



Review article

The current role of decompressive craniectomy for severe traumatic brain injury



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ARTICLE INFO

Article history:

Received 16 January 2017

Accepted 22 April 2017

Keywords:

Decompressive craniectomy

Traumatic brain injury

Randomised controlled trials

ABSTRACT

There is little doubt that decompressive craniectomy can reduce mortality however, the results of a recent study has provided more evidence to inform the debate regarding clinical and ethical concerns that it merely converts death into survival with severe disability or in a vegetative state. The recently published RESCUEicp trial compared last-tier secondary decompressive craniectomy with continued medical management for refractory intracranial hypertension after severe traumatic brain injury. Patients were randomly assigned to decompressive craniectomy with medical therapy or to receive continued medical therapy with the option of adding barbiturates. The results of the study support the findings of the stroke studies in that the reduction in mortality was almost directly translatable into survival with either severe disability or in a vegetative state. The question remains as to whether there is a subset of patients who obtain benefit from surgical decompression and it is in this regard that the use of observational cohort studies and sophisticated outcome prediction models may be of use. Comparing the percentage prediction with the observed long outcome provides an objective assessment of the most likely outcome can be obtained for patients thought to require surgical intervention. Whilst there will always be limitations when using this type of data they may help prompt appropriate patient-centred discussions regarding realistic outcome expectations. A broader debate is also needed regarding use of a medical intervention that may leave a person in a condition that they may feel to be unacceptable and also places a considerable burden on society.

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1. Introduction

Over the past three decades there has been considerable interest in the use of decompressive craniectomy in the context of traumatic brain injury [1–4] and ischaemic stroke [5–8] and more recently following subarachnoid haemorrhage [9,10], infection [11,12] and encephalitis [13]. Overall there seems little doubt that surgical decompression can be a lifesaving intervention and many patients can go on to make a good long term functional recovery. However this is by no means always the case and for many years the concern has been that any reduction in mortality may come at the expense of an increased number of survivors with severe neurological disability and loss of independence [14].

In an attempt to address this particular clinical question, the last decade has seen a number of multicentre prospective randomised controlled trials investigating efficacy of decompressive surgery initially in the context of ischaemic stroke [15–17] and more recently in the context of severe traumatic brain injury [18]. In the early 2000's three European trials compared decompressive hemicraniectomy with standard medical therapy for patients under 60 years of age who clinically deteriorated following middle cerebral artery infarction [15–17]. Each trial independently demonstrated a significant survival benefit in the patients randomised to receive decompressive surgery. Thereafter a pooled analysis of the 93 patients involved in all three trials reported an increase in the number of patients with a favourable outcome [19]. However, this finding was only possible by reclassifying the category of favourable to include patients with a modified Rankin score of 4 (indicating that the patient is unable to walk or function independently). Indeed, closer inspection of the data confirms that the increase in survival came as a direct result of an increase in the

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number of patients with a mRS of 4 [20,21]. The DESTINY II trial investigated efficacy of the procedure in patients over 60 years of age and the results were similar in that most survivors in the hemispherectomy group were adjudged to have a mRS scores of either 4 or 5 [22]. Furthermore most of the survivors had such severe aphasia or neuropsychological deficits that they were unable to provide an answer to a question regarding retrospective consent [21].

The results of decompressive surgery in the context of severe traumatic brain injury are similar. The DECompressive CRAniectionomy (DECRA) study investigated the role of early decompressive bifrontal decompressive craniectomy in the context of diffuse cerebral swelling [18]. Notwithstanding some criticisms of the trial it unequivocally demonstrated that the reduction in intracranial pressure (ICP) observed in the patients in the surgical arm was not translated into clinical benefit. At six month follow up 70% of patients in the craniectomy group had an unfavourable outcome versus 51% of patients in the standard care group. It has been suggested that at the trial enrolment ICP threshold (>20 mmHg for 15 min as recruitment criterion) there was insufficient ongoing secondary brain injury to justify surgical intervention and therefore any potential improvement obtained by surgical decompression was offset by surgical morbidity [23].

Therefore the results of the recently published Randomised Evaluation of Surgery with Elevation of Intracranial Pressure (RESCUEicp) are particularly pertinent in that it was used in patients with a higher ICP threshold and sometimes following evacuation of a mass lesion [24].

