

# Role of Decompressive Craniectomy in the Management of Traumatic Brain Injury - A Meta-Analysis of Randomized Controlled Trials

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## Abstract

**Background:** Traumatic brain injury (TBI) is a serious medical condition that often leads to significant morbidity and mortality. Decompressive craniectomy (DC) is now widely recognized as a primary or secondary treatment option for managing intracranial pressure (ICP) in patients with severe TBI. However, there is a lack of clarity in reviews regarding the impact of DC on TBI outcomes. **Objectives:** The aim of this study is to evaluate the effectiveness of DC in terms of overall mortality and long-term prognosis among patients with TBI. **Materials and Methods:** We conducted a systematic search of four common databases to include all parallel-arm randomized controlled trials (RCTs). We selected studies that reported outcomes for TBI cases, with DC as a treatment option. The outcomes examined included reduction in mortality, ICP levels, and the proportion of patients with a Glasgow Outcome Scale score >4. **Results:** Our review finally included eight RCTs [ $n = 1458$ , with 749 and 709 patients in the DC and control groups, respectively]. The weighted mean difference for ICP was estimated at  $-4.01$  (95% Confidence interval [CI]:  $-5.31$ – $-2.71$ ), indicating a statistically significant reduction in ICP levels in the DC group compared to the control group. The pooled risk ratio was  $0.67$  (95% CI:  $0.51$ – $0.89$ ), suggesting a statistically significant 31% decrease in mortality levels in the DC group. Subgroup and sensitivity analyzes were also conducted to address heterogeneity. **Discussion and Conclusion:** In conclusion, based on our meta-analysis, we find that DC can be considered a crucial surgical intervention for reducing mortality among patients with TBI when compared to control groups.

**Keywords:** Decompressive craniectomy, intracranial pressure, meta-analysis, mortality, traumatic brain injury

## INTRODUCTION

Traumatic brain injury (TBI) is a serious medical condition that often leads to intracerebral bleeding, brain edema, hydrocephalus, and increased intracranial pressure (ICP).<sup>[1-3]</sup> Global burden of disease study estimated that around 27 million new cases of TBI occurred in 2016 alone.<sup>[3]</sup> The primary goal in treating TBI is to maintain cerebral perfusion pressure (CPP) and manage ICP. While pharmacological interventions such as barbiturate coma, hyperosmolar therapy, sedation, therapeutic hypothermia, and ventricular drainage have proven beneficial, some patients fail to respond, resulting in refractory intracranial hypertension (RICH).<sup>[4,5]</sup>

Recently, decompressive craniectomy (DC), a surgical technique, has gained attention for managing RICH following TBI.<sup>[6]</sup> Decompressive craniectomy is used as a primary, prophylactic, or secondary procedure to address elevated ICP in severe TBI cases.<sup>[7]</sup> It can be categorized as primary or secondary. Primary DC involves removing a significant bone flap after evacuating cerebral lesions and is commonly performed during the acute phase of TBI.<sup>[8]</sup> However, the utility of DC in managing persistent post-traumatic intracranial hypertension remains controversial due to the lack of randomized controlled trials (RCTs).

Studies in TBI patients have shown that DC increases CPP and improves long-term functional outcomes while reducing costs.<sup>[9,10]</sup> However, other studies have reported conflicting results.<sup>[11]</sup> Nevertheless, recent research, including a large RCT (RESCUEicp study), has indicated that DC can reduce ICP, mortality, and improve prognosis.<sup>[12]</sup> Therefore, the purpose of our study is to examine the impact of DC on overall mortality and long-term prognosis in patients with TBI.

## MATERIALS AND METHODS

**Research Question:** What is the effect of DC on overall mortality and long-term prognosis among patients with TBI?

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**Type of studies to be included:**

**Inclusion Criteria:** For this review, we included all parallel-arm individual RCTs. We restricted the publication language to English from the beginning until May 2022.

**Exclusion Criteria:** We excluded studies published as abstracts only or with unpublished data, as well as studies published in languages other than English.

**Type of Participants:** We included all studies involving adult patients (>18 years) with traumatic brain injury (TBI).

**Type of Intervention:** Our meta-analysis included studies that investigated DC as a management option for TBI patients. This intervention was compared to a control group receiving medical management or standard care for TBI.

**Type of outcome measure**

**Primary Outcome:** The primary outcome of interest was the overall six-month mortality rate, defined as the total number of patients who died within six months of the initial event.

**Secondary Outcomes:** Other secondary outcomes assessed at the end of six months included:

1. Change in Glasgow Outcome Scale (GOS) and extended Glasgow Outcome Scale (GOS-E).
2. Change in ICP measured in mmHg.
3. Length of hospital stay (in days).

We included all studies reporting any of the above-mentioned outcomes in both the intervention and control groups.

**Search Strategy:** We conducted an extensive electronic search in the following databases: MEDLINE, Google Scholar, ScienceDirect, and Cochrane Central Register of Controlled Trials. Additionally, we searched clinical trial registries such as ClinicalTrials.gov and the World Health Organization (WHO) International Clinical Trials Registry Platform. A combination of Medical Subject Headings (MeSH) and free-text terms was used to conduct the literature search. Medical Subject Headings terms including “TBI,” “DC,” “ICP,” “mortality,” and keywords such as “RCT,” “controlled trial,” or “clinical trial” were used in various combinations across all search engines for the aforementioned databases.

**Searching other resources:** We reviewed the references of primary trials obtained through the electronic search and included relevant articles in the review and analysis. If clarification or additional information was needed for the methodological assessment of the included studies, we contacted the authors of the published trials.

