Chapter 12. Decompressive craniectomy for the treatment of intracranial hypertension

I. RECOMMENDATIONS

Strength of Recommendations: Weak.

Quality of Evidence: Low, from poor and moderate-quality class III studies.

A. Level I

There are insufficient data to support a level I recommendation for this topic.

B. Level II

There are insufficient data to support a level II recommendation for this topic.

C. Level III

Decompressive craniectomy (DC) with duraplasty, leaving the bone flap out, may be considered for pediatric patients with traumatic brain injury (TBI) who are showing early signs of neurologic deterioration or herniation or are developing intracranial hypertension refractory to medical management during the early stages of their treatment.

II. EVIDENCE TABLE (see Table 1)

III. OVERVIEW

DC in the setting of TBI is a controversial procedure that has recently become widely considered as a treatment option. It may be performed concomitantly with the removal of a mass lesion to either treat observed brain swelling or act as prophylaxis of anticipated swelling (secondary DC). Alternatively, it may be performed as a standalone procedure for the purpose of treating cerebral herniation or established intracranial hypertension, wherein the timing of the decompression may be predicated on the clinical examination, course of neurologic deterioration, initial degree of intracranial pressure (ICP) elevation, or the resistance of that elevation to various thresholds of medical treatment (primary DC). These two conditions of employment are actually quite different and it is the second (DC as a primary treatment for cerebral swelling) that is the focus on this section.

The nature of the procedure varies widely. It may consist of uni- or bilateral subtemporal decompressions, hemispheric craniectomies of varying sizes (from relatively small to quite expansive), circumferential craniectomy, or bifrontal craniectomy. The choice of procedure may depend on the underlying pathology, as demonstrated on computed tomography imaging, or may simply be focused on developing the maximum possible compliance compartment. The management of the underlying dura also may vary, ranging from leaving it intact through simple scoring to opening it widely (with or without expansive duraplasty). Furthermore, the treatment of the dura may vary independently with the choice of bony decompressive procedure.

With respect to the use of DC for ICP control in adults, two randomized controlled trials were underway, the DECRA Trial (1) (international multicenter randomized controlled trial (on Early Decompressive Craniectomy in Traumatic Brain Injury), which recently reported their findings (2) of reduced ICP but significantly worsened outcomes, and the RescueICP Trial (3) (randomized evaluation of surgery with craniectomy for uncontrollable elevation ICP). No similar studies are ongoing for the pediatric population.

IV. PROCESS

For this update, MEDLINE was searched from 1996 through 2010 (Appendix B for search strategy), and results were supplemented with literature recommended by peers or identified from reference lists. Of 20 potentially relevant studies, seven new studies were included as evidence for this topic.

V. SCIENTIFIC FOUNDATION

Eight class III studies met the inclusion criteria for this topic and provide evidence to support the recommendations (4–11). These studies vary in critical areas such as their selection criteria for DC, the DC techniques used, and their outcome parameters. In addition, none of them defined the study population to an extent adequate to allow rigorous interstudy comparisons. The lack of internal comparison groups or matched controls weakens the analyses that can be applied.

Is Decompressive Craniectomy Effective in Lowering ICP?

The issue with respect to the efficacy of DC in lowering ICP is not the statistical significance of the change in ICP from before surgery to the postoperative state but rather it is in lowering severely or medically intractable ICP elevation with respect to the treatment threshold such that intracranial hypertension is no longer encountered (optimal outcome) or is easily controlled after surgery.

A study by Hejazi et al (6) was performed investigating early unilateral or bilateral DC with duraplasty for Glasgow Coma Scale score of 3–5 in seven pediatric patients with TBI within 70 mins from trauma resulting from "massive" bilateral or unilateral swelling, compressed supratentorial ventricular spaces, and perimesencephalic cisterns. The DC was frontotemporal and did not include the parietal and occipital regions. A low craniectomy was performed in all patients to decompress the brainstem. The initial ICP exceeded 45 mm Hg in all patients. In six of the seven, ICP remained <20 mm Hg after surgery. Persistent intracranial hypertension (although not to the level of preoperative) in the one patient was controlled with medical therapy. This suggests that DC might be effective in controlling ICP.

