Chapter 40
The Management of Traumatic Brain Injury: The Development of Guidelines and Their Influence

Raymond F. Sekula, M.D. and Jack E. Wilberger, M.D., F.A.C.S.

INTRODUCTION

Trauma is a leading cause of death and disability in the United States. By conservative estimates, approximately 500,000 traumatic head injuries occur yearly, constituting a significant public health issue. More than 17,000 of the most severe head injuries result in death (23). Many more patients survive with significant disability. Although most frequent between the ages of 15 and 24 years, injury to the central nervous system occurs in significant numbers in children under the age of 5 and adults over the age of 75. Acute and chronic care of patients suffering central nervous system trauma constitutes a significant proportion of health care expenditures. The estimated cost to society from both productive years and income potential following traumatic brain injury (TBI) has been estimated at forty billion dollars annually (8).

The Brain Trauma Foundation and the Neurotrauma Foundation, in concert with the American Association of Neurologic Surgeons (AANS) and the Congress of Neurologic Surgeons (CNS), have been instrumental in forming evidence-based consensus groups to comprehensively review the available literature and provide standards, guidelines and options for the medical and surgical management of TBI (5). These in-depth reviews exposed a mixed group of well-founded practices along with frequently used, but unproven, intervention, giving basis both for strong recommendations of action and for future areas of research. These efforts led the way for the entry of traumatic neurosurgical practice into the evidence-based era of medical care.

PREGUIDELINES

Today, tremendous impetus for improving the care of patients with TBI exists. Significant advancements in the area of TBI have occurred over the past five decades. Data collection on large numbers of patients with TBI was begun in the late 1960s by Jennett et al. in Glascow. The first multinational coma data bank involved centers from Scotland, The Netherlands, and the United States. The resulting data bank was of considerable value in identifying factors responsible for a good or poor outcome after TBI (12).

The introduction of computed tomography (CT) in 1972 allowed for the first time ever the direct visualization of the brain and specific delineation of traumatic abnormalities. Given its revolutionary nature, it was impossible to perform comparative studies with previously available diagnostic tests such as pneumoencephalography and angiography. Despite the introduction of magnetic resonance imaging (MRI), CT has remained the primary diagnostic test in the acute evaluation of TBI. Although multiple studies have demonstrated superiority of MRI over CT in the detection of traumatic abnormalities such as diffuse axonal injury (9), various comparative studies have found CT to be superior to MRI in delineating the types of acute hemorrhagic lesions important in early management of TBI (13, 29).

In 1974, the Glascow Coma Scale (GCS) was developed by Teasdale and Jennett and has since been universally accepted as a reliable, objective measure of level of consciousness and head injury severity (30). The scale has

provided a common language for clinicians and investigators interested in TBI. In 1979, the National Traumatic Coma Data Bank (16, 18), a cooperative effort of six clinical head-injury centers in the United States, was developed to study the impact of a multitude of variables such as prehospital and emergency care management and other elements that may be responsible for the ultimate outcome in patients suffering acute TBI. Data was provided concerning the impact of emergency care, the role of rehabilitation in recovery, and ultimate prognosis in patients with TBI.

During the late 1970s and 1980s, the concept of secondary injury was appreciated and efforts were focused on management to prevent secondary insults to the brain (2, 17). As early as 1977, Becker, et al. published encouraging results of a uniform and aggressive method of treating patients with TBI (2). Critical areas in the management of TBI were identified and included early evacuation of mass lesions, control of intracranial pressure (2, 17, 20, 22), artificial ventilation, and medical therapy, including the use of barbiturates, osmotic agents, and steroids.

By the 1990s, optimization of cerebral perfusion pressure (CPP) emerged as a primary end-point in the management of patients with TBI, primarily based on the work of Rosner et al., who described improved outcomes in 158 patients in whom CPP was kept above 70mm Hg (27, 28). The authors provided Class II evidence that a CPP-driven protocol was superior to an intracranial pressure(ICP)-driven protocol in yielding lower mortality rates and higher Glasgow Outcome Score (GOS) in patients after TBI.

Over the past 20 years, however, randomized studies have begun to question some of the central tenets of secondary injury prevention. Evidence accrued that steroids do not improve outcome or lower ICP in patients with TBI (3, 6, 7). Muizelaar et al. produced a prospective randomized study demonstrating improved outcomes at 3 and 6 months when prophylactic hyperventilation was not used as compared to when it was used (21). Robertson et al. compared ICP-targeted therapy with CPP-targeted. They found no significant difference in GOS between the two groups, but the incidence of acute respiratory distress syndrome (ARDS) was significantly higher in the CPP-targeted group (25, 26).

