EDITORIAL

Severe traumatic brain injury and decompressive craniectomy**P. David Adelson, MD**

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WHILE traumatic injuries and in particular traumatic brain injury (TBI) remain a leading cause of death and disability in children, some have argued that we have made few gains in the appropriate initial assessment and treatment to affect outcome. Most of the improvements in understanding for the treatment of children following TBI have come from single-institution series, with very few prospective multicenter trials. Collation and analysis of these studies through meta-analyses and evidence-based medicine methodologies have resulted in guidelines that have been limited in their scope as to the best approach and recommendations for management of these children's injuries. There have been many challenges to pushing the science in this area forward. These include the variability of presentation, clinical course, and recovery—elements that have not been well defined to provide a deep characterization of each person/child suffering injury.

The recent literature on decompressive craniectomy (DC) has highlighted the difficulties that have been encountered in attempting to apply a treatment modality broadly across severe TBI. Whereas early history was very unfavorable to the use of DC in TBI, the experience of its use in the recent conflicts in the Middle East as a primary upfront modality for blast and penetrating injuries seemed to point toward a more favorable result, with markedly reduced mortality and improved long-term outcome.¹ In civilian TBI, DC has for the most part been used as a primary therapy following failure of medical management for brain swelling and herniation, or as a secondary therapy on evacuation of a mass lesion. Recent attempts at studying its use in randomized controlled trials have not been successful to show its efficacy.² There have been no large-scale randomized clinical trials for the use of DC in the management of children with severe TBI, and therefore the evidence for the use of DC in children has come from case series and from single-institution studies,

with Class III evidence. The sole recommendations in the Pediatric Guidelines have been that DC may be effective in reversing early neurological deterioration or herniation, and has been correlated with improving outcomes in patients with intracranial hypertension refractory to medical management.³

In an attempt to address the question of whether DC would improve outcome in children following severe TBI, Mhanna and colleagues⁴ used a retrospective, case-control study in which patients treated with DC over a 10-year period were matched to patients who were treated medically without DC. In this study, 17 children were treated with DC and 17 with just medical management; the latter were chosen during the same time period, and classified as contemporarily treated. In this paradigm, patients were able to be matched for age, sex, weight, Glasgow Coma Scale score, and highest intracranial pressure (ICP). There were differences though: the first in CT findings of a higher rate of herniation and cerebral edema among the patients who had DC as compared to medical management alone; and the second in the use of external ventricular drainage, which was higher in the medical management/control group. The authors did find that, although there was no significant difference in survival between the groups, among the survivors those patients who underwent DC had improved outcome based on Glasgow Outcome Scale (GOS) scores. The authors conclude that early DC in pediatric patients with severe TBI improves outcome in survivors, even in the presence of imaging findings of herniation and/or severe cerebral edema. They attribute their improved outcomes to the aggressive management of these patients; the median time from injury to decompression was 2 hours.

Although I applaud the authors for taking on the challenge of studying pediatric TBI and its management, this study suffers from many of the same issues that have hampered advancement in our clinical knowledge base in TBI

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for both adults and children. This again is a small retrospective study of patients treated over the span of 10 years that varies by surgeon and patient presentation, and that despite improved outcomes does not provide insight into decision making for the use of surgical intervention for cranial decompression as compared to medical management alone—there was no algorithm for decision making in these patients. Because of the retrospective nature of the study, and despite case controls being obtained from contemporary patients not treated with surgical intervention, the design is still unable to address whether DC might be preferable in certain types of injuries. The findings of differences between groups on imaging might suggest that early DC for impending herniation or severe cerebral edema might be useful, but because of the small groups and limited number of similar patients, no conclusions can be made. Similarly, because they did not address the specific surgical complications of the patients with surgical intervention, the relative impact of DC on global or long-term outcomes could not be determined.

