Decompressive craniectomy for severe traumatic brain injury

- Post-traumatic hydrocephalus after decompressive craniectomy: a multidimensional analysis of clinical, radiological, and surgical risk factors
- Risk factors for the development of hydrocephalus in traumatic brain injury: a systematic review and meta-analysis
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- Decompressive Craniectomy and Outcomes in Severe Traumatic Brain Injury in Children and Adolescent Patients
- Noninvasive 3D-head-scan used for 3D-printed customized helm by patient undergoing decompressive hemicraniectomy

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Indications

Decompressive craniectomy for severe traumatic brain injury Indications

Outcome

Early decompressive craniectomy (DC) has been used as the first stage treatment to prevent secondary injuries in cases of severe traumatic brain injury (TBI). Postoperative management is the major factor that influences outcome.

Intracranial pressure monitoring in conjunction with postoperative treatment, after early DC, is associated with a significantly reduced risk of death [1].

Patients surviving from DC need a second operation to repair the bone defect.

In the 2010s the use of decompressive craniectomy (DC) in everyday neurosurgical practice has largely increased, even though the effectiveness of this procedure is still uncertain [2].

Complications

see Decompressive craniectomy complications.

Systematic review and meta-analysis

In medically refractory intracranial hypertension after severe traumatic brain injury, secondary decompressive craniectomy is the last resort treatment option to control intracranial pressure (ICP). Randomized controlled studies have been extensively performed on secondary decompressive craniectomy and its role in the management of severe traumatic brain injuries. Indications, prognostic factors, and long-term outcomes in primary decompressive craniectomy during the evacuation of an epidural, subdural, or intracerebral hematoma in the acute phase are still a matter of ongoing research and controversy to this day. Prospective trials have been designed, but the results are yet to be published. In isolated epidural hematoma without underlying brain injury, osteoplastic craniotomy is likely to be sufficient. In acute subdural hematoma (ASDH) with relevant brain swelling and preoperative CT signs such as effaced cisterns, overly proportional midline shift compared to a relatively small acute subdural hematoma, and accompanying brain contusions as well as pupillary abnormalities, intraventricular hemorrhage, and coagulation disorder, primary decompressive craniectomy is more likely to be of benefit for patients with traumatic brain injury. The role of intracranial pressure monitoring after primary decompressive craniectomy is recommended, but prospective trials are pending. More refined guidelines and hopefully class I evidence will be established with the ongoing trials: randomized evaluation of surgery with craniectomy for patients undergoing evacuation of acute subdural hematoma (RESCUE-ASDH), prospective randomized evaluation of decompressive ipsilateral craniectomy for traumatic acute epidural hematoma (PREDICT-AEDH), and pragmatic explanatory continuum indicator summary (PRECIS) [3].

High intracranial pressure (ICP) is the most frequent cause of death and disability after severe traumatic brain injury (TBI). It is usually treated with general maneuvers (normothermia, sedation, etc.) and a set of first-line therapeutic measures (moderate hypocapnia, mannitol, etc.). When these measures fail, second-line therapies are initiated, which include: barbiturates, hyperventilation, moderate hypothermia, or removal of a variable amount of skull bone (secondary decompressive craniectomy).

Sahuquillo and Dennis assessed the effects of secondary decompressive craniectomy (DC) on outcomes of patients with severe traumatic brain injury in whom conventional medical therapeutic measures have failed to control raised ICP.

The most recent search was run on 8 December 2019. They searched the Cochrane Injuries Group's Specialised Register, CENTRAL (Cochrane Library), Ovid MEDLINE(R), Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid OLDMEDLINE(R), Embase Classic + Embase (OvidSP) and ISI Web of Science (SCI-EXPANDED & CPCI-S). They also searched trial registries and contacted experts.

They included randomized studies assessing patients over the age of 12 months with severe TBI who either underwent DC to control ICP refractory to conventional medical treatments or received standard care.

They selected potentially relevant studies from the search results, and obtained study reports. Two review authors independently extracted data from included studies and assessed the risk of bias. They used a random-effects model for meta-analysis. They rated the quality of the evidence according to the GRADE approach.

