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Reconsidering the role of decompressive craniectomy for neurological emergencies

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ABSTRACT

Objective: There is little doubt that decompressive craniectomy can reduce mortality. However, there is concern that any reduction in mortality comes at an increase in the number of survivors with severe neurological disability.
Method: Over the past decade there have been several randomised controlled trials comparing surgical decompression with standard medical therapy in the context of ischaemic stroke and severe traumatic brain injury. The results of each trial are evaluated.
Results: There is now unequivocal evidence that a decompressive craniectomy reduces mortality in the context of "malignant" middle infarction and following severe traumatic brain injury. However, it has only been possible to demonstrate an improvement in outcome by categorizing a mRS of 4 and upper severe disability as favourable outcome. This is contentious and an alternative interpretation is that surgical decompression reduces mortality but exposes a patient to a greater risk of survival with severe disability.
Conclusion: It would appear unlikely that further randomised controlled trials will be possible given the significant reduction in mortality achieved by surgical decompression. It may be that observational cohort studies and outcome prediction models may provide data to determine those patients most likely to benefit from surgical decompression.

Contents

1. Introduction

The management of patients with severe traumatic brain injury continues to evolve and many therapies that once formed the cornerstone of neurointensive care management are being re-evaluated in the light of clinical evidence for efficacy. For many years, patients were routinely hyperventilated [1,2], frequently placed in a barbiturate coma [3,4], or more recently rendered hypothermic [5,6], because it could be clearly demonstrated that these measures consistently reduced intracranial pressure (ICP). Given the strong association between intracranial hypertension and poor outcome [7,8] the rationale was that lowering the intracranial pressure would improve cerebral perfusion, prevent secondary brain injury and therefore improve clinical outcome.

However subsequent clinical studies failed to demonstrate clinical benefit and in certain instances, these therapies may have caused harm [1,4,9-11]. Whilst this would seem counterintuitive, studies that

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have investigated the effect that these therapies have on cerebral blood flow, suggest a reason for treatment failure. Notwithstanding the neuroprotective potential of barbiturates and hypothermia [12-15], the mechanism by which these three therapies reduce ICP, is predominantly because of cerebral vasoconstriction and this has been demonstrated by perfusion studies [16-19]. This does not mean that their use has been abandoned, but rather that they are used more selectively and are generally reserved for situations in which the patient is thought unlikely to survive, without therapeutic intervention.

A similar re-evaluation may be required for decompressive craniectomy as a treatment for malignant intracranial hypertension, in the light of the results of recent randomised controlled trials.

2. Decompressive craniectomy for neurological emergencies

The procedure itself is technically straightforward and first became popular in the early 1970's, predominantly in the context of severe traumatic brain injury (TBI) [20,21] and ischaemic stroke [22]. However, a combination of poor clinical outcomes [23,24] and experimental studies that seemed to suggest that decompression may worsen cerebral oedema, led to its use being almost abandoned in the latter part of that decade [25]. Interest in the procedure returned throughout the 1980s and 1990's and there was a progressive increase in the number of publications reporting surgical intervention, not only in the context of TBI [26,27] and stroke [28,29] but also following other neurological emergencies, such as subarachnoid haemorrhage [30,31], cerebrovenous thrombosis [32,33], severe intracranial infection [34,35], inflammatory demyelination [36,37] and encephalopathy [38,39].

These studies supported the claim that mortality could be reduced and many patients were reported to make a good functional and neurocognitive recovery. However, that was not always the case and there was concern that surgical intervention merely converted death into survival with severe disability and dependency [40]. To address this issue the last decade has seen a number of prospective multicentre randomised controlled trials investigating clinical efficacy of decompressive craniectomy initially in the context of ischaemic stroke [41-43] and more recently in the context severe traumatic brain injury [44,45].

3. Decompressive craniectomy following ischaemic stroke

The evidence obtained from the trials investigating efficacy of decompressive caniectomy in the context of ischaemic stroke, overwhelmingly confirm that the procedure is a lifesaving intervention [41-43]. The pooled analysis of the three European trials that investigated efficacy of decompressive craniectomy in the context of "malignant" middle cerebral artery infarction, in patients under sixty years of age, demonstrated a reduction in mortality from 71% in the medical arm of the trial, to 22% in the surgical arm (Table 1) [46]. However, this reduction in mortality came about as an almost direct result of an increase in the number of patients who survived, with moderately severe disability.

