

## Original Article

# Primary decompressive craniectomy is associated with worse neurological outcome in patients with traumatic brain injury requiring acute surgery

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## Abstract

**Background:** The role of decompressive craniectomy in treating raised intracranial pressure (ICP) after traumatic brain injuries (TBI) is controversial. The aim of this study was to assess the differences in prognosis of patients initially treated by decompressive craniectomy, craniotomy, or conservatively.

**Methods:** We conducted a single-center retrospective study on adult blunt TBI patients admitted to a neurosurgical intensive care unit during 2009–2012. Patients were divided into three groups based on their initial treatment – decompressive craniectomy, craniotomy, and conservative. Primary outcome was 6-month Glasgow Outcome Scale (GOS) dichotomized to favorable outcome (independent) and unfavorable outcome (dependent). The association between initial treatment and outcome was assessed using a logistic regression model adjusting for case-mix using known predictors of outcome.

**Results:** Of the 822 included patients, 58 patients were in the craniectomy group, 401 patients in the craniotomy group, and 363 patients in the conservatively treated group. Overall, 6-month unfavorable outcome was 48%. After adjusting for case-mix, patients in the decompressive craniectomy group had a statistically significantly higher risk for poor neurological outcome compared to patients in the conservative group (OR 3.06, 95% CI 1.45–6.42) and craniotomy group (OR 3.61, 95% CI 1.74–7.51).

**Conclusion:** In conclusion, patients requiring primary decompressive craniectomy had a higher risk for poor neurological outcome compared to patients undergoing craniotomy or were conservatively treated. It is plausible that the poor prognosis is related to the TBI severity itself rather than the intervention. Further prospective randomized trials are required to establish the role of decompressive craniectomy in the treatment of patients with TBI.

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**Key Words:** Craniotomy, decompressive craniectomy, mortality neurological outcome, surgery traumatic brain injury

## INTRODUCTION

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.<sup>[1,2]</sup>

Raised intracranial pressure levels increases the risk for secondary brain ischemia and is highly correlated with poor outcome, which highlights the importance of aggressive ICP-directed treatment.<sup>[3-9]</sup> Today it is unknown whether patients requiring acute surgery for raised intracranial pressure should be treated primarily by craniotomy and hematoma evacuation or by decompressive craniectomy.<sup>[2,9-13]</sup> To date, no clinical trial has shown any benefit of primary decompressive craniectomy in terms of patient outcome, although it is effective in acutely lowering ICP.<sup>[14,15]</sup> Recently, the RESCUE-ICP trial, which compared conservative management versus decompressive craniectomy for refractory intracranial hypertension, showed lower mortality rates in the craniectomy group, but with higher disabilities at 6 months following injury.<sup>[16]</sup> Yet, few previous studies have the choice of craniotomy versus craniectomy as a firstline surgical therapy for patients with severe TBI requiring surgery.

The aim of this study was to assess the independent relationship between initial treatment (decompressive craniectomy, craniotomy, or conservative treatment) and patient prognosis in patients with TBI treated in a neurosurgical intensive care unit (ICU).

## MATERIALS AND METHODS

We conducted an open-cohort retrospective study among 822 adult ( $\geq 18$  years) blunt TBI patients admitted to the neurosurgical ICU of Töölö Hospital, University hospital of Helsinki, between January 1, 2009 and December 31, 2012. Töölö hospital is one of the largest trauma I hospitals in Northern Europe, covering a population of approximately 2 million people.

Patient data was retrospectively gathered from electronic hospital charts. Patient admission variables were assessed by the treating neurosurgeon and collected from subsequent electronic records. All admission head computerized tomography (CT) scans were classified by two authors (R.R, R.K).<sup>[17,18]</sup>

Patients were divided based on their primary neurosurgical intervention into conservative treatment, acute craniotomy and mass lesion evacuation (craniotomy),

and decompressive craniectomy (craniectomy). Patients who first underwent craniotomy and later had to be treated with decompressive craniectomy were classified as decompressive craniectomy patients.