EVIDENCE-BASED GUIDELINES

In the late 1980s and 1990s, interest in practice guidelines spread rapidly throughout the American health care system as a means of reducing inappropriate care, controlling geographic variations in practice patterns, and maximizing health care resources. Plans for guideline development or enforcement emerged in the federal government, specialty societies and other physician organizations, hospitals and hospital organizations, academic research centers, insurance carriers and managed care plans, and commercial enterprises that provide precertification and utilization review services, as well as health care advocacy initiatives such as the Leapfrog Group (32). The development of practice guidelines was slow to be embraced by all physicians for a variety of reasons and concerns. Although there was general agreement that guidelines can have a positive impact on patient outcomes, many feared that guidelines would have negative consequences such as: 1) threat of malpractice litigation associated with observing or deviating from practice guidelines (19), 2) inappropriate use or interpretation of available scientific evidence (33), and 3) restrictive application by third party payers and utilization reviewers limiting access of patients to services deemed “unnecessary or inappropriate” according to the guidelines.

Through the mid-1990s, only informal guidelines relying on expert opinion and “authoritative texts” existed for the

treatment of patients with traumatic brain injury. No standardized management guidelines had been developed nationally for TBI. The head injury guidelines effort began in part in response to significant variability in head injury care documented in an 1991 survey of trauma centers (10). Ghajar et al. collected data from 261 randomly selected hospitals from a total pool of 624 trauma centers comprised of 49% level I centers, 32% level II centers, and 2% level III centers. Tremendous variability in management was noted specifically in the use of intracranial pressure monitoring, use of cerebrospinal fluid drainage, barbiturates, and hyperventilation, osmotic diuretics for intracranial hypertension, and general use of corticosteroids for traumatic brain injury. Particularly concerning was that 29% of centers reported aiming for Paco2 values of <25 torr despite class I evidence against the use of hyperventilation. The study confirmed what many experts in the area of TBI had suspected: despite the best available scientific evidence, ICP monitoring was not used routinely in comatose patients, hyperventilation was used aggressively, and administration of corticosteroids was common in patients with TBI.

By this time, many experts in the area of TBI felt that the generation of treatment parameters based on the best available scientific evidence and their general acceptance and practice would at the least improve the likelihood of improved neurological outcome. In 1993, with the support of the Brain Trauma Foundation, a task force of neurosurgeons, each with expertise in the area of TBI, was assembled to produce evidence-based guidelines for the management of severe TBI. Each expert was initially assigned a topic and conducted a MEDLINE search, reviewed and graded articles pertinent to the topic, and produced a summary report. These reports were revised by the entire task force and by representatives of a European Advisory Committee and various stakeholders, including the AANS Guidelines and Outcomes Committee. In 1995, the task force published the Guidelines for the Management of Severe Head Injury (5), sponsored by the Brain Trauma Foundation and endorsed by the American Association of Neurological Surgeons. The Guidelines were distributed at no cost to every neurosurgeon in North America.

The authors provided evidenced-based standards, guidelines, or options, reflecting a high, moderate, and uncertain degree of clinical certainty, respectively, for 14 topics ranging from trauma systems and initial resuscitation to indications for intracranial monitoring, guidelines for cerebral perfusion pressure, use of hyperventilation, use of mannitol, the role of steroids, and several other areas of management. In their introduction, the authors wrote “our intent is that these Guidelines will clearly state the current scientific basis for our clinical practice. For most clinical practice parameters, scientific evidence if insufficient for standards of care, as is generally the case in most of current medical practice. Upgrading clinical practice parameters from option to guideline to standard will require focused, well-designed and carefully implemented research trials.” In fact, of the 14 topics analyzed, only three topics were deemed sufficiently scientifically sound to garner a designation as a standard. Comparable guidelines were also published by the European Brain Injury Consortium in 1997 (14). A revised version of the Guidelines for the Management of Severe Traumatic Brain Injury was most recently published in 2000 (1).

POSTGUIDELINES COMPLIANCE

From a global perspective, the treatment principles contained in the Guidelines for the Management of Severe Traumatic Brain Injury should offer a unique opportunity to study the impact of the use of guidelines on the effectiveness of current treatment in improvement, if any, and outcome. Although the Guidelines have been widely disseminated both in print and electronic media to not only neurosurgeons, but also trauma surgeons and critical care specialists, their implementation has been limited.