A study by Ruf et al (9) was also performed on unilateral or bilateral DC with duraplasty when the ICP exceeded 20 mm Hg for >30 mins in six pediatric patients

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Table 1. Evidence table

Reference	Study Description	Data Class, Quality, and Reasons	Results and Conclusion
Study from previous guidelines			
Cho et al, 1995 (4)	Design: case series N = 13 Age: 2–14 months Protocol: medical treatment in first 4 and DC in 9 ICP and scores on COS measured between 6 months and 6 yrs postinjury (mean, 3.2 yrs) DC: bifrontal DC for diffuse swelling, or large unilateral frontotemporoparietal DCs for unilateral hemispheric swelling	Class III Poor quality: no control for confounders, very small sample and no power calculation	In the surgical group, DC lowered the mean ICP measurements from 54.9 mm Hg to 11.9 mm Hg; effect of medical treatment on ICP was not reported For the medically treated group, scores on the COS, measured at a mean of 3.2 years (range, 6 months to 6 yrs), were 2 dead (COS 5) and 2 vegetative (COS 4); for the surgical group, 2 patients had an "excellent" recovery (COS 1), 2 had a moderate recovery (COS 2), 4 had severe disability (COS 3), and 1 was vegetative; notably, although DC was performed based on ICP elevation alone, a mean of 32 mL of subdural blood was removed during the surgery
New studies			
Figaji et al, 2003 (5)	Design: case series N = 5 Age: 5–12 yrs Protocol: DC for clinical deterioration in patients presenting with or deteriorating rapidly to GCS ≤ 8 in intensive care unit; ICP not monitored before surgery Outcome: GOS DC: unilateral craniotomy with duraplasty either leaving the bone out or loosely suturing it in place (floating flap)	Class III Poor quality: no control for confounders, very small sample, and no power calculation	All patients had early clinical improvement after surgery and were GOS 4 or 5 at long term follow-up (14–40 months) In the 4 patients with postoperative ICP monitoring, 2 had no ICP elevations and 2 had mild, easily controlled elevations
Hejazi et al, 2002 (6)	Design: retrospective case series N = 7 Age: 5–14 yrs GCS: 3–5 on admission and bilateral swelling with compression of the perimesencephalic cisterns on CT; initial ICP >45 mm Hg in all patients Protocol: patients with traumatic brain injury treated with early DC Outcome: survival, ICP DC: unilateral craniectomy, frontal temporal only with duraplasty leaving the bone out or bilateral craniectomy with stellate dural opening	Class III Poor quality: no control for confounders, very small sample and no power calculation	All patients survived despite severe baseline intracranial hypertension; decompression decreased ICP from >45 mm Hg to < 20 mm Hg immediately and it remained controlled in 6 of 7 patients; one patient later developed intracranial hypertension but not to the level present before decompression All patients achieved a "complete recovery" on follow-up of >8 months although this is not defined
Jagannathan et al, 2007 (7)	Design: retrospective case series N = 23 Age: mean 1.9 yrs (2 patients: 19 yrs old and 21 of 23 patients <19 yrs old) GCS: mean 4.6 (3–9) Protocol: patients with traumatic brain injury treated with DC done for either 1) ICP >20 mm Hg refractory to maximal medical therapy; or 2) mass lesion Outcome: long-term functional outcome and independence levels were evaluated using the GOS and a Likert patient quality-of-life rating scale DC: large, wide with duraplasty; unilateral for hemispheric swelling or bifrontal for diffuse swelling; in bifrontal, the sagittal suture was suture ligated and falx sectioned	Class III Poor quality: no control for confounders, very small sample, and no power calculation	Survival rate of 70%; mortality was seen primarily in patients with multisystem trauma ICP control in 19 of 23 patients; high ICP associated with increased mortality; mean follow-up using GOS over 5 years was 4.2 (range, 1–5); majority had "good" outcomes (17 of 23) at 2 yrs 13 of 17 survivors returned to school

