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What's new in decompressive craniectomy in neurological emergencies: the good, the bad and the ugly

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Conflicts of interest

MS was a member of the Independent Data Monitoring and Ethics Committee (IDMEC) of the RESCUEicp trial, and is chair of the IDMCE of the RESCUE-ASDH trial.

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Raised intracranial pressure (ICP) is associated with worse outcomes after acute brain injury. Tiered management of intracranial hypertension, moving from lower (safer) to higher (more dangerous) tier therapies, is well established in the management of TBI [1]. Secondary decompressive craniectomy (DC), a surgical procedure in which part of the skull is removed and the dura opened to reduce brain swelling-related high ICP, is widely used as a final-tier (life-saving) intervention in patients with severe intracranial hypertension refractory to other interventions [2]. DC has been reported in a number of conditions but only evaluated in randomized controlled trials (RCTs) after TBI and acute ischaemic stroke (AIS).

Traumatic brain injury

Two RCTs have investigated secondary DC to control elevated ICP after severe TBI. The DECRA study [3] sought to determine the role of DC as a relatively early intervention, and provoked interesting debate. Randomisation to DC or continuing medical care was triggered by a short period of modestly raised ICP (> 20 mmHg for > 15 min in a single hour), and a large proportion of TBI patients (those with intracranial mass lesions) were excluded. DECRA confirmed that there is no role for DC as an early (second tier) intervention to treat TBI-related intracranial hypertension. The RESCUEicp study [4] investigated the impact of DC as a final-tier intervention in all severe TBI patients if ICP remained > 25mmHg for at least 1 h despite first- and second-tier ICP-lowering interventions. At 6 months DC resulted in lower mortality, but higher rates of vegetative state and lower and upper severe disability compared with medical treatment (including addition of barbiturates after randomisation), with similar rates of moderate disability and good recovery. Patients undergoing DC continued to improve beyond 6 months. The contrasting results in the DECRA and RESCUEicp trials are related to differences in hypotheses, eligibility criteria, and therapeutic protocols that have been extensively discussed elsewhere [5]. In the absence of equivocal evidence of benefit beyond reduced mortality, expert consensus guidelines outlining the role and timing of secondary DC in the management of TBI, and areas of continued uncertainty, have recently been published [2].

The evidence for DC in the management of TBI is primarily based on data collection and protocol development in high-income countries, and is not easily generalisable to low and middle-income countries (LMICs) where the majority of TBI-related deaths occur [6]. In resource poor settings, in the absence of any type of neuromonitoring including the possibility of repeating CT scans because of related costs, DC is often used as a preventive measure to control ICP in patient with ‘high risk’ CT findings on admission [7]. Clinical decisions must always be made in the context of local expertise, resources and capacity for long-term care and rehabilitation.

Acute ischaemic stroke

A small but significant proportion of patients develop clinically relevant cerebral oedema and intracranial hypertension after AIS, typically following distal internal carotid artery or proximal middle cerebral artery (MCA) occlusion. ‘Malignant’ MCA syndrome leads to clinical deterioration in two-thirds of affected patients within 48 hours of stroke onset [8], and has a mortality rate of almost 80% if untreated and in excess of 50% despite maximal medical management. A pre-specified pooled analysis of 3 RCTs including patients aged between 18 and 60 years found that DC within 48 h of AIS onset resulted in a substantial reduction in 12-month mortality compared to conservative management, and a higher proportion of survivors with ‘favourable’ outcomes as defined by a modified Rankin score (mRS) of 0-4 [9]. The role of DC in elderly stroke patients is more controversial. In the DESTINY II trial [10], DC in patients aged between 61 and 82 years resulted in lower mortality but a higher proportion of survivors with severe disability compared to medical treatment; no patient survived with no or minimal disability in this study. In contrast, a large Japanese database study in which more than 80% of AIS patients were aged over 60 years found no independent association between age and early mortality after DC [11].