**Data collection and analysis**

**Study Selection:** Two independent investigators (QZ and YL) performed a literature search and screened the titles, abstracts, and keywords of all identified studies for possible inclusion in the review. Full-text articles were obtained for studies deemed relevant. The abstracts and full texts of the retrieved articles were further screened independently by primary and secondary investigators (QZ and YL) to select studies that met the eligibility criteria. The selection process was based on

the PICOS (Population, Intervention, Control, and Outcome Study) design. Disagreements between the investigators were resolved through consensus or consultation with a third investigator (XC). The overall review process was monitored by the third investigator, and the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) checklist was used to report the review.<sup>[13]</sup>

**Data Extraction and Management:** The primary investigator (QZ and YL) extracted all relevant study characteristics from the included studies for the review. The extracted data included the date of extraction, study title, authors, study design, participants, study setting, total number of participants in each arm, baseline and end-line outcome measures, inclusion and exclusion criteria, details of the intervention and control groups, follow-up duration, primary and secondary outcomes, time of outcome assessment, and other necessary details for assessing study quality.

When studies reported multiple arms within a single trial, only the relevant arms were included for the review. In the outcome section, primary and secondary outcomes mentioned in the study, such as six-month mortality, GOS and GOS-E scores, change in ICP, duration of hospital stay, time of outcome assessment, and other details necessary for assessing the quality of studies, were included. The primary investigator transferred the obtained data into the statistical software Stata 14.2, and data entry was double-checked for correctness by the third investigator.

**Risk of bias assessment in included studies:** Using the Cochrane risk of bias tool for RCT, two independent investigators evaluated the risk of bias for the included studies.<sup>[14]</sup> The following domains, including random sequence generation, allocation concealment, participant blinding, outcome assessment, data completeness, and result reporting with bias, were evaluated. The risk of bias was rated as low (if sufficient information was provided), high (if sufficient information was not provided or performed), and unclear for each of the aforementioned domains (if the information was missing).

**Statistical analysis:** We evaluated the pooled effect of DC in the management of TBI patients through the inverse variance method using the mean difference and standard deviation (if the included studies used the same scale) or standardized mean difference (if studies used different scales). Finally, the pooled estimate was reported as the mean difference with a 95% confidence interval (CI). Binary outcomes (presence or absence of mortality at 6 months) were combined across studies in both arms using the Mantel-Haenszel method and expressed as risk ratios (RR) with a 95% CI. Meta-analysis was performed with the selected studies using Stata 14.2. In case of missing data, the author of the included trial was contacted, and if the necessary data could not be retrieved, imputation methods were used.

**Assessment of heterogeneity:** Evidence of between-study variance due to heterogeneity was assessed through the Chi-square test of heterogeneity and I<sup>2</sup> statistics to quantify

the inconsistency.  $I^2$  less than 25% was considered mild, 25–75% was considered moderate, and more than 75% was considered substantial heterogeneity. Study-specific and pooled estimates were graphically represented through a forest plot.

**Assessment of reporting biases:** Reporting bias was assessed by checking whether the included trial was registered in a trial registry or if the full protocol was available. If available, the list of outcomes in the protocol was compared with the list of outcomes mentioned in the full published trial.

**Subgroup analysis and investigation of heterogeneity:** To explore the potential sources of heterogeneity, subgroup analysis was performed.

**Sensitivity analysis:** Sensitivity analysis was performed to assess the impact of the high risk of bias in the included studies. Separate pooled estimates were obtained by including only studies with a low risk of bias and studies with a high risk of bias, and the difference in the pooled estimate was estimated.

## RESULTS

### Study selection

Through our systematic review, a total of 1380 (1367 + 13) articles were identified and screened, of which 917 duplicates were removed. During the primary screening, \*397 articles were excluded as they did not match our inclusion criteria. Of the remaining articles, 53 were chosen for secondary screening, and 8 were included for the systematic review and meta-analysis (total number of participants  $n = 1458$ , with 749 and 709 patients in the DC group and control groups, respectively).<sup>[4,15-21]</sup> The PRISMA 2009 flow diagram is explained in Figure 1. The detailed search strategy is also explained in Supplementray File 1.

### Characteristics of the included studies

Table 1 explains the study characteristics of our included studies. Of the eight included studies, four studies were from Asia (two from China and two from India), one was from Australia, one was from the United Kingdom, and two were multicentric studies. The study participants ranged from 1 to 65 years of age. Only English-language articles were included. All included studies were RCTs. The duration of follow-up ranged from 1 month to 24 months.

**Excluded Studies:** Out of the 53 full-text articles that we extracted, we excluded 45 studies: 29 had different study participants (not including patients with TBI), 7 had a different intervention group, 2 were non-RCTs, 3 had different outcomes, 3 were study protocols, and 1 was published in a language other than English.

**Risk of Bias in Included Studies:** Table 2 explains the summary of the risk of bias in the included studies, assessed by the Cochrane Risk of Bias 2 tool. Randomization was used for the allocation of study participants into intervention and control arms in all the included studies. Out of the eleven

studies included in our review, five had a high risk of bias with respect to blinding and were categorized as high risk of bias. The remaining six studies were categorized as having an unclear risk of bias due to unclear information on blinding and outcome assessment. The risk of bias was summarized based on the study by Higgins *et al.*<sup>[14]</sup>