Our primary outcome was 6-month neurological outcome, defined according to the Glasgow Outcome Scale (GOS). We dichotomized neurological outcome to favorable and unfavorable outcomes. Unfavorable outcome was defined as GOS 1 (death), 2 (vegetative state), and 3 (severe disability). Favorable outcome was defined as GOS 4 (moderate disability) and 5 (good recovery). The GOS was assessed based on follow-up visits with a neurosurgeon or neurologist. As a secondary outcome of interest, we used 6-month mortality which was determined from the Finnish population registry (available for all Finnish citizens).

The treatment protocol for patients with severe TBI are based upon the Brain Trauma Foundation's guidelines.<sup>[19]</sup> In general, patients with operable hematomas without signs of diffuse brain injury and raised ICP are treated by craniotomy and hematoma evacuation. Primary decompressive craniectomy is usually reserved for those with signs of severe intracranial hypertension on the admission head CT (e.g., obliterated basal cisterns, diffuse bilateral swelling, or midline shift non-proportional to the size of the hematoma).

## Statistical methods

Categorical variables are presented as N (%) and tested using a two-sided Chi-square test. Continuous data were tested for skewness – normally distributed data are presented as mean (SD) and skewed data as median (IQR). Normally distributed data are tested using a *t*-test and skewed data are tested using the Mann–Whitney U test. To test the independent effect of decompressive craniectomy on outcome, we created a binary logistic regression model adjusting for factors previously known to predict outcome after TBI. The included covariates were age, the Glasgow Coma Scale (GCS) motor score, pupillary light reactivity, hypoxia, hypotension, hemoglobin, glucose, and the Helsinki CT score.<sup>[15,18]</sup> The results from the logistic regression model are presented as odds ratios (OR) with 95% confidence intervals (CI).

## RESULTS

Of the 822 included patients, 401 underwent craniotomy (49%), 58 craniectomy (7%), and 363 patients (44%) did not require surgery (conservative group). Table 1 shows study baseline characteristics. The patients forming the

**Table 1: Study population baseline characteristics**

Variables	No operation n=363	Craniotomy n=401	Craniectomy n=58	P
Age	57 (42-67)	61 (50-71)	45 (29-55)	<0.001
GCS				
3-8	133 (36.6%)	183 (45.6%)	42 (72.4%)	<0.001
9-12	83 (22.9%)	100 (24.9%)	13 (22.4%)	
13-15	147 (40.5%)	118 (29.4%)	3 (5.2%)	
Motor score				
None/extension	68 (18.7%)	85 (21.2%)	23 (39.7%)	<0.001
Normal/abnormal flexion	39 (10.7%)	70 (17.5%)	11 (19.0%)	
Localizes/obeys	256 (70.5%)	246 (61.3%)	24 (41.4%)	
Pupillary light reactivity				
None	63 (17.4%)	52 (13.0%)	7 (12.1%)	<0.001
One	17 (4.7%)	66 (16.5%)	11 (19.0%)	
Both	283 (78.0%)	283 (70.6%)	40 (69.0%)	
Hypoxia	66 (18.2%)	48 (12.0%)	13 (22.4%)	0.019
Hypotension	36 (9.9%)	22 (5.5%)	4 (6.9%)	0.067
Midline shift (mm)	0 (0-4)	9 (4-14)	4 (0-11)	<0.001
Basal cisterns				
Normal	273 (75%)	160 (40%)	18 (31%)	<0.001
Compressed or obliterated	90 (25%)	241 (60%)	40 (69%)	
Marshall CT				
II	216 (59.5%)	42 (10.5%)	10 (17.2%)	<0.001
III	22 (6.1%)	4 (1.0%)	10 (17.2%)	
IV	14 (3.9%)	11 (2.7%)	5 (8.6%)	
EML/NEML	111 (30.6%)	344 (85.8%)	33 (56.9%)	
Rotterdam				
1	15 (4.1%)	13 (3.2%)	0 (0.0%)	<0.001
2	76 (20.9%)	52 (13.0%)	1 (1.7%)	
3	183 (50.4%)	90 (22.4%)	15 (25.9%)	
4	35 (9.6%)	116 (28.6%)	18 (31.0%)	
5	34 (9.4%)	97 (24.2%)	15 (25.9%)	
6	20 (5.5%)	33 (8.2%)	9 (15.5%)	
Helsinki CT score (IQR)	4 (2-6)	5 (4-7)	6 (4-8.25)	<0.001
Glucose mmol/l	7.2 (6.2-8.7)	7.2 (5.9-8.8)	7.6 (6.7-9.4)	0.058
Hemoglobin (g/L)	130 (116.0-142.0)	121 (109.0-134.0)	129 (117.0-138.0)	<0.001
Length of stay				
ICU	1.8 (1.0-4.0)	2.5 (1.0-5.6)	11 (5.4-15.6)	<0.001
Hospital	7 (3.0-11.0)	8 (4.0-15.0)	18 (12.0-25.0)	<0.001
Six month outcome				
Unfavourable outcome	148 (40.8%)	214 (53.4%)	35 (60.3%)	<0.001
Mortality	85 (23.4%)	107 (26.7%)	16 (27.6%)	0.536

