Suboptimal compliance with evidence-based guidelines in patients with traumatic brain injuries

Clinical article

SHAHID SHAHI, M.D., M.P.H., SUNNI A. BARNES, PH.D., D MILLAR, M.D.,
JUSTIN SOBRINO, M.D., RUSTAM KUDIYAKOV, M.D., M.P.H., CANDICE BERRYMAN, B.S.,
NADINE RAYAN, M.H.A., ROSEMARY DUBIEL, M.D., RUAL COIMBRA, M.D., PH.D.,
LOUIS J. MAGNOTTI, M.D., GARY VERCURYSE, M.D., LYNETTE A. SCHERER, M.D.,
GREGORY J. JURKOVICH, M.D., and RAMINDER NIRULA, M.D., M.P.H.

1Institute for Health Care Research and Improvement and 2Baylor Institute for Rehabilitation, Baylor Health Care System, Dallas, Texas; 3Department of Surgery, University of California San Diego, California; 4Department of Surgery-General, University of Tennessee Health Science Center, Memphis, Tennessee; 5Division of Trauma/Surgical Critical Care, Emory University, Atlanta, Georgia; 6Department of Surgery, University of California Davis, Sacramento, California; 7Department of Surgery, Denver Health Medical Center, Denver, Colorado; and 8Department of Surgery, University of Utah, Salt Lake City, Utah

Object. Evidence-based management (EBM) guidelines for severe traumatic brain injuries (TBIs) were promulgated decades ago. However, the extent of their adoption into bedside clinical practices is not known. The purpose of this study was to measure compliance with EBM guidelines for management of severe TBI and its impact on patient outcome.

Methods. This was a retrospective study of blunt TBI (11 Level I trauma centers, study period 2008–2009, n = 2056 patients). Inclusion criteria were an admission Glasgow Coma Scale score ≤ 8 and a CT scan showing TBI, excluding patients with nonsurvivable injuries—that is, head Abbreviated Injury Scale score of 6. The authors measured compliance with 6 nonoperative EBM processes (endotracheal intubation, resuscitation, correction of coagulopathy, intracranial pressure monitoring, maintaining cerebral perfusion pressure ≥ 50 cm H2O, and discharge to rehabilitation). Compliance rates were calculated for each center using multivariate regression to adjust for patient demographics, physiology, injury severity, and TBI severity.

Results. The overall compliance rate was 73%, and there was wide variation among centers. Only 3 centers achieved a compliance rate exceeding 80%. Risk-adjusted compliance was worse than average at 2 centers, better than average at 1, and the remainder were average. Multivariate analysis showed that increased adoption of EBM was associated with a reduced mortality rate (OR 0.88; 95% CI 0.81–0.96, p < 0.005).

Conclusions. Despite widespread dissemination of EBM guidelines, patients with severe TBI continue to receive inconsistent care. Barriers to adoption of EBM need to be identified and mitigated to improve patient outcomes.

Key Words • evidence-based management • quality of care • traumatic brain injury • quality chasm • variations in care

Abbreviations used in this paper: AIS = Abbreviated Injury Scale; BTF = Brain Trauma Foundation; CMS = Centers for Medicare and Medicaid Services; EBM = evidence-based management; GCS = Glasgow Coma Scale; ICP = intracranial pressure; ISS = Injury Severity Score; O-E = observed-to-expected; POC = process of care; SBP = systolic blood pressure; TBI = traumatic brain injury.

T he Trauma Quality Improvement Project of the American College of Surgeons has demonstrated significant variations in risk-adjusted outcomes of patients with moderate to severe injuries at designated trauma centers despite the availability of optimal resources (http://www.facs.org/trauma/ntdb/tqip.html). Donabedian principles of quality management suggest that if patient outcomes are inconsistent among centers despite adequate resources, there must be differences in clinical practices among centers.3 Evidence-based management (EBM) protocols have been developed to improve clinical practices (http://www.east.org/resources/treatment-guidelines).4 In fact, the Centers for Medicare and Medicaid Services (CMS) and the Joint Commission for Accreditation of Health Care Organizations now require compliance with several EBM protocols as quality measures, such as congestive heart failure and surgical care (http://www.medicare.gov/hospitalcompare/search.html). Despite these efforts, compliance with several evidence-based processes of care (POCs) remains just over 50%.7,8,11