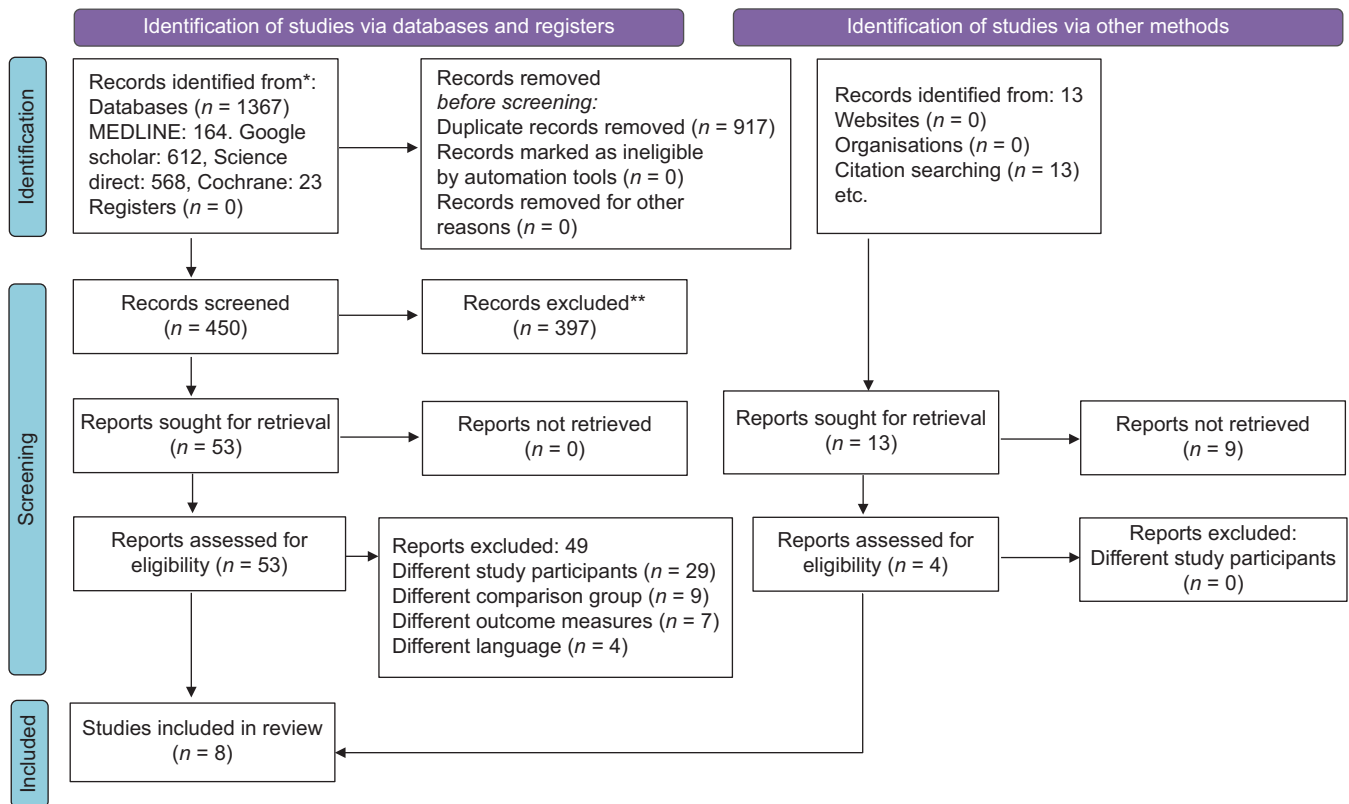
### Effects of interventions

**Effect of TBI on Mortality:** Out of the total eight studies included in the review, seven reported overall mortality in the DC and control groups as the primary outcome ( $n = 1431$ , DC;  $n = 735$ , control group). It was estimated that DC reduced mortality at a pooled RR of 0.67 (95% CI: 0.51–0.89), indicating a statistically significant 31% reduction in the levels of mortality in the DC group compared to the control group [Figure 2]. We found high heterogeneity between the studies in reporting this outcome ( $I^2 = 71.5\%$ ,  $P = 0.002$ ), and thus we utilized the random effects model to cumulate the pooled differences.

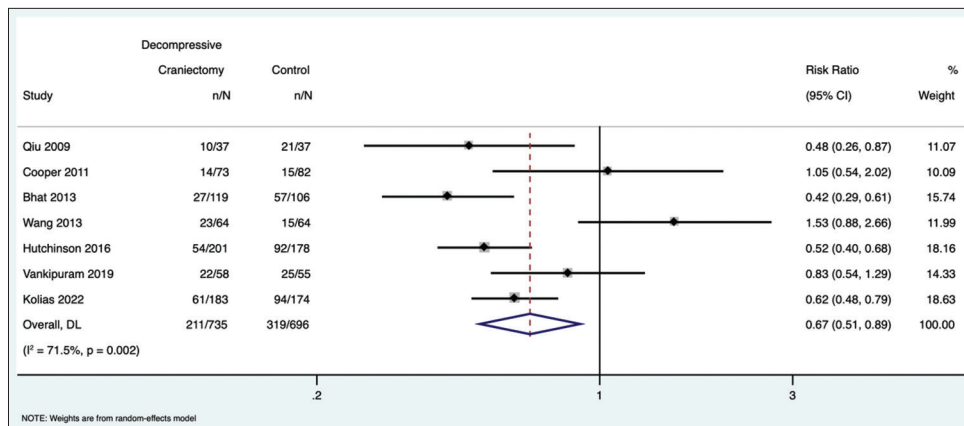
**Effect of TBI on ICP:** Out of the total 8 studies included in the review, 4 reported differences in ICP across the study groups as a secondary outcome ( $n = 645$ , DC;  $n = 325$ , control group). It was estimated that there was a weighted mean difference (WMD) of -4.01 (95% CI: -5.31–-2.71), indicating a statistically significant reduction in ICP in the DC group compared to the control group [Figure 3]. We found moderate heterogeneity between the studies in reporting this outcome ( $I^2 = 59.9\%$ ,  $P = 0.058$ ).

**Effect of TBI on GOS (categorized as scores >4):** Out of the total 8 studies included in the review, only 4 reported the proportion of participants who had GOS scores >4 ( $n = 454$ , DC;  $n = 233$ , control group), with a pooled RR of 0.71 (95% CI: 0.44–1.14). This indicates a nonsignificant reduction in the proportion of TBI cases with GOS >4 in the DC group compared to the control group [Figure 4]. We also observed high heterogeneity between the studies in reporting this outcome ( $I^2 = 76.9\%$ ,  $P = 0.007$ ).

