Decompressive craniectomy for severe traumatic brain injury Guidelines

Level of Evidence 1

Level of Evidence 1

There was insufficient evidence to support a Level I recommendation for this topic.

Level of Evidence 2

Level of Evidence 2A

When the fourth edition of the Brain Trauma Foundation's Guidelines for the Management of Severe Traumatic Brain Injury was finalized in late 2016, it was known that the results of the RESCUEicp (Trial of Decompressive Craniectomy for Traumatic Intracranial Hypertension) randomized controlled trial of decompressive craniectomy would be public after the guidelines were released. The guideline authors decided to proceed with publication but to update the decompressive craniectomy recommendations later in the spirit of “living guidelines,” whereby topics are updated more frequently, and between new editions, when important new evidence is published. The update to the decompressive craniectomy chapter presented here integrates the findings of the RESCUEicp study as well as the recently published 12-mo outcome data from the DECRA (Decompressive Craniectomy in Patients With Severe Traumatic Brain Injury) trial. Incorporation of these publications into the body of evidence led to the generation of 3 new level-IIA recommendations; a fourth previously presented level-IIA recommendation remains valid and has been restated. To increase the utility of the recommendations, Hawryluk et al. added a new section entitled Incorporating the Evidence into Practice. This summary of expert opinion provides important context and addresses key issues for practitioners, which are intended to help the clinician utilize the available evidence and these recommendations. The full guideline can be found at https://braintrauma.org/guidelines/guidelines-for-the-management-of-severe-tbi-4th-ed/ [1].

Bifrontal decompressive craniectomy is not recommended to improve outcomes as measured by the Extended Glasgow Outcome Scale (GOS-E) score at 6 months post-injury in severe TBI patients with diffuse injury (without mass lesions), and with ICP elevation to values >20 mm Hg for more than 15 minutes within a 1-hour period that are refractory to first-tier therapies. However, this procedure has been demonstrated to reduce ICP and to minimize days in the intensive care unit (ICU).

A large frontotemporoparietal DC (not less than 12 x 15 cm or 15 cm diameter) is recommended over a small frontotemporoparietal DC for reduced mortality and improved neurologic outcomes in patients with severe TBI.

*The committee is aware that the results of the RESCUEicp study may be released soon after the publication of these Guidelines.

The results of this trial may affect these recommendations and may need to be considered by treating physicians and other users of these Guidelines. We intend to update these recommendations after the results are published if needed. Updates will be available at https://braintrauma.org/coma/guidelines.

EVALUATION OF THE EVIDENCE

The Class 2 studies either compared DC to medical management or compared DCs of different sizes, in terms of their effect on patient mortality and functional outcomes. Class 3 studies addressed these questions, and also comparison of DC to craniotomy and assessment of the use of DC earlier or later in the course of treatment.

For the first two questions addressed by Class 2 evidence, the quality of the body of evidence was moderate. The RCT that compared DC to initial medical management was rated Class 1.

This study was high quality but was a single study, and replication is needed for high confidence in the results. Both RCTs that compared size of DCs were rated Class 2.

For the third and fourth questions for which only Class 3 evidence was identified, the body of evidence was rated as insufficient, primarily because the results were inconsistent, with different studies reporting positive, negative, and no effects. As the studies were of poor quality, it was not possible to reconcile these differing results or to use the studies to support Level III recommendations.

Applicability The applicability differs across questions and studies. The Class 1 study comparing DC to initial medical management was conducted in three countries over an 8-year period, and included 15 centers.

While this diversity may have limited the ability to detect an effect, it could increase the applicability of the study. The two studies rated Class 2 that compare size of DCs were both conducted in one country (China).15, 16 Incomplete reporting about these studies limited the ability to fully understand key elements such as the standard of care and characteristics of the populations.

SUMMARY OF THE EVIDENCE Process Of the 31 potentially relevant studies reviewed, 21 were excluded because they did not meet the inclusion criteria. Of the remaining 10 studies, one Class 114 and two Class 215, 16 studies were included as evidence to support recommendations for this topic. The remaining seven were rated Class 3.

The DECRA trial, an RCT that compared bifrontotemporoparietal DC to initial medical management for refractory raised ICP, recruited patients in 15 tertiary care hospitals in Australia, New Zealand, and Saudi Arabia between December 2002 and April 2010.

This study found poorer GOS-E scores for patients in the DC group than those in standard care at 6 months post- injury, and lower ICP and fewer ICU days for patients in the DC group. Despite randomization, the proportion of patients in the DC group with reactivity in neither pupil on admission was higher (27% vs. 12%, p=0.04) than in controls. Planned baseline covariate adjustment did not change the results, but post hoc adjustment for this difference in pupil reactivity at admission resulted in outcome differences that were no longer significant. Based on this, the authors reported that “…the overall effect size did not change, although the harmful effect of craniectomy was no longer significant. A beneficial effect of craniectomy was excluded.”

The two studies that compared different sizes of DC were both conducted in China.

One was conducted at five medical centers, while the other was conducted at a single site. They differed in the requirements for inclusion; Jiang, 2005 et al. required refractory intracranial hypertension while Qiu, 200916 included patients based on a computed tomography (CT) scan showing a swollen hemisphere. Both studies found better outcomes with larger DCs; however, the differences in patients, procedures, and treatment, as well as the fact that these studies did not adjust for any covariates, limited the ability of these studies to provide a definitive answer to this question. Of importance, these studies did not make a comparison of different sizes with no decompression. Thus, the evidence did not allow an estimate of the effect of decompression compared with no decompression.

Both of the two Class 3 studies that compared DC to medical management reported no significant difference in mortality; however, one reported poorer functional outcomes with DC while the other found no difference in function.

The one Class 3 study comparing large and small DC reported lower mortality with larger DC. These results were similar to the Class 2 studies that addressed this question. For these questions, higher quality Class 2 evidence was available, and the Class 3 evidence was not used to inform the recommendations.

The studies that compared DC to craniotomy reported lower, but not statistically significant, mortality rates and conflicting findings about function and complications.

Similarly, the results of two studies of the timing of DC were inconsistent. One reported reduced mortality, and one reported no difference.

Given the quality of the studies and the inconsistency of the findings, the quality of the body of evidence was rated as insufficient and these studies were not used as the basis for recommendations.

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