Abbreviations: GCS: Glasgow Coma Scale, ICU: Intensive Care Unit

decompressive craniectomy group were significantly younger (median 45 years, IQR 29–55) than the two other study groups [median 61 years (IQR 50–71) for craniotomy and median 57 years (42–67) for conservative group, <0.001].

The majority of patients (72%) who underwent decompressive craniectomy had GCS score of 8 or lower, whereas these patients were significantly less frequent

in the craniotomy and conservative groups (46% and 37%,  $P < 0.001$ ). An abnormal pupillary light reaction was significantly more frequent in the decompressive craniectomy group compared to the craniotomy and conservative groups (31%, 29%, and 22%, respectively;  $P < 0.001$ ).

Patients in the decompressive craniectomy group (4 mm, IQR 0–11) and patients in the craniotomy

group (9 mm, IQR 4–14) had significantly more midline shift on their primary head-CT scan than patients in the conservative group (0 mm, IQR 0–4) ( $P < 0.001$ ). Of patients in the decompressive craniectomy group, 69% had compressed or obliterated basal cisterns on their admission head-CT scan compared to 60% and 25% in the craniotomy and conservative groups, respectively. Further, the median Helsinki CT score was significantly higher in the decompressive craniectomy group compared to the craniotomy and conservative groups (median score 6 out of 14 vs. 5 out of 14 and 4 out of 14, respectively).

### Unadjusted outcome

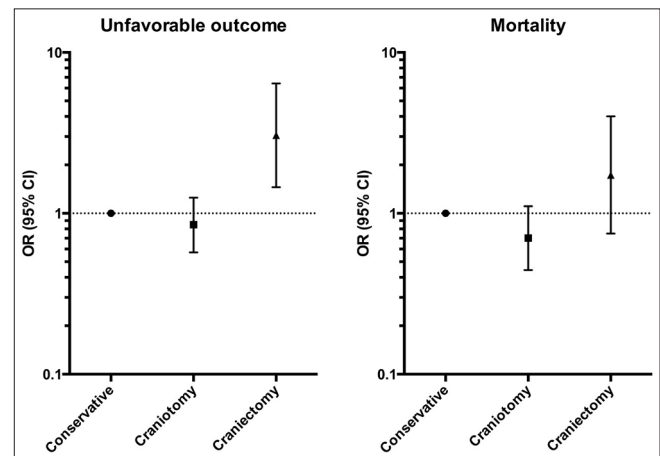
Regarding outcome, 60% of the patients in the decompressive craniectomy group had an unfavorable outcome compared to 53% and 41% in the craniotomy and conservatively treated groups, respectively ( $P < 0.001$ ). There were, however, no significant difference in unadjusted 6-month mortality rate between the groups (range 23–28%,  $P = 0.536$ ).