**Subgroup Analysis:** We decided to perform a subgroup analysis based on the duration of follow-up, the sample size for the primary outcome, and time of assessment for the secondary outcome of estimating the ICP. We observed that the statistically significant reduction in mortality in the intervention group became insignificant for 6 months of follow-up (5 studies), with a pooled RR of 0.75 (95% CI: 0.49–1.15). However, the other two follow-up durations had only one study [Supplementray File 2]. In the case of subgroup analysis by sample size, we observed that the reduction in mortality in the intervention group remained statistically significant when the sample size was more than 150, with a pooled RR of 0.57 (95% CI: 0.44–0.73) [Supplementray File 3]. We also conducted a subgroup analysis using the time of assessment for the secondary outcome of reducing ICP. We observed a statistically significant reduction in ICP when the assessment was conducted at 24 hours (WMD of -4.75, 95% CI: -5.68–-3.82) and at 12 hours. However,



**Figure 1:** PRISMA Flowchart depicting the study selection process. \*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers). \*\*If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools



**Figure 2:** Forest plot showing the pooled risk ratio of mortality between the intervention and control group

there was only one study included for the 12-hour and 48-hour assessments [Supplementary File 4].

**Sensitivity Analysis:** A sensitivity analysis was performed to examine the change in the pooled WMD with respect to the change in the risk of bias status of the individual studies. Out of the total eight studies, approximately four had a low risk of bias, three had a high risk of bias, and one study had an unclear risk of bias. We observed a statistically significant reduction in mortality among the studies with a low risk of bias, which enhances the validity of our study findings

[Supplementary File 5]. Publication bias was not assessed since the number of studies included in the review was only eight.

## DISCUSSION

The results of our systematic review and meta-analysis, where we combined approximately 8 RCTs with varying qualities of evidence, indicate that DC is beneficial in reducing mortality and ICP compared to the control group among patients with TBI. However, we did not observe any significant difference in the proportion of TBI cases with GOS > 4 between the DC

**Table 1: Study characteristics of the included studies, *n*=8**

Study	Country	Study participants	Age and gender	Sample size	Time interval to treatment	Duration of follow up
Qiu <i>et al.</i> , 2009 <sup>[4]</sup>	China	Patients who met the criteria: a history of TBI, Glasgow Coma Scale (GCS) of 8 or less at admission, and swollen hemisphere (43 left and 31 right, with midline shift >5 mm and contusions <25 ml and compressed basal cisterns) apparent on CT scans were included. Patients below the age of 18 years or above 65 years, with multiple injuries, with any previous disabling neurological disease, intracerebral haematoma of more than 3 cm in diameter, previous craniectomy, extra-axial hematoma greater than 0.5 cm in thickness, spinal cord injury, penetrating brain injury, fixed dilated pupils and GCS score of 3 with no chance of survival, were excluded.	Mean age (SD): 39.9 (1.9) in DC, and 40.2 (11.9) in control group. Males: 73% vs 65% in DC and control group	74	2-24 hours	1 month
Cooper <i>et al.</i> , 2011 <sup>[15]</sup>	Australia, New Zealand, and Saudi Arabia	Patients between the ages of 15 and 59 years and had a severe, nonpenetrating traumatic brain injury. Patients were excluded if they were not deemed suitable for full active treatment by the clinical staff caring for the patient or if they had dilated, unreactive pupils, mass lesions (unless too small to require surgery), spinal cord injury, or cardiac arrest at the scene of the injury.	Median age (range) of 23.7 (19.4–29.6) in DC, and 24.6 (18.5–34.9) in control group. Males: 81% vs 74% in DC and control group	155	Within the first 72 h after injury	6 months
Taylor <i>et al.</i> , 2011 <sup>[16]</sup>	Australia	All children over 12 months of age if they had sustained a TBI and had a functioning intraventricular catheter and evidence of herniation were included.	Median of 120.9 months (range 13.6–176.4 months) Gender: Not available	27	Not available	6 months
Bhat <i>et al.</i> , 2013 <sup>[17]</sup>	India	All patients with GCS score 3–8 following trauma with significant acute subdural hematoma (>25 ml volume) causing midline shift (>5 mm) and severe brain edema due to underlying multiple haemorrhagic and non-hemorrhagic contusions, subarachnoid haemorrhages and diffuse axonal injury were included.	Around 65% of cases and controls were in the age group of 21–40 years Gender: Not available	225	Within 30 min to 6 h of trauma	6 months
Wang <i>et al.</i> , 2013 <sup>[18]</sup>	China	Inclusion criteria: (1) Patients developing delayed intracranial hematoma; (2) Preoperative diffuse brain swelling or local brain swelling; (3) Large volume preoperative hematoma (≥50 mL) and obvious compression of the brain tissue (deviation from the midline >1 cm); (4) Extended (>2 h) unilateral pupil dilation (≥3 mm diameter, delayed or no response to light); (5) Bilateral dilated pupils.	Mean age (SD): 41.8 (13.9) in DC, and 44.2 (14.2) in control group. Males: 78% vs 90% in DC and control group	128	Not available	6 months
Hutchinson <i>et al.</i> , 2016 <sup>[19]</sup>	United Kingdom	Patients between 10 and 65 years of age, with TBI with an abnormal computed tomographic (CT) scan of the brain, have an intracranial-pressure monitor already in place, and have raised intracranial pressure (>25 mm Hg for 1–12 hours, despite stage 1 and 2 measures)	Mean age (SD): 32.3 (13.2) in DC, and 34.8 (13.7) in control group. Males: 81.7% vs 80% in DC and control group	379	Within 6 h	12 months
Vankipuram <i>et al.</i> , 2019 <sup>[20]</sup>	India	Patients aged >18 years with TBI where primary decompressive craniectomy was the treatment provided	Mean age (SD): 37.51 (13.33) in DC, and 40.23 (13.93) in control group. Males: 61% vs 68% in DC and control group	113	Not available	6 months
Kolias <i>et al.</i> , 2022 <sup>[21]</sup>	Multi-centric study	Eligibility criteria included age 10–65 years who sustained a traumatic brain injury.	Mean age (SD): 32.3 (13.2) in DC, and 34.8 (13.7) in control group. Males: 81% vs 80% in DC and control group	357	Not available	24 months

Contd...