2. The RESCUEicp trial

This international, multicentre randomised controlled trial compared last-tier secondary decompressive craniectomy with continued medical management for refractory intracranial hypertension after severe traumatic brain injury. The trial was started in 2004 and recruitment was closed in 2014. Amongst 2008 eligible patients, 409 patients were randomised at 52 centres in 20 countries. The trial differed from the DECRA study in that the enrolment criteria were a higher ICP threshold (25 mmHg for 1–12 h despite maximal medical treatment: except that of barbiturates) and also included patients who had had an intracranial haematoma evacuated (as long as the operation was not a craniectomy). Eligible patients were randomly assigned to undergo either surgical decompression with medical therapy or to receive continued medical therapy with the option of adding barbiturates. The surgical technique was either a unilateral frontotemporoparietal craniectomy or a bifrontal craniectomy depending on the imaging characteristics and surgical discretion.

The results of the study were consistent with the findings of the stroke studies in that the reduction in mortality was almost directly translated into survival with severe disability [19–21].

Overall the investigators should be congratulated on a well-constructed and executed study based on genuine clinical equipoise. There are however issues that require clarification when considering the ongoing use of the procedure. In the first instance there was a relatively high crossover of patients from the medical arm of the trial to the surgical arm. Amongst the 196 patients randomised to receive medical therapy seventy-three went on to have a decompressive procedure. This seems to indicate that, for the patients who crossed over the attending neurosurgeons were no longer in equipoise regarding efficacy of the procedure because the patients developed what was considered to be genuinely intractable intracranial hypertension. Indeed, it could be argued that for those patients who were randomised to receive medical therapy either the ICP was insufficiently intractable to justify surgery or that all those patients with genuine medically intractable

ICP had decompressive surgery regardless of allocation. How that should affect the interpretation of the results is difficult to determine but as the authors state, the observed treatment effect may be somewhat diluted.

The second issue is what constitutes a favourable outcome. As the authors point out, because of the anticipated high proportion of poor outcomes in the overall trial population the category of upper severe disability category was included in the definition of favourable outcome. In doing so it was possible to conclude that favourable outcomes occurred in 42.8% of those patients in the surgical group and in 34.6% in those in the medical group. This finding would seem to support to the ongoing use of the procedure in the context of severe TBI, however it does raise ethical issues.

First, including upper severe disability within the favourable category is problematic. This approach was similar to that of the European stroke trials in which a modified Rankin score of 4 was categorized as favourable. In order to justify this change in the traditional outcome dichotomy, previous investigators have asked patients who have survived with severe disability (where it possible to ask them) whether they regret having had the surgical decompression and whether they would have provided consent if they had known their eventual outcome [15–17]. These studies have shown relatively high levels of so called “retrospective consent” which has been taken as justification for categorizing survival with upper severe disability as acceptable.

However, an alternative and perhaps more realistic interpretation of these positive responses is that patients may have adapted to a level of neurological disability that they might previously have deemed unacceptable, a phenomenon previously observed in the context of both stroke and severe TBI [25,26]. Nevertheless to treat this as a variation of the genuine consent process and a true validation of the surgical intervention no matter what the eventual outcome would perhaps be injudicious.

Informed consent forms one of the fundamental tenets of modern medicine and requires that an individual has a clear understanding of the facts, implications, and future consequences of an action [27,28]. Secondly, the individual concerned must be competent [29,30]. A number of studies have investigated opinion regarding survival with severe disability amongst competent individuals most of whom felt that this outcome would be unacceptable [31,32].

It is in this regard that the results of the RESCUEicp trial require careful consideration because as in the ischaemic stroke studies, if a patient survives following medical therapy there is a reasonable chance that they will recover to a level of independence. However, surgical decompression significantly increases the possibility of survival with severe disability, an outcome that should be reflected in the decision making paradigm.

In the context of an acute TBI it is difficult to withhold decompressive surgery in a young person who develops intractable intracranial hypertension if it is thought that there was at least some chance of survival with an acceptable level of disability and the possibility of unacceptable dependency is acknowledged and accepted by those making the decision. Likewise, for certain individual's, life is sacrosanct based on certain religious, cultural or personal values and may be considered worth preserving at any cost. Other individuals may want to run the “risk” of survival with disability in the hope that they might either survive with a good outcome or learn to adapt to a level of disability that they might previously have deemed unacceptable. Surgical intervention in any of these circumstances can be justified even if the eventual outcome seems regrettable because there are inevitable risks and uncertainties in all fields of medicine.

However, the results of the RESCUEicp trial highlight our responsibilities to a patient who has expressed a definite view that they would not want to survive with severe disability. In such a

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