As the authors cite in their discussion, ICP has been used as an indication for DC in patients with severe TBI, and it has been used as a target in previous studies of indications for this treatment as well as in other therapeutic clinical trials. Because of the early DC in this patient population, it is unclear what the ICP value was prior to surgery, and thus the impact of DC on ICP in this group of patients is unknown. Postoperatively there were no differences in ICP or cerebral perfusion pressure, and therefore at least in this study ICP was not related to treatment or to outcome in survivors. It is clear that ICP alone is not a sufficient end point, specifically for outcome or to predict long-term outcome, and so more comprehensive long-term evaluations of these patients are required. Future approaches to the collection of ICP may require more continuous measures as well as a multimodal approach to correlate the complex physiological changes that occur in the brain following severe TBI and their impact on long-term functional outcome. Similarly, there have been a number of new additions to global outcome measures and scales, including the GOS-Extended (GOS-E), the GOS-E Pediatric, and others. The optimal battery of tests remains to be defined, but the aforementioned tests were not used in this study.

Clinical research in TBI remains a challenge. For example, numerous articles on TBI are published each year, but unfortunately they only provide limited and weak evidence, often conflicting with previous work, and the clinician is given little to no direction in the management of these patients. Despite the lessons learned in developing the guidelines concerning articles that meet criteria to provide sufficient evidence for inclusion, the vast majority of what is published gets excluded. Also, even if a study is well intentioned (i.e., a randomized clinical trial), not all clinical trials provide adequate levels of evidence to justify changes in the recommendations for management. Similar to our colleagues in other fields, we need to appreciate that head injuries in any one patient are not the same as in the next patient, even if contemporary. This will require multiple approaches of study, including basic translational science and ongoing clinical studies using

trauma registries; prospective studies (both randomized and with novel clinical models); and statistical analyses that are well designed up front, such as those composed of effectiveness research and randomized trials from large-scale registries, to better align with the complexity that patients with TBI present and to provide sufficient information and guidance for clinical practice.

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Response

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We agree with Dr. Adelson that most of the studies on TBIs come from single-institution series and are retrospective studies. Severe TBI contributes to one-third of all injury-related deaths in the US,¹ and it has been difficult to study in children. Severe TBI represents less than 1% of all TBIs in children;² therefore there is a need for collaboration among investigators to recruit a large number of patients to address the best ways to treat these individuals. Few hospitals in the US treat a large number of children with severe TBI;³ hence it is important that these centers collaborate and implement multicenter, interventional-based studies of severe TBI.

Awaiting the results of a well-designed prospective multicenter study, we sought to shed light on the beneficial effect of DC in children with severe TBI. We agree with Dr. Adelson that the limitations of our study stem from its retrospective nature, the small number of patients enrolled from a single institution, the long duration of enrollment, and the lack of a priori criteria for DC. To adjust for such limitations, we designed our study as a contemporary case-control study to account for potential changes in the management of severe TBI over the years.

Despite our best efforts to control for most confounders, we could not control for the presence of external ventricular devices between the groups. There was a higher percentage of children with external ventricular drainage in the control group, yet children with DC had a better

long-term outcome, which was not related to a difference in ICP between the groups. This finding suggests that DC had an effect on TBI outcome that was not related to the control of the ICP alone, which could have been achieved by CSF drainage. This remains speculative because our study was a retrospective study, and ICP values were abstracted from the medical records. It is possible that sudden changes in ICP could have been missed if they were not recorded by the nursing staff. It is also possible that we might have diluted our numbers by averaging out our daily high and low parameters for statistical analysis.

We also agree with Dr. Adelson that despite our design, we are unable to address the actual indication for DC, except that children who underwent a DC had a higher percentage of herniation and cerebral edema in comparison to their controls. This higher severity of illness may in part be the rationale for an early surgical intervention, but again it is speculative. Short of a prospective, randomized controlled trial, it would only be speculative to recommend early DC in children with severe TBI coupled with herniation and/or cerebral edema on their head CT scans.

Our study sheds light on the short- to mid-term outcome

of children with severe TBI who underwent a DC; however, long-term outcome studies are needed to elucidate the impact of DC on the long-term functional outcomes. In addition, there is a great need for conducting a large, multi-center, randomized clinical trial in severe TBI to determine the best ways to prevent the devastating complications of this condition.

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