**Table 1: Contd...**

Study	Decompressive craniotomy	Control	Endpoints
Qiu <i>et al.</i> , 2009 <sup>[4]</sup>	All patients underwent lateral craniotomy within 24 hours after injury and other medical management such as dehydration with mannitol. The surgery mode of DC was elective at the frontoparietotemporal region, based on the lesion location and midline shift determined by CT scans	Standard care	The main outcome was mortality at 1 month Other outcomes: (1) Temperature, heart rate, respiration rate and blood pressure, arterial oxygen saturation (2) Continuous recording of ICP was applied in all patients for 96 hours (3) Complications. Mainly inclusive of delayed intracranial hematoma, pulmonary infection, digestive tract hemorrhage, and electrolytes disorders. The data were recorded every 12 h for 7 days, and every 24 hours for another 7 days after craniotomy. (4) Glasgow Outcome Scale (GOS) scores
Cooper <i>et al.</i> , 2011 <sup>[15]</sup>	A standardized surgical approach, modelled on the Polin technique was used. This approach included a large bifrontotemporoparietal craniectomy with bilateral dural opening to maximize the reduction in intracranial pressure. The sagittal sinus and falx cerebri were not divided.	Standard care	Hourly intracranial pressure and mean arterial pressure measurements were recorded for 12 h before randomization and 36 hours after randomization. The original primary outcome was the proportion of mortality 6 months after injury. Secondary outcomes were intracranial pressure measured hourly, the intracranial hypertension index, the proportion of survivors with a score of 2–4 on the Extended Glasgow Outcome Scale, and the numbers of days in the ICU and in the hospital at 6 months.
Taylor <i>et al.</i> , 2011 <sup>[16]</sup>	A bitemporal craniotomy was performed in each patient via a bilateral vertical incision in the mid-temporal region.	Standard care	Outcomes assessed: Intracranial pressure, Cerebral perfusion pressure, duration of stay, Glasgow outcome scale
Bhat <i>et al.</i> , 2013 <sup>[17]</sup>	“Multi-dural stabs” or SKIMS- technique is a decompressive procedure for acute subdural hematoma in the presence of severe brain edema and midline to preserve the anatomical integration of the arachnoid, pia, brain tissue, and its vasculature by opening dura less than or equal to a gyral size at one place	Standard care	The outcome assessed were mortality and Glasgow Outcome Scale at the time of discharge and up to six months after discharge
Wang <i>et al.</i> , 2013 <sup>[18]</sup>	Not available	Conventional craniectomy	The outcome assessed were mortality and Glasgow Outcome Scale at six months after discharge
Hutchinson <i>et al.</i> , 2016 <sup>[19]</sup>	Large unilateral frontotemporoparietal craniectomy (hemispheric craniectomy), which was recommended for patients with unilateral hemispheric swelling, or bifrontal craniectomy, which was recommended for patients with diffuse brain swelling that affected both hemispheres on imaging studies. The exact type of craniectomy was left to the discretion of the surgeons.	Standard care	The primary outcome measure was assessed with the use of the Extended Glasgow Outcome Scale (GOS-E) at 6 months. The secondary outcomes included: GOS-E results at 12 and 24 months after randomization; mortality at 6, 12, and 24 months after randomization; quality of life at 6, 12, and 24; assessment of intracranial- pressure control; time in the ICU; time to discharge and economic evaluation.
Vankipuram <i>et al.</i> , 2019 <sup>[20]</sup>	For unilateral decompressive craniectomy, the patient was supine with a small rolled towel placed underneath the ipsilateral shoulder and the head turned towards the contralateral side	Standard care	The primary outcome studied was the functional status at six months using the Glasgow outcome scale extended (GOS-e) and proportion of mortality among both the groups
Kolias <i>et al.</i> , 2022 <sup>[21]</sup>	Not available	Standard care	The primary outcome was measured with the 8-point Extended Glasgow Outcome Scale and mortality in both groups

TBI: Traumatic brain injury, DC: Decompression craniotomy, ICU: Intensive care unit

group and the control group. Our review included the majority of low-risk studies; however, we did not observe a significant reduction in ICP in the DC group compared to the control arm.

It is documented that severe head trauma can lead to cerebral edema, progressive brain swelling, increased ICP, reduced oxygen delivery and cerebral blood flow, metabolic failure, and ischemia. Thus, the principle of TBI management revolves around measures to reduce ICP.<sup>[23]</sup> DC, accompanied by dural augmentation, results in the enlargement of the intracranial space, thereby allowing the edematous cerebral hemisphere

to expand further, avoiding brainstem compression and herniation.<sup>[24,25]</sup>

**Comparison with other studies:** Our study results suggest that DC significantly reduces mortality and ICP among TBI cases compared to the control group. Various other studies have shown that DC increases intracranial volume by reducing ICP,<sup>[24,26-28]</sup> improves cerebral compliance and CPP,<sup>[24,26,29,30]</sup> increases brain tissue oxygenation<sup>[31,32]</sup> and microvascular perfusion,<sup>[33,34]</sup> and normalizes metabolic parameters.<sup>[31]</sup> These findings are consistent with the results

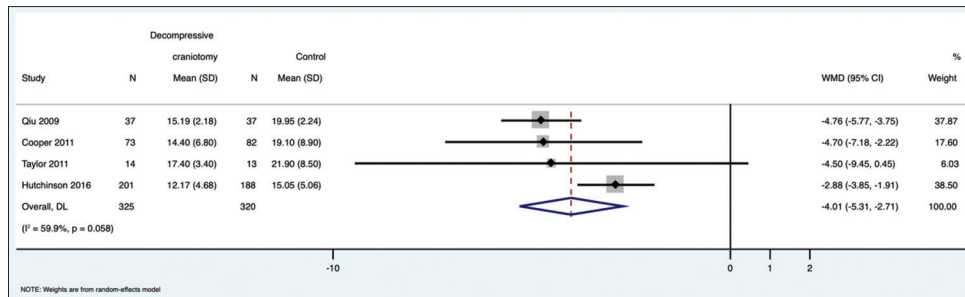


Figure 3: Forest plot showing the pooled mean difference of ICP between the intervention and control group