They included three trials (590 participants). One single-site trial included 27 children; another multicenter trial (three countries) recruited 155 adults, the third trial was conducted in 24 countries, and recruited 408 adolescents and adults. Each study compared DC combined with standard care (this could include induced barbiturate coma or cooling of the brain, or both). All trials measured outcomes up to six months after injury; one also measured outcomes at 12 and 24 months (the latter data remain unpublished). All trials were at a high risk of bias for the criterion of performance bias, as neither participants nor personnel could be blinded to these interventions. The pediatric trial was at a high risk of selection bias and stopped early; another trial was at risk of bias because of atypical inclusion criteria and a change to the primary outcome after it had started. Mortality: pooled results for three studies provided moderate quality evidence that risk of death at six months was slightly reduced with DC (RR 0.66, 95% CI 0.43 to 1.01; 3 studies, 571 participants; I2 = 38%; moderate-quality evidence), and one study also showed a clear reduction in risk of death at 12 months (RR 0.59, 95% CI 0.45 to 0.76; 1 study, 373 participants; high-quality evidence). Neurological outcome: conscious of controversy around the traditional dichotomization of the Glasgow Outcome Scale (GOS) scale, we chose to present results in three ways, in order to contextualize factors relevant to clinical/patient decision-making. First, we present results of death in combination with vegetative status, versus other outcomes. Two studies reported results at six months for 544 participants. One employed a lower ICP threshold than the other studies, and showed an increase in the risk of death/vegetative state for the DC group. The other study used a more conventional ICP threshold, and results favoured the DC group (15.7% absolute risk reduction (ARR) (95% CI 6% to 25%). The number needed to treat for one beneficial outcome (NNTB) (i.e. to avoid death or vegetative status) was seven. The pooled result for DC compared with standard care showed no clear benefit for either group (RR 0.99, 95% CI 0.46 to 2.13; 2 studies, 544 participants; I2 = 86%; low-quality evidence). One study reported data for this outcome at 12 months, when the risk for death or vegetative state was clearly reduced by DC compared with medical treatment (RR 0.68, 95% CI 0.54 to 0.86; 1 study, 373 participants; high-quality evidence). Second, we assessed the risk of an 'unfavorable outcome' evaluated on a non-traditional dichotomized GOS-Extended scale (GOS-E), that is, grouping the category 'upper severe disability' into the 'good outcome' grouping. Data were available for two studies (n = 571). Pooling indicated little difference between DC and standard care regarding the risk of an unfavorable outcome at six months following injury (RR 1.06, 95% CI 0.69 to 1.63; 544 participants); heterogeneity was high, with an I2 value of 82%. One trial reported data at 12 months and indicated a clear benefit of DC (RR 0.81, 95% CI 0.69 to 0.95; 373 participants). Third, we assessed the risk of an 'unfavorable outcome' using the (traditional) dichotomized GOS/GOS-E cutoff into 'favorable' versus 'unfavorable' results. There was little difference between DC and standard care at six months (RR 1.00, 95% CI 0.71 to 1.40; 3 studies, 571 participants; low-quality evidence), and heterogeneity was high (I2 = 78%). At 12 months one trial suggested a similar finding (RR 0.95, 95% CI 0.83 to 1.09; 1 study, 373 participants; high-quality evidence). With regard to ICP reduction, pooled results for two studies provided moderate quality evidence that DC was superior to standard care for reducing ICP within 48 hours (MD -4.66 mmHg, 95% CI -6.86 to -2.45; 2 studies, 182 participants; I2 = 0%). Data from the third study were consistent with these, but could not be pooled. Data on adverse events are difficult to interpret, as mortality and complications are high, and it can be difficult to distinguish between treatment-related adverse events and the natural evolution of the condition. In general, there was low-quality evidence that surgical patients experienced a higher risk of adverse events.

AUTHORS' CONCLUSIONS: Decompressive craniectomy for the treatment of high intracranial pressure in closed traumatic brain injury holds the promise of reduced mortality, but the effects of long-term neurological outcomes remain controversial and involve an examination of the priorities of participants and their families. Future research should focus on identifying clinical and neuroimaging characteristics to identify those patients who would survive with an acceptable quality of life; the best timing for DC; the most appropriate surgical techniques; and whether some synergistic treatments

used with DC might improve patient outcomes [4].

Although many studies have been conducted in this topic, there is still much uncertainty about the effectiveness of surgical treatment in TBI [5].