### Multivariate analysis

Results from the multivariate logistic regression analysis is shown in Table 2. Higher age was highly associated with a higher risk for unfavorable outcome (OR 1.06, 95% CI 1.05–1.07) and 6-month mortality (OR 1.06, 95% CI 1.05–1.08). The number of reactive pupils had an inverse correlation with poor outcome. The GCS motor score, Helsinki CT score, and admission hemoglobin levels strongly associated with 6-month outcome, as well [Table 2].

For 6-month unfavorable neurological outcome, patients in the decompressive craniectomy group had a 3.06

(95% CI 1.45–6.42,  $P < 0.001$ ) higher odds for unfavorable neurological outcome compared to conservatively treated patients and a 3.61 (95% CI 1.74–7.51,  $P < 0.001$ ) higher odds compared to patients in the craniotomy group [Figure 1]. For 6-month mortality, decompressive craniectomy was not associated with an increased risk for death (OR 1.73, 95% CI 0.75–4.01,  $P = 0.199$ ) compared to conservatively treated patients but was associated with an increased risk for death compared to patients in the craniotomy group (OR 2.47, 95% CI 1.10–5.55,  $P = 0.029$ ).



**Figure 1: Results from the multivariate analysis. To the left the independent effect of primary operation technique on six-month mortality and to the right the effect on six-month unfavorable outcome. Decompressive craniectomy was independently associated with an increased risk for unfavorable neurological outcome but not mortality. Abbreviations: OR, Odds Ratio; CI, Confidence Intervals**

**Table 2: Results from the multivariate analysis**

Variables	Unfavorable outcome		Mortality	
	Odds ratio (95% CI)	P	Odds ratio (95% CI)	P
Age	1.06 (1.05-1.07)	<0.001	1.06 (1.05-1.08)	<0.001
Pupil reactivity				
None		0.006		<0.001
One	0.50 (0.23-1.08)	0.078	0.30 (0.15-0.59)	<0.001
Both	0.34 (0.17-0.67)	<0.001	0.19 (0.10-0.36)	<0.001
Motor score				
None/extension		<0.001		<0.001
Normal/abnormal flexion	0.54 (0.29-1.04)	0.065	0.57 (0.31-1.07)	0.081
Localizes/obeys	0.31 (0.17-0.55)	<0.001	0.33 (0.18-0.60)	<0.001
Glucose	0.99 (0.92-1.07)	0.878	1.11 (1.03-1.20)	0.008
Hemoglobin	0.98 (0.97-0.99)	<0.001	0.98 (0.97-0.99)	<0.001
Hypoxia	1.52 (0.91-2.53)	0.107	1.48 (0.87-2.51)	0.148
Hypotension	0.79 (0.37-1.69)	0.548	1.04 (0.47-2.32)	0.917
Operation				
No operation		0.003		0.052
Craniotomy	0.85 (0.57-1.25)	0.401	0.70 (0.44-1.11)	0.128
Decompressive craniectomy	3.06 (1.45-6.42)	<0.001	1.73 (0.75-4.01)	0.199
Helsinki CT score	1.21 (1.13-1.29)	<0.001	1.18 (1.10-1.30)	<0.001

Abbreviations: CT: Computerized Tomography, CI: Confidence Interval

## DISCUSSION

### Key findings

In this study, we investigated the association between decompressive craniectomy versus craniotomy and outcome, as the first line surgical treatment, in patients with TBI treated in the ICU requiring acute surgery. As a control group we used patients conservatively treated in the ICU. We examined unfavorable neurological outcome and mortality and found that decompressive craniectomy was associated with a higher risk for unfavorable outcome and mortality compared to patients undergoing craniotomy. Our study is retrospective and, thus, one should be careful to draw any far going conclusions regarding the application of decompressive craniectomy based on our results. We highlight that the purpose of the study was not to assess the effectiveness of decompressive craniectomy but rather to assess the differences in outcome between patients undergoing decompressive craniectomy and craniotomy as the firstline surgical treatment.