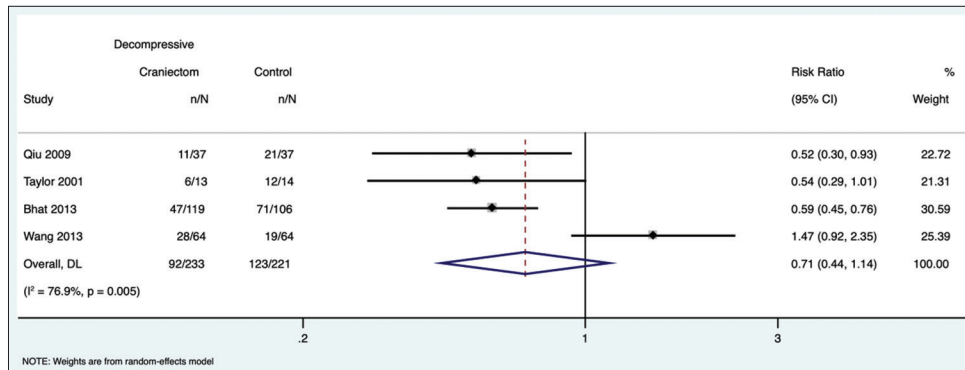


Figure 4: Forest plot showing the pooled risk ratio of GOS >4 between the intervention and control group

Table 2: Risk of bias statement for the included RCTs using Cochrane Risk of Bias tool, n=8

Study	Random sequence generation	Allocation concealment	Blinding of the participants and personal	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias	Overall risk of bias
Qiu 2009	×	×	×	×	×	×	×	Low
Cooper 2011	×	×	×	×	×	×	Unclear	Low
Taylor 2011	×	✓	×	×	✓	✓	×	Unclear
Bhat 2013	✓	✓	✓	✓	×	✓	✓	High
Wang 2013	✓	✓	✓	✓	×	✓	✓	High
Hutchinson 2016	×	×	×	×	×	×	×	Low
Vankipuram 2019	✓	×	✓	✓	×	✓	✓	High
Angelos 2022	×	×	×	×	×	×	Unclear	Low

✓ - Presence of Bias (High) | × - Low risk of bias

of our study. However, a few other studies have also indicated that DC can lead to adverse outcomes and complications. Some studies have suggested that DC can worsen cerebral edema due to cerebral hyperemia resulting from increased postoperative CPP and cerebral inflammation.<sup>[35]</sup> Controlling CPP and uncoupling metabolism can help overcome this potential increase in post-operative cerebral hyperemia and edema.<sup>[36]</sup>

Our study results also indicate a high heterogeneity among the included studies, which can likely be attributed to methodological differences in the study population, choice and timing of surgical approaches, management protocols, and surgeon performance, in addition to existing statistical heterogeneity. The results of a Cochrane Collaboration review published in 2009 suggested that DC should only be used

as a rescue therapy and not as a primary treatment for TBI. However, this review had the limitation that none of the studies included were RCTs.<sup>[3]</sup>

Although there are a few systematic reviews and meta-analyses available on the same research question, our study has attempted to overcome the limitations of previous research. Our study is more updated and comprehensive than a previous study conducted by Garg *et al.*<sup>[22]</sup> in 2019, which failed to address methodological heterogeneity through subgroup analysis and included only 4 RCTs. Our study also provides more comprehensive evidence than studies by Bor-Seng-Shu *et al.*<sup>[9]</sup> and Zhang *et al.*,<sup>[37]</sup> as we included more outcomes and only incorporated RCTs in the review. The Brain Trauma Foundation has recently published guidelines recommending the use of a large frontotemporo-parietal DC rather than a

small frontotemporoparietal craniotomy. They also mention that in severe TBI patients with diffuse injury (without mass lesions and ICP elevation to values of 20 mmHg for more than 15 minutes) refractory to first-tier therapies, a bifrontal DC is not advised to improve outcomes.<sup>[22]</sup>

Our study had a number of strengths. It is one of the few studies that have sought to compile a higher form of evidence (from individual RCTs) on the efficacy of DC in reducing mortality and ICP. Although a previous study on the same research issue is available, our review is more thorough because we incorporated more recent research publications, subgroup analyses, and sensitivity analyses. Two independent authors independently screened all studies and assessed them using the ROB system. We solely incorporated RCTs, which enhances the quality of the collected evidence. However, there are a few limitations of our review that must be taken into consideration. First, we excluded gray literature from our review and only used free full-text papers in English, which could have introduced a linguistic bias. We also overlooked the impact of patient characteristics related to the primary diagnosis from the various trials on the clinical outcomes. Additionally, the included studies exhibited high heterogeneity as we collected articles from various study settings. However, we attempted to address this through sensitivity and subgroup analyzes. Lastly, we did not examine the complications following DC, which is a major limitation of our review.

## CONCLUSION

Despite these drawbacks, our results have significant clinical implications, including the finding that DC appears to significantly lower ICP and reduce death rates. However, more large-scale RCTs with long-term follow-ups are required to confirm the precise impact of DC on the length of hospital stay, assess the potential benefits of early surgery on functional outcomes, and evaluate the complications associated with its use. Due to the scarcity of large-scale RCTs and the notable heterogeneities across the included research, caution is needed when interpreting these results. Therefore, further well-designed and less biased randomized interventional studies are necessary to better understand the true effects of DC on TBI.

## Ethical statement

Ethical approval was not required since it was secondary data analysis, which does not involve any human subjects.