In 2000, Marion published the results of a questionnaire mailed in 1997 to all 3,156 board-certified neurosurgeons in North America regarding their management of patients with severe TBI. Roughly 40% completed questionnaires (15). The questions were similar to Ghajar¡¯s survey from 1991. Ninety-three percent of the respondents indicated they were familiar with the guidelines. Despite differences in the design of the two studies (most apparent was that Marion¡¯s questionnaire was sent to neurosurgeons and Ghazar¡¯s questionnaire was sent to nurse managers, clinical specialists, and staff nurses), results indicated that there was a significant increase in the proportion of neurosurgeons who felt that patients with TBI should have ICP monitoring and a decrease in the proportion who used prophylactic hyperventilation and steroids. Ninety-seven percent of the respondents agreed with the statement ¡°Cerebral perfusion pressure should be maintained at >70 mm Hg whenever possible,¡± despite its designation in the Guidelines at the level of an option rather than a standard or guideline. The overall impression from the survey was that ¡°there have been significant changes in the acute management of patients with severe TBI since 1991. Current practices more closely reflect the recommends of evidence-based guidelines.¡± In 2002, Bulger et al. published the results of a retrospective data collection for consecutive patients with closed head injury and GCS¡Ü8 treated at 34 academic trauma centers (28 level I, 6 level II). There was considerable variation in the rates of prehospital intubation, ICP monitoring, ICP-directed therapy, and the use of head CT scans across centers (4). In 2002, Hesdorffer et al. (11) published the results of a survey in 1999 and 2000 from all designated United States trauma centers managing patients with TBI to determine the degree of guideline compliance and to identify predictors. Of 924 centers identified, 828 (90%) participated. Only 16% of centers were fully compliant with the guidelines. The authors identified three factors predicting high guideline compliance: 1) a neurosurgical residency program, 2) state designation or ACS verification, and 3) established hospital-based protocol based on the Guidelines for the Management of TBI. The authors concluded that patients with TBI should be directed to such centers.

POSTGUIDELINES OUTCOMES

One explanation for low compliance with the Guidelines is the paucity of published studies documenting the impact of their use on outcome. This is in part owing to the limitations in study design as, at least in the United States, it is not possible to prospectively study guideline- versus nonguideline-based TBI care. A few studies, however, have been attempted.

In 1998, Spain et al. demonstrated a 22% reduction in intensive care unit days, a 24% decrease in ventilator days, and a 20% reduction in survivors¡¯ hospital costs after the implementation of ¡°a clinical pathway for severe TBI¡± developed by a multidisciplinary team at the University of Louisville Hospital. No clinical outcome data was provided. This study was completed just before the release of the Guidelines for the Management of Severe Head Injury. Based on the positive response to their own internal clinical pathway, the authors have since modified their TBI pathway to incorporate the recommendations of the Guidelines.

An effort was begun in the late 1990s to introduce the Guidelines to several Eastern European countries (Croatia, Hungary, Slovakia, and Slovenia) where, because of severely limited resources, there existed virtually no treatment for TBI. This offered the opportunity not only to improve medical care, but to prospectively evaluate whether the guidelines improved the ¡°natural history¡± of TBI. They looked at outcome in 16 patients treated before the guidelines and 23 patients after a portion of the guidelines was instituted (31). Preliminary data found the 2-week mortality reduced from 47 to 24% and GR/MD at 6 months improved from 18 to 29% after introduction of the guidelines along with the technology, such as ICP monitoring with which to implement them.

In a community hospital setting, Palmer et al. reported an odds ratio of 3.0 favoring a good outcome in 56 guidelines-managed patients as compared with 37 preguidelines patients. The proportion of deaths declined by more than half, and the proportion of good outcomes more than doubled following implementation of the Guidelines, even though the costs increased by almost $100,000 per patient. These findings, however, are controvertible as the sample size was small and, although the Guidelines were followed for the most part, confounding variables exist such as the reported use of decompressive craniectomy ¡°both preemptively and in response to uncontrollable ICP¡± in selected patients from both cohorts (24).

Bulger et al. collected data on patients treated at 34 academic trauma centers in the United States. They categorized centers as ¡°aggressive¡± versus ¡°nonaggressive¡± defined by whether they placed intracranial pressure monitors in >50% of patients meeting the Guidelines¡® criteria for ICP monitoring. Management at an aggressive center was associated with a significant reduction in the risk of mortality, but there was no statistically significant difference in functional status at the time of discharge for survivors (4).

The most comprehensive study was undertaken by Fakhry, et al allocating patients into three cohorts from 1991 to 2000 (preGuidelines, 1991¨C1994; low Guidelines compliance, 1995¨C1996; and high Guidelines compliance, 1997-2000). The overall mortality rate showed a reduction of 4% from 1991¨C1994 to 1997¨C2000 (17.8 versus 13.8%), although this was not statistically significant. On the basis of the GOSe, in 1997¨C2000, 61.5% of patients had either ¡°good recovery¡± or only ¡°moderate disability,¡± compared with 50.3% in 1995¨C1996 and 43.3% in 1991¨C1994. Additionally, reduction in hospital days and charges was also documented, although this may have more to do with more aggressive overall TBI care such as tracheostomy and nutritional support (8).

THE FUTURE

It is thus a paradox that it is unlikely that the efficacy of evidence-based guidelines will ever be proven with the same level of scientific rigor that the guidelines to some extent themselves are based. Does this mean that guidelines for TBI should be abandoned? Common sense and expert opinion would hold otherwise.

A new version of the Guidelines for the Management of Traumatic Brain Injury is expected in December 2005. The authors will update previous recommendations and provide new recommendations concerning such controversial topics such as use of hyperosmolar therapy, hypothermia, and the role of decompressive craniectomy.

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