention to detail as opposed to the guidelines themselves?

Did you make any measurement of GCS score of these patients on discharge from the intensive care unit? Perhaps this would have been a better indicator of guidelines for improving the management of head injury, which should result in improved neurologic outcome.

You noted a trend toward improvement in survival. Did you study attributable mortality rates? Was this reduction attributable to the improvement of the head injury? Did your patients die as a result of the head injury or did they die as a result of pneumonias or other complications?

The additional difference of 5 days in your historical control patients is problematic to me, because I'm not sure whether they were being actively medically treated or whether they were sitting on the floor awaiting transfer or discharge home. Finally, how do you plan on revising your protocol, and are you assessing individual components for efficacy?

I have two final comments for this body. First, these are guidelines, not standards. Unless we put forward a multicenter trial to evaluate these guidelines specifically, we're not going to have answers that we want in the decades to come.

The other issue that this article addresses is the turf issue. They've pointed out this has been the domain of neurosurgeons predominantly. The question is, for nonoperative traumatic head injury, are trauma surgeons as good if not better than neurosurgeons at managing these patients? That issue is going to have to be addressed at some point. I believe, as many members here do, that no group of professionals can lay claim to any area of medicine. I would like to thank both the authors and the Association for allowing me to review this article.

Dr. Jeffrey S. Hammond (New Brunswick, New Jersey): I enjoyed the article, and I agree with its conclusions. However, I think we would need some additional information before we could say that they've actually been fully demonstrated.

With regard to the question of length of stay, there are so many confounding variables that go into that that we would need to know. For example, were there any changes on the trauma service that would reduce the length of stay, other than adherence to this protocol? Was there a new social worker brought on board, case managers, changes in the trauma surgeons, new transfer agreements with rehabilitation centers, or other factors with regard to length of stay in the

ICU? Was that possibly attributable to, in that 6-year period, a step-down or intermediate care unit being brought on board?

As the discussant mentioned, I think there were other outcome variables better than death that could also have been measured, and perhaps there's a way of going back, if you have those data in your registry or can recreate them from your charts, in terms of looking at outcomes of neurologic status on discharge, such as the Glasgow Outcome Score, the Ranchos Dos Amigos Score, and the Disability Rating Score.

Dr. Arthur L. Trask (closing): Dr. Chendrasekhar, I appreciate your comments very much. We believe that the statistical diagnostics for the study were appropriate. There was one significant outlier that was trimmed prior to the analysis.

The issue of changes before 1995 and after really were all about the same—all of the people involved were the same, so we had the same number of social workers and the same number of patient care providers, just better organization. The idea of conducting a multicenter trial to expand on this seems worthwhile.

Finally, we agree that looking at more than death is important, and so we have formed the Mid-Atlantic Traumatic Brain Injury Consortium, and we are developing a database that will study all of the different outcomes that can be looked at, both early on after hospital discharge and then 5 and 6 years later. Thank you very much.

EDITORIAL COMMENT

How can we prove that implementation of standardized management guidelines improves patient outcomes? This is one of the biggest challenges of the entire guidelines effort. After all, guidelines are constructed by careful analysis of the strength of individual studies. Only a few studies represent the highest class of evidence, that is, prospective, randomized, controlled, blinded, well-executed, and properly analyzed. According to such standards, investigations about whether guidelines improve outcome would have to randomize half of the enrolled patients to guideline-based treatment and the other half to treatment that is not based on any guidelines. Of course, ethical prohibitions would make such a study impossible to conduct.

These are the stormy waters that Fakhry et al. chose to sail when they undertook this study. The review of this article caused a fair amount of controversy and disagreement at the Journal's editorial office. All the reviewers seemed to want to believe the basic message of this article, that is, that implementation of evidence-based guidelines is a good thing. Fur-

thermore, the reviewers realized that it was not possible to test this hypothesis by means of a randomized, prospective study. Thus, the authors had to use historical controls. However, the authors were accused of taking some liberties with the phrase, "an evidence-based medicine protocol." Specifically, although the authors used the Brain Trauma Foundation's guidelines as a starting point, they also incorporated many management principles that were not addressed in the guidelines. Simultaneously, they implemented several specific management protocols at their hospital. Thus, some of the reviewers felt that the authors were not assessing the effects of evidence-based guidelines per se as much as the effects of renewed interest in the most expeditious management of brain-injured patients. Some of their interventions were based on thoroughly reviewed guidelines, but others were based on institutional preferences.

Some reviewers also pointed out that, depending on its current practices, an individual hospital may see either increases or decreases in costs of hospitalization, lengths of stay, and similar measures. Hospitals that tend to adopt a rather cavalier attitude toward these patients may notice that length of stay goes down as standardized protocols expedite the performance of tracheostomies, insertion of percutaneous feeding tubes, and transfer of patients to rehabilitation or to long-term care. However, hospitals that currently direct only minimal resources toward the management of brain-injured patients may find that their costs and lengths of stay increase as they spend more money on monitoring, imaging, aggressive and expensive intensive care unit management, and so forth.

How should we interpret this article? It is indeed an irony that guidelines based on class I evidence may not be able to find anything other than class III evidence to support their efficacy. The current widespread infatuation with evidence-based medicine often overlooks the fact that even the most solidly supported guidelines must be tempered by common sense and must be applied in the real world. It is hard to argue with the basic premise of Fakhry et al. that patients do better if physicians and hospitals direct more time, effort, and resources to their management. This common-sense conclusion should not be discarded simply because class I evidence to support it is impossible to generate.

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