Traumatic brain injury (TBI) is the leading cause of death and disability due to injuries in all age groups.1 The Brain Trauma Foundation (BTF) has developed evidence-based practice management guidelines for treating severe TBI.2 The purpose of the current study was to measure compliance with several BTF guidelines in a multicenter sample of TBI patients.
This is a secondary analysis of data that were collected by the Multi-Institutional Trial Committee of the American Association for the Surgery of Trauma for a study on decompressive craniectomy. Patients were accrued over a 2-year period (1/1/2008 through 9/9/2009) from 11 Level I trauma centers (n = 3074). These included patients with blunt TBI in whom the admission Glasgow Coma Scale (GCS) score was ≤ 13 and in whom admission CT had demonstrated evidence of a TBI; patients aged 99 years or older were excluded. The current study was restricted to patients with severe TBI defined as an admission GCS score ≤ 8 and excluding those with non-survivable head injuries (defined as an Abbreviated Injury Scale [AIS] score of 6). Final study population consisted of 2056 patients. Detailed information on patient demographics, injury characteristics, treatment interventions, and hospital outcomes were obtained from participating centers by utilizing a retrospective chart review and trauma registry data.

Traumatic Brain Injury Processes of Care

The most recently published evidence-based guidelines of the BTF were reviewed. Based on these guidelines, a list of 6 nonoperative POCs was developed (Table 1). These 6 processes were selected because they are generally accepted practices, do not require any specialized equipment or resources beyond those available at trauma centers, and compliance with them could be measured in a retrospective study. Use of intracranial pressure (ICP) monitoring remains controversial, but as of the writing of this manuscript, BTF continues to recommend its use.

Operative interventions such as craniotomy and craniectomy were not included in the current study, as we felt that the complexity of decision making for operative interventions could not be adequately captured in a retrospective study. For each POC, we identified patients who were eligible for that process and whether they received the care or not. An explicit definition of eligibility was developed for each POC based on BTF guidelines. The eligibility criteria were further restricted to maximize the likelihood that only patients who were absolutely likely to require the intervention will be included. Using these definitions, patients in the study population were eligible for a total of 5021 POCs. Values for patients who were eligible for each specific process are reported as percentage of total study population. Values for patients who received the care are reported as percentage of patients who were eligible for that POC. In addition, for each patient, a compliance score was calculated based on the opportunity model used by CMS for reporting compliance with their core measures. For example, if a patient was eligible for 5 POCs and received 3 of them, his compliance score was 60. Similarly, if a patient was eligible for 2 POCs and received both, his compliance score was 100. Compliance rates with 95% confidence intervals are reported for each of the 6 POCs as well as for each of the 11 centers.

Statistical Analysis

All analyses were conducted using SAS version 9.3 (SAS Institute). Test statistics with an associated probability of p ≤ 0.05 were considered statistically significant unless otherwise noted. Data are summarized as mean (± SD) and median (with IQR) for continuous variables and proportions for categorical variables. Odds ratios with 95% confidence intervals are reported when appropriate.

Outcomes. The primary outcome of interest was compliance with each POC. Patients in this study (n = 2056) were eligible for a total of 5021 POCs that constituted units of observations for the primary outcome. The secondary outcome of interest was in-hospital mortality. For this analysis, each patient was treated as a unit of observation. The relationship between outcomes and various predictors was measured using generalized estimating equation with a logit link. Generalized estimating equations take into account the correlation among outcomes within a unique patient because several patients were eligible for more than 1 POC. The patient nested within the center was the cluster effect in compliance models, and the trauma center was the cluster effect in mortality models. Univariate analysis was carried out first, and then a multivariate model was developed to identify independent predictors of outcomes after adjusting for potential confounding factors listed below. The final model for mortality was also used to estimate the number of lives that may be saved by improvements in compliance scores.

Predictors. Several predictors that may affect the outcomes of interest were explored: 1) patient characteristics were age, sex, race/ethnicity (minority vs others), insurance status (uninsured vs others), comorbidities (present vs absent); and 2) injury characteristics were Injury Severity Score (ISS), systolic blood pressure (SBP) on admission, heart rate on admission, and severity of head injuries as measured by the GCS score on admission, head AIS score, and the Marshall score for the first head CT scan.