## Author contributions

- Conceptualization: XC
- Data curation: QZ, YL, XC
- Formal analysis: QZ, YL
- Investigation: QZ, YL, XC
- Methodology: QZ, YL, XC
- Project administration: QZ, YL, XC
- Resources: QZ, YL, XC
- Software QZ

- Supervision: XC
- Validation: QZ, YL, XC
- Visualization: QZ, YL, XC
- Writing—original draft: QZ, YL
- Writing—review and editing: QZ, YL, XC

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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## SUPPLEMENTARY FILES

### Supplementray File 1: Search strategy

#### Search strategy:

#### PUBMED

S.no	Search terms	Results
#1	<p>Search: (“patient s”[All Fields] OR “patients”[MeSH Terms] OR “patients”[All Fields] OR “patient”[All Fields] OR “patients s”[All Fields]) AND (“familiarities”[All Fields] OR “familiarity”[All Fields] OR “familiarily”[All Fields] OR “familials”[All Fields] OR “familie”[All Fields] OR “family”[MeSH Terms] OR “family”[All Fields] OR “familial”[All Fields] OR “families”[All Fields] OR “family s”[All Fields] OR “familys”[All Fields]) AND “Centred”[All Fields] AND “Care”[All Fields] AND (“intervention s”[All Fields] OR “interventions”[All Fields] OR “interventive”[All Fields] OR “methods”[MeSH Terms] OR “methods”[All Fields] OR “intervention”[All Fields] OR “interventional”[All Fields] OR “intensive care units”[MeSH Terms] OR (“intensive”[All Fields] AND “Care”[All Fields] AND “units”[All Fields]) OR “intensive care units”[All Fields] OR (“intensive”[All Fields] AND “Care”[All Fields] AND “unit”[All Fields]) OR “intensive care unit”[All Fields]) AND (“patient s”[All Fields] OR “patients”[MeSH Terms] OR “patients”[All Fields] OR “patient”[All Fields] OR “patients s”[All Fields]))</p> <p>Translations</p> <p>Patient: “patient’s”[All Fields] OR “patients”[MeSH Terms] OR “patients”[All Fields] OR “patient”[All Fields] OR “patients’s”[All Fields]</p> <p>Family: “familiarities”[All Fields] OR “familiarity”[All Fields] OR “familiarily”[All Fields] OR “familials”[All Fields] OR “familie”[All Fields] OR “family”[MeSH Terms] OR “family”[All Fields] OR “familial”[All Fields] OR “families”[All Fields] OR “family’s”[All Fields] OR “familys”[All Fields]</p> <p>interventions: “intervention’s”[All Fields] OR “interventions”[All Fields] OR “interventive”[All Fields] OR “methods”[MeSH Terms] OR “methods”[All Fields] OR “intervention”[All Fields] OR “interventional”[All Fields]</p> <p>intensive care unit: “intensive care units”[MeSH Terms] OR (“intensive”[All Fields] AND “care”[All Fields] AND “units”[All Fields]) OR “intensive care units”[All Fields] OR (“intensive”[All Fields] AND “care”[All Fields] AND “unit”[All Fields]) OR “intensive care unit”[All Fields]</p> <p>patients: “patient’s”[All Fields] OR “patients”[MeSH Terms] OR “patients”[All Fields] OR “patient”[All Fields] OR “patients’s”[All Fields]</p>	167
#2	<p>Search: ((traumatic brain injury) AND (decompressive craniotomy)) AND (mortality)</p> <p>(“brain injuries, traumatic”[MeSH Terms] OR (“brain”[All Fields] AND “injuries”[All Fields] AND “traumatic”[All Fields]) OR “traumatic brain injuries”[All Fields] OR (“traumatic”[All Fields] AND “brain”[All Fields] AND “injury”[All Fields]) OR “traumatic brain injury”[All Fields]) AND (“decompressive craniectomy”[MeSH Terms] OR (“decompressive”[All Fields] AND “craniectomy”[All Fields]) OR “decompressive craniectomy”[All Fields] OR (“decompressive”[All Fields] AND “craniotomy”[All Fields]) OR “decompressive craniotomy”[All Fields]) AND (“mortality”[MeSH Terms] OR “mortality”[All Fields] OR “mortalities”[All Fields] OR “mortality”[MeSH Subheading])</p> <p>Translations</p> <p>traumatic brain injury: “brain injuries, traumatic”[MeSH Terms] OR (“brain”[All Fields] AND “injuries”[All Fields] AND “traumatic”[All Fields]) OR “traumatic brain injuries”[All Fields] OR (“traumatic”[All Fields] AND “brain”[All Fields] AND “injury”[All Fields]) OR “traumatic brain injury”[All Fields]</p> <p>decompressive craniotomy: “decompressive craniectomy”[MeSH Terms] OR (“decompressive”[All Fields] AND “craniectomy”[All Fields]) OR “decompressive craniectomy”[All Fields] OR (“decompressive”[All Fields] AND “craniotomy”[All Fields]) OR “decompressive craniotomy”[All Fields]</p> <p>mortality: “mortality”[MeSH Terms] OR “mortality”[All Fields] OR “mortalities”[All Fields] OR “mortality”[Subheading]</p>	344
#3	<p>Search: ((traumatic brain injury) AND (decompressive craniotomy)) AND (mortality) Filters: Randomized Controlled Trial</p> <p>((“brain injuries, traumatic”[MeSH Terms] OR (“brain”[All Fields] AND “injuries”[All Fields] AND “traumatic”[All Fields]) OR “traumatic brain injuries”[All Fields] OR (“traumatic”[All Fields] AND “brain”[All Fields] AND “injury”[All Fields]) OR “traumatic brain injury”[All Fields]) AND (“decompressive craniectomy”[MeSH Terms] OR (“decompressive”[All Fields] AND “craniectomy”[All Fields]) OR “decompressive craniectomy”[All Fields] OR (“decompressive”[All Fields] AND “craniotomy”[All Fields]) OR “decompressive craniotomy”[All Fields]) AND (“mortality”[MeSH Terms] OR “mortality”[All Fields] OR “mortalities”[All Fields] OR “mortality”[MeSH Subheading])) AND (randomizedcontrolledtrial[Filter])</p> <p>Translations</p> <p>traumatic brain injury: “brain injuries, traumatic”[MeSH Terms] OR (“brain”[All Fields] AND “injuries”[All Fields] AND “traumatic”[All Fields]) OR “traumatic brain injuries”[All Fields] OR (“traumatic”[All Fields] AND “brain”[All Fields] AND “injury”[All Fields]) OR “traumatic brain injury”[All Fields]</p> <p>decompressive craniotomy: “decompressive craniectomy”[MeSH Terms] OR (“decompressive”[All Fields] AND “craniectomy”[All Fields]) OR “decompressive craniectomy”[All Fields] OR (“decompressive”[All Fields] AND “craniotomy”[All Fields]) OR “decompressive craniotomy”[All Fields]</p> <p>mortality: “mortality”[MeSH Terms] OR “mortality”[All Fields] OR “mortalities”[All Fields] OR “mortality”[Subheading]</p>	10

Contd...