Table 1. —*Continued*

Reference	Study Description	Data Class, Quality, and Reasons	Results and Conclusion
Kan et al, 2006 (8)	Design: case series N = 6 Age: 0.3–14 yrs GCS: mean 4.6 Protocol: DC performed in the absence of mass lesion; all 6 with very severe injuries; DC done in 5 for refractory ICP >25 mm Hg and 1 for herniation Outcome: mortality and ICP DC: large unilateral craniectomy with duraplasty	Class III Poor quality: no control for confounders	5 of 6 patients died 3 of the 4 patients with postoperative ICP monitoring had ICP <20 mm Hg
Ruf et al, 2003 (9)	Design: retrospective case series N = 6 GCS: 3–7 Age: 5–11 yrs Protocol: DC for refractory ICP >20 mm Hg for >30 mins Outcome: 6-month survival and neurological assessment DC: unilateral or bilateral craniectomy (depending on CT) with duraplasty	Class III Poor quality: no control for confounders, very small sample, and no power calculation	3 patients were without disability; 2 had mild to moderate deficits at 6-month follow-up Postoperative ICP <20 mm Hg in 5 of 6 patients; sixth patient required contralateral subsequent DC, then ICP was maintained at ≤ 20 mm Hg
Rutigliano et al, 2006 (10)	Design: retrospective case series N = 6 Age: <20 yrs with 5 <18 yrs (range, 12–15 yrs) and having distinct data Protocol: DC done for refractory "elevated ICP" Outcome: Functional Independence Measure score and ICP DC = bifrontal craniectomies with duraplasty	Class III Poor quality: no control for confounders, very small sample, and no power calculation	All 5 had Functional Independence Measurement scores of independent or minimal assistance at discharge 5 of the 6 patients had no postoperative ICP elevations; 1 had ICP elevations requiring a second surgery for débridement, with no subsequent ICP elevations
Skoglund et al, 2006 (11)	Design: retrospective case series N = 19 Age: 8 <18 yrs (range, 7–16 yrs) and having distinct data GCS: mean 7 (3–15), with deterioration, evidence of herniation, or refractory ICP Protocol: DC done for either 1) ICP >20 mm Hg refractory to Lund therapy; or 2) acute neurologic deterioration immediately after trauma with CT showing diffuse edema Outcome: GOS at 1 yr DC: large with duraplasty; unilateral for hemispheric swelling or bifrontal for diffuse swelling	Class III Moderate quality: unclear if outcome assessment methods were unbiased	At ≥ 1 yr follow-up, 3 patients with GOS = 5, 1 GOS = 4, 3 GOS = 3, and 1 dead; 5 of these patients with neurologic deterioration or pupillary changes at the time of surgery

DC, decompressive craniectomy; ICP, intracranial pressure; COS, Children's Outcome Scale; GCS, Glasgow Coma Scale; GOS, Glasgow Outcome Scale; CT, computed tomography.

with severe TBI. In five of the six, ICP remained <20 mm Hg after surgery. Persistent intracranial hypertension in the sixth patient prompted a return to surgery for a contralateral DC, which resulted in sustained ICP control. This suggests that DC might be effective in controlling ICP. Unfortunately, further information on how the choice of operation was made in these patients is lacking.

A study by Kan et al (8) was performed to investigate a large unilateral DC with duraplasty in pediatric patients with TBI, either in conjunction with the removal of a mass lesion (45 patients) or primarily for brain swelling (six patients, five for refractory ICP >25 mm Hg, and one for herniation). The six patients relevant to this topic were very severely injured with low admission Glasgow Coma Scale scores, evidence of herniation, or severe secondary insults common among them. For these six patients, three of the four who received postoperative ICP monitoring had sustained ICP values <20 mm Hg. The fourth had intracranial hypertension requiring further treatment. Five of the six patients died.

A study by Rutigliano et al (10) was performed which was a retrospective case series of six patients with TBI of age <20 yrs who underwent DC for elevated ICP (without a specified definition), which was refractory to guidelines-based treatment. Five of these patients were <18 yrs of age and could be analyzed separately. They performed wide bifrontal/biparietal craniectomies with duraplasty. Four of the five had no postoperative ICP elevations. The fifth patient required a return to surgery for intracranial hypertension whereupon débridement of the contused brain resulted in resolution.

A study by Jagannathan et al (7) was performed as a retrospective case series of 23 patients with TBI of age <20 yrs who underwent DC for initial mass lesion requiring evacuation or elevated ICP (>20 mm Hg), which was refractory to guidelines-based treatment. Twenty-one of these patients were <18 yrs of age and could be analyzed separately. They performed wide bifrontal/biparietal craniectomies with duraplasty and sectioning of the falx or unilateral DC if there was a mass lesion or unilateral swelling. Ten of the 23 patients underwent early DC, 11 had later DC, and two even later as a result of medical instability. Mean ICP

reduced from 30 mm Hg preoperatively to 18 mm Hg postoperatively. Nineteen of 23 patients had control of postoperative ICP elevations with maximal medical management. Two patients continued to have refractory ICP.