Our results should not be surprising as decompressive craniectomy is often reserved to presenting with signs of severe intracranial hypertension who have the poorest baseline prognosis. This is supported by our study as patients in the craniectomy group more frequently displayed abnormal basal cisterns, lower GCS scores, and abnormal pupils than patients in the craniotomy group. Thus, it is plausible that the TBI severity in itself is the major determinant of patient outcome, regardless of the surgical technique performed (craniotomy or decompressive craniectomy). There is, however, a possibility that craniectomy allowed some of the most severe TBI patients to survive at the cost of neurological function, something that should be considered before performing the surgery.

Noteworthy, patients in the craniotomy group had a higher degree of midline shift but less compression of the basal cisterns than patients in the craniectomy group, indicating removable mass lesions in the craniotomy group and more diffuse swelling in the craniectomy group. The fact that craniotomy was not associated with an increased risk for poor outcome compared to conservatively treated patients that these patients' prognosis can be improved through adequate mass lesion evacuation.

### Previous studies

Decompressive craniectomy has for long been one of the most controversial topics in neurotrauma. Some studies have addressed this matter by presenting somewhat similar conclusions.<sup>[10-12,14,20,21]</sup> Contrary to our results, studies report no significant difference in outcome between the two operations.<sup>[10-13]</sup> It is also shown that decompressive craniectomy accounts for higher mortality.<sup>[12,13,20-22]</sup> It is also suggested that the role of the operation type is irrelevant.<sup>[11,23]</sup> The results of our study finds some support in previously conducted research where the outcome of

decompressive craniectomy is poorer than for the rest.<sup>[24,25]</sup> Regarding outcome, decompressive craniectomy has been determined the worse option of the two operations, which also aligns with our results.<sup>[25,26]</sup>

Almost without exception, the conducted studies are of retrospective nature and some lack proper randomization<sup>[10,26]</sup> and thus, cannot provide us the most reliable results we need. Recently, the RESCUE-ICP study was published.<sup>[16]</sup> In the study, decompressive craniectomy was compared to maximal conservative treatment for patients with refractory intracranial hypertension, and not primary surgery, as in the current study. Yet, the RESCUE-ICP results align with the results provided by our study. Both studies showed a higher risk for poor neurological outcome in patients undergoing decompressive craniectomy. This supports the results of our study, which highlights a similar trend in outcome. The recently started RESCUE-ASDH trial aim to compare primary decompressive craniectomy and craniotomy. The study will give us the best evidence till date regarding the preferred surgical technique. Until then, our present study is one of the largest retrospective surgical series presented on this topic.

### Limitations

There are a few limitations to our study that should be discussed. First, the study was of retrospective nature, which meant that case-mix differences between the decompressive craniectomy, craniotomy, and conservatively treated group are unavoidable. We accounted for some case-mix differences by applying a logistic regression model adjusting for the previously known predictors of outcome after TBI. However, such case-mix adjustment is only as good as the model used and variables not included are not adjusted for. It should be stressed that the aim of this study was not to assess the effectiveness of decompressive craniectomy but to assess the association between the need for decompressive craniectomy as the primary surgery and outcome. Second, this was a single-center study, which means that broader one should be careful to generalize our results. Our institution is, however, of the largest trauma units in Northern Europe, covering almost 2 million people and, thus, represent a large portion of severe TBI cases in Europe. Third, as a primary outcome of interest we used neurological outcome, defined by the GOS. The GOS does not account for important aspects of recovery after TBI such as patient quality of life and neuropsychological outcome.

