

COMMENTARY

Is decompressive craniectomy useless in severe traumatic brain injury?

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Abstract

Recently, a multicenter randomized controlled trial (RCT) by Cooper and colleagues indicated that decompressive craniectomy (DC) may be associated with a worse functional outcome in patients with diffuse traumatic brain injury (TBI), although DC can immediately and constantly reduce intracranial pressure (ICP). As this trial is well planned and of high quality, the unexpected result is meaningful. However, the evidence of the study is insufficient and the effect of DC in severe TBI is still uncertain. Additional multicenter RCTs are necessary to provide class I evidence on the role of DC in the treatment of refractory raised ICP after severe TBI.

Decompressive craniectomy (DC) is a straightforward procedure that for more than a century has been widely used to treat medically refractory intracranial hypertension of patients with severe traumatic brain injury (TBI). Although a series of clinical studies demonstrated that the procedure is the one of the most effective treatments in reducing intracranial pressure (ICP) [1,2], no large prospective randomized controlled trial (RCT) had investigated the relation between successful or sustained reduction of increased ICP and functional outcomes after DC. An updated Cochrane review published in 2009 identified only one prospective randomized clinical trial ($n = 27$ participants) that evaluated the effect of DC in severe TBI [3]. The same year, a small ($n = 74$ patients) RCT that was published by Qiu and colleagues [4] indicated the beneficial effects of DC in patients with acute post-traumatic brain swelling.

In March of this year, a multicenter RCT by Cooper and colleagues [5] was published in the *New England*

Journal of Medicine. Before this multicenter RCT, a pilot randomized trial [6] was completed to enable the multicenter DC study protocol. This multicenter RCT enrolled 155 adults with severe non-penetrating TBI and medically refractory intracranial hypertension from December 2002 through April 2010 but excluded patients with mass lesions. The results showed that, although DC can immediately and constantly reduce ICP (mean ICP of 14.4 mm Hg versus 19.1 mm Hg; $P < 0.001$), the craniectomy group that received bifrontotemporoparietal DC ($n = 73$) may be associated with a worse functional outcome than the standard-care group ($n = 82$) (odds ratio of 1.84 and 95% confidence interval of 1.05 to 3.24; $P = 0.03$). As this trial is well planned and of high quality, the unexpected result is meaningful and should be considered a reference for an evidence-based guideline. However, the evidence of the study is insufficient. First, the relatively small sample size is inadequate to provide a strong conclusion. Second, the thresholds for defining medically refractory intracranial hypertension (ICP of greater than 20 mm Hg for more than 15 minutes within a 1-hour period after first-tier interventions) are not what many physicians would consider refractory. Third, in almost 3,500 potentially eligible patients, only 155 patients were enrolled (patients with a cerebral mass lesion were excluded). Therefore, the study cannot be generalized to all patients with severe non-penetrating brain injury. Fourth, after random assignment, more patients in the DC group had fixed and dilated pupils than patients in the medical therapy group (no reactivity of bilateral pupils: 27% versus 12%), and this should be considered a potential risk of bias. Lastly, 15 patients (18%) in the standard-care group underwent delayed DC as a lifesaving intervention. Although the investigators used intention-to-treat analysis, the bias introduced by the compassionate use of DC in the standard-care group should not be overlooked.

For these reasons, total disapproval of the effect of DC in severe TBI by some authors [7] is inappropriate. Additional multicenter RCTs are necessary to provide further conclusions on the efficacy of this procedure. In 2006, an international multicenter RCT comparing DC with medical management for refractory raised ICP was

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sponsored by the University of Cambridge [8]. This RESCUEicp (Randomized Evaluation of Surgery with Craniectomy for Uncontrollable Elevation of Intracranial Pressure) study planned to recruit 650 patients with refractory ICP after TBI (50 for the pilot phase and 600 for the main study) in an attempt to provide class I evidence on the role of surgical decompression in the treatment of raised ICP after severe TBI. Recently, an updated protocol [9] revealed that the RESCUEicp trial had recruited over 280 patients from more than 40 centers in 17 countries. We anxiously await the results of this international multicenter RCT and hope that they will enhance the evidence to guide the treatment of severe TBI.

Abbreviations

DC, decompressive craniectomy; ICP, intracranial pressure; RCT, randomized controlled trial; RESCUEicp, Randomized Evaluation of Surgery with Craniectomy for Uncontrollable Elevation of Intracranial Pressure; TBI, traumatic brain injury.

Competing interests

The authors declare that they have no competing interests.

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