A study by Cho et al (4) was a case series of 23 children <2 yrs of age presenting with nonaccidental trauma. Children were included based on their ICP regardless of their presenting level of consciousness. A subgroup of 13 patients with a Children's Coma Score equivalent to severe on the Glasgow Coma Scale, and ICP values >30 mm Hg, were treated medically (n = 4) or with DC (n = 9) based on either family wishes or being admitted before DC became a routine part of treatment for this disease. On the nine surgical patients, bifrontal DC was performed for diffuse swelling or large unilateral frontotemporoparietal DCs for unilateral hemispheric swelling. They included a section of the anterior sagittal sinus and an expansive duraplasty. The decompression was performed within 24 hrs of injury in the majority. In the surgical group, DC lowered the mean ICP measurements from 54.9 mm Hg to 11.9 mm Hg.

In summary, it appears that DC may be effective in lowering ICP to below the threshold for treatment in patients refractory to medical management. This limited conclusion would add some support to choosing to perform DC for ICP control when intracranial hypertension is resistant to nonsurgical management and the ICP levels maintained are considered hazardous to the patient.

Does Decompressive Craniectomy Improve Clinical Outcomes?

This section focuses on whether DC performed for severe or intractable intracranial hypertension or clinical herniation is associated with a beneficial influence on outcome.

All of the studies in this section are retrospective case series. All used retrospectively collected data, except for the Rutigliano et al (10) study that used a prospectively collected database, which was not designed specific to the question of DC. None of them have internal or matched external controls and there were no randomized controlled trials. Common to all of these studies is the absence of sufficient data on the injury characteristics of the study group to predict their outcomes independent of the surgical decompression using predictive modeling.

A study by Hejazi et al (6) reported that all of the patients with early DC had a "complete recovery" although this is not defined. There was no mortality and complication rate was low with only subdural effusions in four of seven.

A study by Figaji et al (5) reported "early [postoperative] clinical improvement" in their decompressed patients. All five cases had Glasgow Outcome Scale scores of 4–5 at 14- to 40-month follow-up. The patients had not had preoperative ICP monitoring and had DC performed for clinical deterioration. The authors felt that the outcomes were better than expected given that each of the patients had an initial Glasgow Coma Scale score ≤8, each had a documented secondary deterioration, which was believed to be the result of raised ICP, pupillary abnormalities were seen in four, and all demonstrated obliteration of the perimesencephalic cisterns (diffuse injury III and IV).

A study by Ruf et al (9) studied six pediatric patients with TBI undergoing DC for refractory ICP >20 mm Hg. One of the six was a posterior fossa DC to treat swelling from a cerebellar contusion. At 6 months, all patients had survived, three being described as "normal" and the others having mild-to-moderate residual deficits.

A study by Rutigliano et al (10) described six pediatric patients with TBI who underwent DC. Five of these patients were <18 yrs of age. A large bilateral frontoparietal DC with duraplasty was performed for "elevated ICP" refractory to tier 1 and tier 2 medical management. They reported early signs of clinical improvement and discharge Functional Independence Measurement scores of independent or minimal assistance for all five patients.

A study by Jagannathan et al (7) described 21 pediatric patients with TBI after undergoing DC either incidentally after evacuation of a mass lesion or for diffuse swelling refractory ICP to medical management. Eighteen of 23 were done for refractory ICP to maximal medical management, three of whom had pupillary changes and did not survive DC. They reported an overall 22% mortality rate despite ICP ≤20 mm Hg in two of the five patients who died. Mean follow-up was 62 months (range, 11–126 months) and the mean Glasgow Outcome Scale score was 4.2 (range, 1–5). The mean score on the quality-of-life questionnaires was 4 (maximum, 5) in the ability to perform activities of daily living, general cognition, interpersonal behavior, and emotional behavior (range, 1–4.75).

In the Cho et al (4) case series, children <2 yrs of age with severe TBI from nonaccidental trauma and ICP values >30 mm Hg were treated with medically (n = 4) or with decompressive craniotomy (n = 9). For the medically treated group, scores on the Children's Outcome Scale (COS), measured at a mean of 3.2 yrs (range, 6 months to 6 yrs), revealed two dead (COS 5) and two vegetative (COS 4). For the surgical group, two patients had an "excellent" recovery (COS 1), two had a moderate recovery (COS 2), four had severe disability (COS 3), and one was vegetative. Notably, although DC was performed based on ICP elevation alone, a mean of 32 mL of subdural blood was removed during the surgery.