Zhang et al. aimed to perform a systematic review and metaanalysis to examine the prognostic value of decompressive craniectomy (DC) in patients with traumatic intracranial hypertension. PubMed, EMBASE, Cochrane Controlled Trials Register, Web of Science, http://clinicaltrials.gov/ were searched for eligible studies. Ten studies were included in the systematic review, with four randomized controlled trials involved in the meta-analysis, where compared with medical therapies, DC could significantly reduce mortality rate [risk ratio (RR), 0.59; 95% confidence interval (CI), 0.47-0.74, $P < 0.001$], lower intracranial pressure (ICP) [mean difference (MD), -2.12 mmHg; 95% CI, -2.81 to -1.43, $P < 0.001$], decrease the length of ICU stay (MD, -4.63 days; 95% CI, -6.62 to -2.65, $P < 0.001$) and hospital stay (MD, -14.39 days; 95% CI, -26.00 to -2.78, $P = 0.02$), but increase complications rate (RR, 1.94; 95% CI, 1.31-2.87, $P < 0.001$). No significant difference was detected for Glasgow Outcome Scale at six months (RR, 0.85; 95% CI, 0.61-1.18, $P = 0.33$), while in subgroup analysis, early DC would possibly result in improved prognosis ($P = 0.04$). Results from observational studies supported pooled results except prolonged length of ICU and hospital stay. Conclusively, DC seemed to effectively lower ICP, reduce mortality rate but increase complications rate, while its benefit on functional outcomes was not statistically significant [6].

Whilst the results of the trials have confirmed the survival benefit that can be achieved this has only been achieved by increasing the number of survivors with severe disability and dependency. Whilst these findings may be difficult to accept they do not necessarily mean that use of the procedure should be abandoned but rather a more nuanced and patient-centered debate regarding the acceptability or otherwise of survival with severe disability is required. In addition the use of long term observation outcome studies in combination accurate outcome prediction models in combination with may be used to highlight those patients likely to benefit from surgical decompression and facilitate discussions regarding realistic outcome expectations [7].

The management of traumatic brain injury progressed significantly in the 1980s and 1990s due to advances in neuroimaging (widespread introduction of CT scanning), prehospital management, neurointensive care (widespread adoption of ICP monitoring and tiered therapeutic protocols) and rehabilitation. This led to a renaissance of interest in decompressive craniectomy (DC) with many uncontrolled studies reporting a survival benefit with DC [8] [9].

Since that time, DC has been increasingly studied in the setting of different conditions, including subarachnoid hemorrhage, and malignant middle cerebral artery infarction.

Furthermore, dural opening, usually followed by insertion of a dural substitute (duraplasty), has meanwhile become an integral part of the decompressive surgery technique [10].

The 21st century, so far, has seen consistent efforts to improve the evidence base for DC following TBI with the conduct of randomized clinical trials [11].

In severely head injured children, a study has shown that decompressive craniectomy resulted in good recovery in all children in the study, suggesting the procedure has an advantage over non-surgical treatment in children.

In one of the largest studies on pediatric patients, Jagannathan et al. found a net 65% favorable outcomes rate in pediatric patients for accidental trauma after craniectomy when followed for more than five years. Only three patients were dependent on caregivers.

This is the only prospective randomised controlled study to date to support the potential benefit of decompressive craniectomy following traumatic brain injury.

In 2006 there was no evidence to support the routine use of secondary DC to reduce the unfavourable outcome in adults with severe TBI and refractory high ICP. In the pediatric population DC reduces the risk of death and unfavorable outcome. Despite the wide confidence intervals for death and the small sample size of the only study identified, this treatment may be justified in patients below the age of 18 when maximal medical treatment has failed to control ICP. To date, there are no results from randomized trials to confirm or refute the effectiveness of DC in adults. However, the results of non-randomized trials and controlled trials with historical controls involving adults, suggest that DC may be a useful option when maximal medical treatment has failed to control ICP. There are two ongoing randomized controlled trials of DC (Rescueicp trial and DECRAN) that may allow further conclusions on the efficacy of this procedure in adults [12].

Case series

Decompressive craniectomy for severe traumatic brain injury case series

Randomized Trials

Two randomized trials assessing the effectiveness of decompressive craniectomy for severe traumatic brain injury were published: DECRA trial in 2011 and RESCUEicp trial in 2016.

2016

From 2004 through 2014, we randomly assigned 408 patients, 10 to 65 years of age, with traumatic brain injury and refractory elevated intracranial pressure (>25 mm Hg) to undergo decompressive craniectomy or receive ongoing medical care. The primary outcome was the rating on the Extended Glasgow Outcome Scale (GOS-E) (an 8-point scale, ranging from death to “upper good recovery” [no injury-related problems]) at 6 months. The primary-outcome measure was analyzed with an ordinal method based on the proportional-odds model. If the model was rejected, that would indicate a significant difference in the GOS-E distribution, and results would be reported descriptively.