Observed to Expected Compliance Scores. Observed-to-expected (O-E) compliance scores were calculated for each center. To do this, we first calculated the expected compliance for each POC after adjusting for the patient factors listed above. Each center’s expected compliance rate was the sum of all individual expected compliance rates for all processes within that center. The O-E compliance ratio for each center was then obtained by dividing the observed compliance rate by the expected compliance rate, with 95% CIs. Ratios were multiplied by 100 to give the final compliance score for each center. Hence, an O-E compliance score with 95% CI overlapping 100 indicated that compliance rates with 6 POCs was just as expected. An O-E score significantly higher than 100 indicated centers with better-than-expected compliance rates, whereas an O-E score significantly lower than 100 indicated centers with worse-than-expected compliance rates.

Sensitivity Analysis. It is possible that recommended care may be withheld from patients who are expected to die because of the severity of their injuries. To minimize this effect, we measured the relationship between compliance and mortality in the entire group and after excluding patients with the highest likelihood of death.
Evidence-based guideline compliance in TBIs

Results

The study population was typical for Level I trauma centers. The patients mean age was 43 ± 20 years, 74% were male, 39% were minorities, and 29% were uninsured. The most common mechanisms of injury were motor vehicle related (55%) and falls (30%). Time from injury to arrival at the trauma center was available for 1829 patients, and 1573 (86%) of these arrived within 6 hours of injury. Patients were severely injured with a mean ISS of 30 ± 13, and the unadjusted mortality rate was 34%. Patients who had sustained severe head injuries; their median head AIS score was 5 (IQR 4–5), and their median GCS score at admission was 3 (IQR 3–6), suggesting a coma-like state. Some patients had sustained associated injuries to the chest (941 patients, median chest AIS Score 3) and the abdomen (541 patients, median abdomen AIS Score 2).

Patients in the study population were eligible for a median of 2 processes per patient (range 1–5 processes). Overall, the mean compliance rate in the entire study population was 73% (95% CI 72%–74%). The mean compliance rate was 67% (IQR 50%–100%). This indicates that half of the patients received only two-thirds of the care they needed. Only 950 patients (46%) received 100% of the indicated care, whereas 1106 (54%) patients did not.

Compliance rates varied by specific processes and by centers. The highest compliance was noted with endotracheal intubation (92%), and the lowest compliance was with ICP monitoring (52%) (Table 1). Rates of ICP monitoring at different centers varied from 23% to 85% even though 10 of the centers reported having a written protocol for ICP-directed management. Among patients who had an ICP monitor placed, target cerebral perfusion pressure was not achieved in one-quarter of the patients. There were wide variations in practices among centers and within centers (Figs. 1 and 2). For example, at Center 4, compliance with the 6 processes ranged from 12% to 92%. Observed-to-expected compliance scores by centers indicated that risk-adjusted compliance with EBM was worse than expected at 2 centers and better than expected at 1; the remainder were within the expected range (Fig. 3).

The mean GCS score at discharge among survivors was 13 ± 3, but only 45% of the patients were discharged to rehabilitation centers. Uninsured patients were less likely to be discharged to rehabilitation centers, after adjusting for the severity of their head injuries and other potential confounding factors (OR 0.42; 95% CI 0.19–0.93).

Multivariate analysis showed that a higher head AIS score, lower Marshall score on initial head CT scan, and higher SBP were associated with a higher likelihood of compliance, whereas increasing age, female sex, and lack of health insurance were associated with lower likelihood of compliance (Table 2). Independent predictors of death included age and injury severity. A higher ISS and higher head AIS score were associated with an increased mortality rate, whereas a higher GCS score and lower Marshall score were associated with a lower mortality rate. Also, operative interventions of craniotomy and craniectomy were associated with lower risk of death.

Notably, increased compliance with these 6 EBM processes was associated with a reduction in the mortality rate (Table 2). Every 10% increase in compliance was associated with a 12% reduction in the risk of death (OR 0.88, 95% CI 0.81–0.96). To minimize the impact of severe and potentially nonsurvivable injuries on the delivery of care, we estimated the association between compliance and mortality after excluding patients with the highest likelihood of death (top decile). In this subgroup of 1853 patients, increased compliance was still significantly associated with a reduced mortality rate (OR 0.89, 95% CI 0.82–0.97). This relationship remained significant even after excluding all patients with greater than 75% probability of death (OR 0.91, 95% CI 0.83–0.99 among a subgroup of 1746 patients with probability of death ≤ 0.75).