## CONCLUSION

Patients requiring primary decompressive craniectomy had a higher risk for poor neurological outcome and mortality compared to patients undergoing craniotomy. It is plausible that the poor prognosis is related to the TBI severity itself rather than to the intervention. Further

prospective randomized trials are required to establish the role of decompressive craniectomy in the treatment of patients with TBI.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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## Commentaries

### Decompressive craniectomy in the treatment of severe traumatic brain injury: The question of quality of survival

In this article, Tapper, *et al.* detail their considerable experience in the treatment of adults with severe traumatic brain injury (TBI) over a four year period. The geography and local health care system overseen by their home institution provide for an outstanding representative example of this disease process. Advantages of this study include the consistent protocol driven care at

a single center of excellence, the extremely high volume of patients cared for over this time period, and the rigorousness of the authors' data collection methodology and statistical analysis. Disadvantages of this study include its retrospective, non-blinded, non-randomized, non-variable adjusted control and comparison groups. Out of the 822 patients seen over this time period that met the study's inclusion criteria, 401 or over 7 times as many patients had a standard craniotomy and lesion evacuation as had a decompressive craniectomy. This discrepancy reflects the authors' operative protocol to restrict decompressive craniectomy to only those patients with the most severe evidence of preoperative intracranial hypertension. 363 or over 40% of the patients

were treated non-operatively (had no operative lesion or evidence of severe intracranial hypertension on admission imaging). Clearly, decompressive craniectomy, as others have also shown,<sup>[1-5]</sup> is a powerful tool to acutely lower intracranial hypertension. This is reinforced here as the 6 month mortality of 27.6% in the decompressive craniectomy group is not statistically different from the mortality of the standard craniotomy and non-operative treatment groups, despite the more dire circumstances in which these patients initially presented. However, as previously revealed in the more powerful, although not equivalent, RESCUEicp trial,<sup>[6]</sup> the authors discovered that survival in general did not translate specifically into a favorable (independent) outcome. Only 40% of decompressive craniectomy patients achieved GOS score 4-5 at 6 months post injury versus almost 50% of standard craniotomy and almost 60% of non-operative patients. But despite the title of the authors' manuscript, given the non-randomized nature of the treatment groups, it would be inappropriate to definitively conclude that standard craniotomy leads to better outcomes than decompressive craniectomy any more than it would be to conclude that non-operative treatment leads to better outcomes than standard craniotomy in the treatment of severe TBI. This study does, however, provide more evidence as to the complicated nature of quantifying a successful outcome in patients undergoing decompressive craniectomy and temper some of the enthusiasm associated with this procedure. As the authors suggest, we await the results

of the ongoing RESCUE-ASDH trial<sup>[7]</sup> to help us better clarify the debate as to the indications and expected outcomes of decompressive craniectomy in the treatment of severe TBI.

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## Comment on results of decompressive craniotomy for trauma

The authors of "Primary decompressive craniectomy is associated with worse neurological outcome in patients with traumatic brain injury requiring acute surgery" present a large single center series of neurotrauma patients who were treated by craniotomy, craniotomy, or nonsurgical means.

The question of the efficacy of craniotomy as a treatment for various neurological injuries associated with secondary brain swelling is an important topic, and the subject of much current discussion.

The question is ripe from both technical and philosophical/ethical perspectives. The technical question is "does the treatment lead to an improved neurological outcome?" The related ethical question is "what do we mean by an improved outcome?" In statistics, the "binning" of data points is an irreducible aspect of the analysis itself. The choice of the grouping borderline between satisfactory

and unsatisfactory outcomes is therefore of necessary interest, and honorable opinions can vary regarding these definitions. The authors present this dilemma.

Attempts were made to adjust for case mix, but "Patients who first underwent craniotomy and later had to be treated with decompressive craniectomy were classified as decompressive craniectomy patients," a comment that shrieks out for further subanalysis. Moreover, the timing of GCS relative to timing of intervention is a significant, and unanswered, question. The authors appropriately note the difficulties inherent in statistical analysis, and the limits of their post-hoc, but necessarily imperfect, attempts to adjust for these difficulties.

The authors present their results, which suggest that craniectomy is not helpful in cases of traumatic brain injury, compared to craniotomy or maximal medical therapy.

Their conclusion that "It is plausible that the poorer prognosis is related to the TBI severity itself rather than to the intervention. Further prospective randomized trials are required to establish the role of decompressive craniectomy in the treatment of patients with TBI,"

is well supported, though the social costs of such randomized control trials may be impossible to pay. They are to be congratulated for illuminating a few data points related to this intractable problem.

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