RESULTS: The GOS-E distribution differed between the two groups (P<0.001). The proportional-odds assumption was rejected, and therefore results are reported descriptively. At 6 months, the GOS-E distributions were as follows: death, 26.9% among 201 patients in the surgical group versus 48.9% among 188 patients in the medical group; vegetative state, 8.5% versus 2.1%; lower severe disability (dependent on others for care), 21.9% versus 14.4%; upper severe disability (independent at home), 15.4% versus 8.0%; moderate disability, 23.4% versus 19.7%; and good recovery, 4.0% versus 6.9%. At 12 months, the GOS-E distributions were as follows: death, 30.4% among 194 surgical patients versus 52.0% among 179 medical patients; vegetative state, 6.2% versus 1.7%; lower severe disability, 18.0% versus 14.0%; upper severe disability, 13.4% versus 3.9%; moderate disability, 22.2% versus 20.1%; and good recovery, 9.8% versus 8.4%. Surgical patients had fewer hours than medical patients with intracranial pressure above 25 mm Hg after randomization (median, 5.0 vs. 17.0 hours; P<0.001) but had a higher rate of adverse events (16.3% vs. 9.2%, P=0.03).

CONCLUSIONS: At 6 months, decompressive craniectomy in patients with traumatic brain injury and refractory intracranial hypertension resulted in lower mortality and higher rates of vegetative state, lower severe disability, and upper severe disability than medical care. The rates of moderate disability and good recovery were similar in the two groups. (Funded by the Medical Research Council and others; RESCUEicp Current Controlled Trials number, ISRCTN66202560 .) [13)].

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31 patients aged 16-72 of either sex who sustained a severe, non-penetrating TBI and underwent a unilateral DC for evacuation of parenchymal or extra-axial hematoma or for failure of medical therapy to control intracranial pressure (ICP).

Review of the electronic medical record of patients undergoing DC for severe TBI and assessment of extended Glasgow Outcome Score (e-GOS) at 6-months following DC.

The mean age was 39.3y ± 14.5. The initial GCS was 5.8 ± 3.2, and the ISS was 29.7 ± 6.3. Twenty-two patients underwent DC within the first 24 h, two within the next 24 h and seven between the 3rd and 7th day post injury. The pre-DC ICP was 30.7 ± 10.3 and the ICP was 12.1 ± 6.2 post-DC. Cranioplasty was performed in all surviving patients 1-4 months post-DC. Of the 29 survivors following DC, the e-GOS was 8 in seven patients, and 7 in ten patients. The e-GOS was 5-6 in 6 others. Of the 6 survivors with poor outcomes (e-GOS = 2-4), five were the initial patients in the series.

In patients with intractable cerebral hypertension following TBI, unilateral DC in concert with practice guideline directed brain resuscitation is associated with good functional outcome and acceptable-mortality [14)].

2009

A case control study comparing a group of patients (n: 16) operated for severe TBI between January 2002 and July 2004 according to an institutional management protocol characterized by an early decompressive craniectomy (DC) approach versus a historical control group (n: 20) managed before the implementation of such protocol. Mortality and Glasgow Outcome Score (GOS) at 6 months were used as the main outcome variables.

An early DC protocol implemented within 12 hours from injury in 16 patients with severe isolated TBI and a Marshall score between III or IV was associated with a lesser mortality than the conventional

approach with ventriculostomy and Intensive Care Unit (ICU) management alone. The GOS was significantly better in the DC group (p=0.0002) than in the control group.

The use of an early DC protocol for severe TBI patients (Glasgow Coma Scale <9) had a significantly improved outcome compared with the conventional approach with ventriculostomy and ICU management in Simòn Bolivar Hospital in Bogotá, Colombia [15].

The choice of acute surgical treatment of patients with traumatic brain injury (TBI) is a controversial subject. Primary decompressive hemicraniectomy is used as the first line surgical therapy in some institutions, whereas smaller craniotomies (with hematoma evacuation) are used in others [16] [17].

Decompressive craniectomy (DC), has been performed for the purpose of relieving intracranial hypertension with outcome improvement in specific TBI patients.

Most of the debate surrounding the role of decompressive craniectomy in the management of severe TBI results from a paucity of data coming from randomized controlled trials (RCTs) assessing this intervention.

There have been variations in neurosurgical techniques, timing, and patient populations in most of the observational studies published in the last 2 decades.

A new RCT, pending publication, will evaluate decompressive craniectomy as a secondary procedure after intracranial pressure (ICP) targeted medical therapies have failed, and will hopefully lend further evidence to support or not support this intervention.

Guidelines

Decompressive craniectomy for severe traumatic brain injury Guidelines.

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