Clinical outcomes

While DC is effective in reducing critically raised ICP and mortality, significant questions remain regarding its impact on functional outcomes and quality of life in survivors. Recent clinical trials have used extended Glasgow outcome score (GOSE) of 4 (upper severe disability) or better, or mRS of 4 or better, to define favourable outcome after TBI and AIS, respectively. GOSE 4 describes a state in which individuals are independent at home for at least 8 hours per day and mRS4 one in which individuals are unable to walk or attend to their bodily needs without assistance. There are valid reasons for using these definitions in studies investigating brain-injured patients requiring DC, given that these are the 10 - 15% most severely injured patients on intensive care units. However, the results of these studies must be considered in the context of the degrees of disability considered satisfactory outcomes by individual patients and their families [12]. The dismal outcome of untreated refractory intracranial hypertension may lead clinicians to recommend DC to improve the chance of survival, but this must be balanced against the prospect of survival with a range of disability. While individuals' attitudes to levels of disability vary considerably, it is overall quality of life (rather than the functional outcome in isolation) that is most important to many [13].

We believe that it is time to move away from the concepts such as 'favourable' versus 'unfavourable' outcomes, and whether studies are 'positive,' 'neutral' or 'negative,' and, instead, recognise that clinical trials provide data that assist in clinical decision making. What is a favourable outcome for one patient and family may not be favourable for another, and vice versa. In this regard, the RESCUEicp study showed that DC in preference to on-going medical management would save 22 more lives, with 5 survivors remaining in a vegetative state, 4 with lower severe disability and 13 with upper severe disability or better. The challenge going forwards is to determine why a particular patient who survives is destined for a particular outcome group. In the meantime, the importance of shared decision making, based on likely outcomes of different therapeutic options,

prolonged recovery times and potential post-procedure quality of life, cannot be over-estimated (table 1).

Reconstructive surgery

Large skull defects leave the brain unprotected, disturb CSF dynamics and can lead to neurological dysfunction that impacts outcomes. Reconstructive cranioplasty restores skull integrity and CSF dynamics after DC, and early cranioplasty (within 3 months) may aid rehabilitation and improve outcomes [14]. However, cranioplasty is not without risk; the overall complication rate has variably been reported to lie between 10.9% and 40.4% [2]. The outcome impact of skull defects and subsequent cranioplasty are not considered fully in current RCTs, potentially over-estimating the impact of DC on longer-term outcomes. Moreover, the costs and logistics of cranioplasty are major factors limiting DC in LMICs. Floating or hinged bone flaps can control moderate brain swelling and obviate the need for subsequent cranioplasty [15].

The optimal timing of, and material used for, cranioplasty, as well as evaluation of alternative techniques for brain decompression, such as hinged bone flaps, are important areas for future research.

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Table 1

Decompressive craniectomy in traumatic brain injury and acute ischaemic stroke

The good

Evidence

- Two RCTs in traumatic brain injury
- One pooled analysis and one RCT in acute ischaemic stroke

Impact

- Decreased mortality
- 59% of survivors at least independent at home (RESCUEicp)
- Improved ICP control
- Reduction in intensive medical treatment (e.g. barbiturates) and associated complications

The Bad

Impact

- Prospect of survival with a range of disability
- Associated with high risk of complications which impact on outcome (not fully considered in current RCTs)
- Requirement for subsequent cranioplasty with associated risks and costs

Other

- Requires early and on-going rehabilitation
- Limited translation to low- and middle-income countries

The Ugly

Outcomes

- Cannot predict the likely degree of disability in individual survivors
- Social impact may be too high for survivors – shared decision making essential
- RCTs focussed on functional outcomes, whereas overall quality of life important to many patients and families

Interpretation of RCTs

- Data from RCTs assist in deciding treatment options and likely impact on outcomes; further studies are required to refine clinical decision-making in individual patients.
- Pre-specified 'favourable' vs. 'unfavourable' outcome categories specified in RCTs, but their results should be considered in the context of the degrees of disability considered satisfactory outcomes by individual patients and their families

ICP, intracranial pressure; RCTs, randomised controlled trials