Two studies reported less favorable outcomes (8, 11). A study by Skoglund et al (11) studied 19 patients with TBI, of whom eight were <18 yrs, treated with DC for either refractory ICP >20 mm Hg or acute neurologic deterioration immediately after trauma with computed tomography scan showing diffuse edema. All patients were medically managed using the Lund approach. Five of the eight pediatric patients had neurologic deterioration or pupillary changes at the time of surgery. Outcome at ≥1 yr after surgery was three patients with Glasgow Outcome Scale score of 5, one with Glasgow Outcome Scale score of 4, three with Glasgow Outcome Scale score of 3, and one death.

A study by Kan et al (8) described 51 pediatric patients with TBI undergoing DC, although the craniectomy was incidental to surgery to evacuate a mass lesion in 45. Five cases were done for refractory ICP >25 mm Hg and the sixth for clinical herniation. These patients were very severely injured. Three were Glasgow Coma Scale score 3 on admission, three were bilaterally fixed and dilated, and two others had a unilateral fixed and dilated pupil. The sixth patient presented with profound hypotension. They reported an 83% mortality rate despite ICP ≤20 mm Hg in three of the four patients monitored after surgery. Five of the six patients died.

Given the paucity of descriptive statistics contained within these studies, it is impossible to accurately compare the pa-

tients studied between these various papers. Adding in the differences in trigger criteria for DC, variations in DC technique, and the wide variations in outcome measurements, no more than simple, qualitative summaries may be made. Given the severity of injury of these children and the physiological abnormalities required to become candidates for DC, cautious interpretation of these outcomes suggests that DC may be effective in improving outcome in patients with medically intractable intracranial hypertension.

VI. INFORMATION FROM OTHER SOURCES

A. Indications From the Adult Guidelines

The *Guidelines for the Surgical Management of TBI* (12), published in 2006, found no class I or II evidence on which to base level I or II recommendations. The level III-equivalent recommendations with respect to DC were based on class III literature, the most prominent of which were the reports of Polin et al (13) and Taylor et al (14) (briefly reviewed subsequently).

The recommendations from the adult guidelines regarding DC were:

- Bifrontal DC within 48 hrs of injury is a treatment option for patients with diffuse, medically refractory posttraumatic cerebral edema and resultant intracranial hypertension.
- Decompressive procedures, including subtemporal decompression, temporal lobectomy, and hemispheric DC, are treatment options for patients with refractory intracranial hypertension and diffuse parenchymal injury with clinical and radiographic evidence for impending transtentorial herniation.

Of note, the recently completed DECRA study by Cooper et al (2) for adults with diffuse severe TBI showed that ICP could be effectively reduced with early bifrontotemporoparietal DC but, interestingly, outcomes were worse in the surgery group than the clinical management group alone.

B. Information Not Included as Evidence

Indications From the 2009 Cochrane Review on Decompressive Craniectomy. In the 2009 update of the Cochrane Review on DC (15), the author found only one publication of sufficient rigor to include, that of Taylor et al (14), which studied a pediatric TBI group. It was concluded that "despite the wide confidence interval for death and the small sample size of this one identified study, the treatment may be justified in patients below the age of 18 yrs when maximal medical treatment has failed to control ICP." With respect to the current evidence report, however, this paper must be excluded as a result of its inclusion of patients with admissions scores above the cutoff ($\leq$8).

VII. SUMMARY

Eight small class III case series suggest that large decompressive surgeries with duraplasty may be effective in reversing early signs of neurologic deterioration or herniation, and in treating intracranial hypertension refractory to medical management, and that these effects may be correlated with improving outcomes in the critically ill pediatric patients who develop such indications. Limited evidence suggests that duraplasties, when done, should be large, and consideration should be given to removing the bone rather than "floating" it *in situ*. There is insufficient evidence to allow defining the patient characteristics that either 1) optimize the beneficial effects of these procedures or 2) render them ineffective.

VIII. KEY ISSUES FOR FUTURE INVESTIGATION

- A primary focus on future research should be performing a randomized controlled trial on DC as a method of controlling increased ICP in pediatric patients with TBI.
- Given the infrequency with which pediatric patients with TBI are admitted to any individual center, it would be very useful to develop a prospective pediatric TBI database to facilitate class II investigations into many of the variables relevant to DC (such as timing, size and placement, and technique), which are unlikely to ever be subject to class I study.
- It would be very useful if the investigators involved in the two adult DC trials, the DECRA trial (1) and the Rescue ICP trial (3), both of which enrolled patients overlapping with the pediatric age group, would parse out this group for separate subgroup analysis of efficacy and technical details. It would be valuable to design or determine standardized and practical techniques to quantify the physiological changes induced by DC, both as a clinically useful measure of efficacy and as a research parameter.

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