The number of survivors with a modified Rankin Scale (mRS) score of 4 (and therefore dependency) was increased from 2% in the medical arm to 31% in the surgical group and the reclassification of this outcome category as favourable, remains controversial [47,48]. The translation of death into survival with severe disability was even more striking in the DESTINY II trial that investigated decompressive craniectomy for patients over 60 years of age [49]. Of the twenty-seven patients who survived following decompressive craniectomy, only two patients achieved a mRS score of 3 and therefore had some degree of independence. Of the remaining twenty-five patients, there was an equal distribution of patients with a mRS of 4 and five and sixteen of these patients had severe aphasia or neuropsychological problems, such that they were unable to answer a relatively simple question regarding retrospective consent (Table 2) [48].

Overall, these trials confirm the ethical concern that decompressive craniectomy reduces mortality, at the expense of survival with severe disability, especially for patients over sixty years of age. The results of recent randomised controlled trials in the context of severe traumatic brain injury have been similar and should therefore be addressed.

4. Decompressive hemicraniectomy following severe traumatic brain injury

The DECRA study investigated the role of early bifrontal decompressive craniectomy in the context of diffuse cerebral swelling and it demonstrated that outcomes were worse in those patients in the surgical arm of the trial [44]. The results of the study evoked considerable debate and one of the key criticisms was that the ICP threshold at which patients were randomised (20 mm Hg for >15 min in the hour), was not representative of current clinical practice (which is to intervene at higher ICP thresholds) [50]. This may be a valid observation, however, it fails to acknowledge the trial hypothesis which was that early decompression, would improve cerebral perfusion, reduce secondary insults and improve clinical outcome.

Given the relatively low ICP threshold at which patients were enrolled, it is unsurprising that the trial did not demonstrate a survival benefit, for those patients randomised to the surgical arm of the trial. However, the trial did clearly show that at that ICP threshold, (20 mm Hg for >15 mins/h), there was insufficient ongoing secondary brain injury and therefore any potential benefit obtained from improved cerebral perfusion, was offset by the increasingly well recognised surgical morbidity. Whilst the patients in the trial may not have been representative of current clinical practice, if the trial had shown benefit these patients would have come to represent the *clinical practice of the future*, which would have had significant impact on neurosurgery [51].

It is in this regard that the results of the recently published RESCUEicp are particularly pertinent, as it was felt to be more reflective of current clinical practice [45]. The trial compared last-tier secondary decompressive craniectomy, with continued medical management in patients with a higher ICP threshold (25 mm Hg for 1 to 12 h despite maximal medical treatment: except for barbiturates). It was conducted over a ten-year period, between 2004 and 2014. Four hundred and nine patients were randomised, amongst 2008 eligible patients, at 52 centres in 20 countries. The results of the trial demonstrated a clear survival benefit in those patients randomised to surgical decompression and these results were consistent with the results of the stroke trials. There were further similarities, in that this reduction in mortality came as an almost direct result of an increase in the number of survivors in either a vegetative state, or with severe disability. At twelve month

Table 1
Pooled analysis from the European randomised controlled trials [46].

mRS	Hemicraniectomy $n = 51$ patients (%)	Conservative $n = 42$ patients (%)
6	11 pts. (22%)	30 pts. (71%)
5	2 pts. (4%)	2 pts. (5%)
4	16 pts. (31%)	1 pt. (2%)
3	15 pts. (29%)	8 pts. (19%)
2	7 pts. (14%)	1 pt. (2%)

Table 2
DESTINY II trial [49].

Amongst 27 patients who had decompressive hemicraniectomy
- 2 patients mRS - 3
- 25 patients mRS - 4 or 5;
  - Sixteen of these patients could not answer a question regarding retrospective consent because of severe aphasia or neuropsychological deficits
  - Amongst the nine patients that 9 that could answer:
    - Five said Yes
    - Four said No