Discussion

There are 2 key findings of this study. First, decades

<table>
<thead>
<tr>
<th>No.</th>
<th>POC No.</th>
<th>Process of Care</th>
<th>Definition</th>
<th>Eligibility (no. eligible)</th>
<th>No. Compliant (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>endotracheal intubation</td>
<td>endotracheal intubation at admission or in the field</td>
<td>all patients (2056)</td>
<td>1890 (92)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>resuscitation</td>
<td>transfusion of packed RBCs in 1st 24 hrs if hypotensive &amp; bleeding</td>
<td>SBP on admission ≤ 90 mm Hg &amp; hematocrit on admission &lt; 30 (64)</td>
<td>48 (75)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>correction of coagulopathy</td>
<td>transfusion of fresh-frozen plasma in 1st 24 hrs if coagulopathic</td>
<td>admission INR &gt; 1.5 (243)</td>
<td>164 (67)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>ICP monitoring</td>
<td>use of ICP monitor or ventriculostomy to measure ICP</td>
<td>total GCS score ≥ 8 at 24 hrs &amp; age ≤ 65 yrs (1569)</td>
<td>818 (52)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>ICP-directed therapy</td>
<td>maintaining CPP ≥ 50 cm H₂O on Day 2</td>
<td>all patients w/ ICP monitor or ventriculostomy on Day 2 (978)</td>
<td>742 (76)</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>physical therapy &amp; rehabilitation after discharge</td>
<td>discharge to rehabilitation w/ persistent deficits at discharge &amp; able to participate in therapy</td>
<td>all patients who survived to discharge &amp; w/ GCS score of 12 or 13 at discharge (111)</td>
<td>71 (64)</td>
<td></td>
</tr>
</tbody>
</table>

* CPP = cerebral perfusion pressure; INR = International Normalized Ratio; RBC = red blood cell.
after the establishment of evidence-based guidelines, the management of patients with severe TBI remains suboptimal. Second, improved compliance with recommended care is associated with improved patient outcomes.

This is the first multicenter study of TBI patients to measure compliance with recommended care and shows significant variations in the quality of care across trauma centers. Unfortunately, the findings are consistent with previous studies of medical diseases. McGlynn et al. studied the management of several acute and chronic diseases and showed that, on average, patients receive about half of the recommended medical care processes.7 Other studies have shown that less than half of patients with acute myocardial infarction who were eligible for thrombolytic therapy received it during hospitalization.9 Only 45% of the patients who suffered heart attacks received beta blockers, whereas only 28% smokers received advice on smoking cessation. In the current study, only 46% of the patients received the care indicated for TBI.

The findings of the present study reflect a significant gap in the quality of care for TBI patients. Currently, the trauma center designation process focuses primarily on provision of “optimal resources” and on delivery of “optimal care.”11 For example, there is no requirement for trauma centers to use EBM protocols. Hence, gaps in clinical practices noted in this study are not surprising. Noncompliance with EBM results in over- or underutilization of specific therapies and increase health care costs with no improvement in patient outcomes.8–11 Our findings also indicate that compliance with EBM may be associated with a reduced mortality rate.

Delivery of optimal care requires adoption of scientific knowledge into routine clinical practice. However, this is a complex process requiring multiple interventions.5,6,12 Approaches to enhance compliance with guidelines include use of standardized order sets, computerized decision support systems, and checklists. A checklist of clinical care processes that a patient is eligible for based on his or her injuries and injury severity may enable providers to monitor these processes at the bedside regularly. Such checklists may also be used as a performance improvement tool.

Limitations

This study has a few limitations that must be acknowledged. It is a retrospective analysis, with all its inherent limitations. Statistical association between compliance and mortality does not establish causal relationships. The findings reflect the experience of a few trauma centers around the country with their own unique characteristics that may not be applicable to other institutions. However, all centers included in this study are Level I academic medical centers of good repute. Compliance with specific processes was determined based on retrospective chart review. Therefore, the findings may simply reflect lack of documentation and not lack of compliance. However, our analysis suggests wide variations in care across several centers and across different processes within each center, suggesting that it was more likely lack of care and not lack of documentation. An important limitation of this study is that we were not able to determine the reasons for noncompliance. For example, it may be appropriate to withhold certain interventions in patients with nonsurvivable injuries or a terminal preexisting condition. In these clinical scenarios, a lack of adherence to practice guidelines by clinicians may not constitute suboptimal care. We attempted to minimize the impact of this issue by excluding patients with the highest likelihood of death. It should be noted that the purpose of this study was not to determine the effectiveness of specific clinical processes, such as ICP monitoring, but to determine if current clinical practices were consistent with published guidelines. In other words, our findings do not identify “best practices” in TBI care. However, they do suggest that compliance with cur-
Evidence-based guideline compliance in TBIs

<table>
<thead>
<tr>
<th>Predictor</th>
<th>OR (95% CI)</th>
<th>Compliance w/ EBM</th>
<th>Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>age</td>
<td>0.98 (0.98–0.99)</td>
<td>1.03 (1.02–1.05)</td>
<td></td>
</tr>
<tr>
<td>female sex</td>
<td>0.76 (0.66–0.87)</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>uninsured</td>
<td>0.81 (0.70–0.93)</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>SBP (admission)</td>
<td>1.001 (1.00–1.003)</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>ISS</td>
<td>NS</td>
<td>1.03 (1.008–1.05)</td>
<td></td>
</tr>
<tr>
<td>GCS score (admission)</td>
<td>NS</td>
<td>0.79 (0.73–0.86)</td>
<td></td>
</tr>
<tr>
<td>head AIS score</td>
<td>1.17 (1.08–1.28)</td>
<td>2.18 (1.52–3.14)</td>
<td></td>
</tr>
<tr>
<td>Marshall score ≥2 (admission)</td>
<td>1.38 (1.20–1.58)</td>
<td>0.11 (0.08–0.15)</td>
<td></td>
</tr>
<tr>
<td>craniotomy</td>
<td>NA</td>
<td>0.45 (0.29–0.72)</td>
<td></td>
</tr>
<tr>
<td>decompressive craniectomy</td>
<td>NA</td>
<td>0.40 (0.25–0.62)</td>
<td></td>
</tr>
<tr>
<td>compliance score (per 10% increase)</td>
<td>NA</td>
<td>0.88 (0.81–0.96)</td>
<td></td>
</tr>
</tbody>
</table>

* NA = not applicable; NS = not significant.
† Predictors explored for the compliance model included age, sex, race/ethnicity, insurance status, comorbidities, SBP and heart rate on admission, ISS, GCS score at admission, head AIS score, and Marshall score on initial head CT scan.
‡ Predictors explored for the mortality model included all of the above plus compliance score, craniotomy, and decompressive craniectomy.

Conclusions

This study suggests significant quality gaps in the management of patients with severe TBI, with potential adverse effect on patient outcomes. Further studies are needed to identify barriers to implementation of evidence-based guidelines and to mitigate them.

Acknowledgment

We wish to thank Kelli R. Trungale, M.L.S., E.L.S., for editorial assistance.

Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Support was provided in part by a grant from the National Institute on Disability and Rehabilitation Research (no. H133A070027-11) and by the American Recovery and Reinvestment Act/National Institute of Neurological Disorders and Stroke (nos. 1RC1NS069066-01 and 5RC1NS069066-02).

Author contributions to the study and manuscript preparation include the following. Conception and design: Shafi, Barnes, Dubiel. Acquisition of data: Kudyakov, Berryman. Analysis and interpretation of data: Barnes, Kudyakov, Rayan. Drafting the article: Shafi, Sobrino. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Shafi. Statistical analysis: Barnes, Rayan. Administrative/technical/material support: Sobrino, Kudyakov, Berryman, Rayan. Study supervision: Dubiel, Nirula.

References


Manuscript submitted June 24, 2013. Accepted December 5, 2013.

Please include this information when citing this paper: published online January 17, 2014; DOI: 10.3171/2013.12.JNS132151.

Address correspondence to: Shahid Shafi, M.D., M.P.H., Institute for Health Care Research and Improvement, Baylor Health Care System, 8080 N. Central Expressway, Ste. 500, Dallas, TX 75206. email: shahid.shafi@baylorhealth.edu.