**Supplementray File 1: Contd...**

**Search strategy:**

**PUBMED**

<b>S.no</b>	<b>Search terms</b>	<b>Results</b>
\$4	Search: ((traumatic brain injury) AND (decompressive craniotomy)) AND (intracranial pressure) AND (randomizedcontrolledtrial[Filter]) Filters: Randomized Controlled Trial (“brain injuries, traumatic”[MeSH Terms] OR (“brain”[All Fields] AND “injuries”[All Fields] AND “traumatic”[All Fields]) OR “traumatic brain injuries”[All Fields] OR (“traumatic”[All Fields] AND “brain”[All Fields] AND “injury”[All Fields]) OR “traumatic brain injury”[All Fields]) AND (“decompressive craniectomy”[MeSH Terms] OR (“decompressive”[All Fields] AND “craniectomy”[All Fields]) OR “decompressive craniectomy”[All Fields] OR (“decompressive”[All Fields] AND “craniotomy”[All Fields]) OR “decompressive craniotomy”[All Fields]) AND (“intracranial pressure”[MeSH Terms] OR (“intracranial”[All Fields] AND “pressure”[All Fields]) OR “intracranial pressure”[All Fields]) AND “randomized controlled trial”[Publication Type]) AND (randomizedcontrolledtrial[Filter]) Translations traumatic brain injury: “brain injuries, traumatic”[MeSH Terms] OR (“brain”[All Fields] AND “injuries”[All Fields] AND “traumatic”[All Fields]) OR “traumatic brain injuries”[All Fields] OR (“traumatic”[All Fields] AND “brain”[All Fields] AND “injury”[All Fields]) OR “traumatic brain injury”[All Fields] decompressive craniotomy: “decompressive craniectomy”[MeSH Terms] OR (“decompressive”[All Fields] AND “craniectomy”[All Fields]) OR “decompressive craniectomy”[All Fields] OR (“decompressive”[All Fields] AND “craniotomy”[All Fields]) OR “decompressive craniotomy”[All Fields] intracranial pressure: “intracranial pressure”[MeSH Terms] OR (“intracranial”[All Fields] AND “pressure”[All Fields]) OR “intracranial pressure”[All Fields] randomizedcontrolledtrial[Filter]: randomized controlled trial [PT]	13
#5	Search: ((traumatic brain injury) AND (decompressive craniotomy)) AND (glasgow outcome scale) AND (randomizedcontrolledtrial[Filter]) AND (randomizedcontrolledtrial[Filter]) Filters: Randomized Controlled Trial (“brain injuries, traumatic”[MeSH Terms] OR (“brain”[All Fields] AND “injuries”[All Fields] AND “traumatic”[All Fields]) OR “traumatic brain injuries”[All Fields] OR (“traumatic”[All Fields] AND “brain”[All Fields] AND “injury”[All Fields]) OR “traumatic brain injury”[All Fields]) AND (“decompressive craniectomy”[MeSH Terms] OR (“decompressive”[All Fields] AND “craniectomy”[All Fields]) OR “decompressive craniectomy”[All Fields] OR (“decompressive”[All Fields] AND “craniotomy”[All Fields]) OR “decompressive craniotomy”[All Fields]) AND (“glasgow outcome scale”[MeSH Terms] OR (“glasgow”[All Fields] AND “outcome”[All Fields] AND “scale”[All Fields]) OR “glasgow outcome scale”[All Fields]) AND “randomized controlled trial”[Publication Type] AND “randomized controlled trial”[Publication Type]) AND (randomizedcontrolledtrial[Filter]) Translations traumatic brain injury: “brain injuries, traumatic”[MeSH Terms] OR (“brain”[All Fields] AND “injuries”[All Fields] AND “traumatic”[All Fields]) OR “traumatic brain injuries”[All Fields] OR (“traumatic”[All Fields] AND “brain”[All Fields] AND “injury”[All Fields]) OR “traumatic brain injury”[All Fields] decompressive craniotomy: “decompressive craniectomy”[MeSH Terms] OR (“decompressive”[All Fields] AND “craniectomy”[All Fields]) OR “decompressive craniectomy”[All Fields] OR (“decompressive”[All Fields] AND “craniotomy”[All Fields]) OR “decompressive craniotomy”[All Fields] glasgow outcome scale: “glasgow outcome scale”[MeSH Terms] OR (“glasgow”[All Fields] AND “outcome”[All Fields] AND “scale”[All Fields]) OR “glasgow outcome scale”[All Fields] randomizedcontrolledtrial[Filter]: randomized controlled trial [PT] randomizedcontrolledtrial[Filter]: randomized controlled trial [PT]	9
#6	#1 AND #2 AND #3 AND #4 AND #5	14

**SCIENCE DIRECT**

<b>S.no</b>	<b>SEARCH TERMS</b>	<b>Search terms</b>
#1	(traumatic brain injury) AND ((decompressive craniotomy) AND (glasgow outcome scale) OR (Mortality) OR (intracranial pressure) OR (Survival) AND (randomized controlled trial)	568

**GOOGLE SCHOLAR:**

Traumatic brain injury

Randomized control trial

Intensive care unit patients

Decompressive craniectomy

Glasgow outcome scale

Intracranial pressure

Mortality

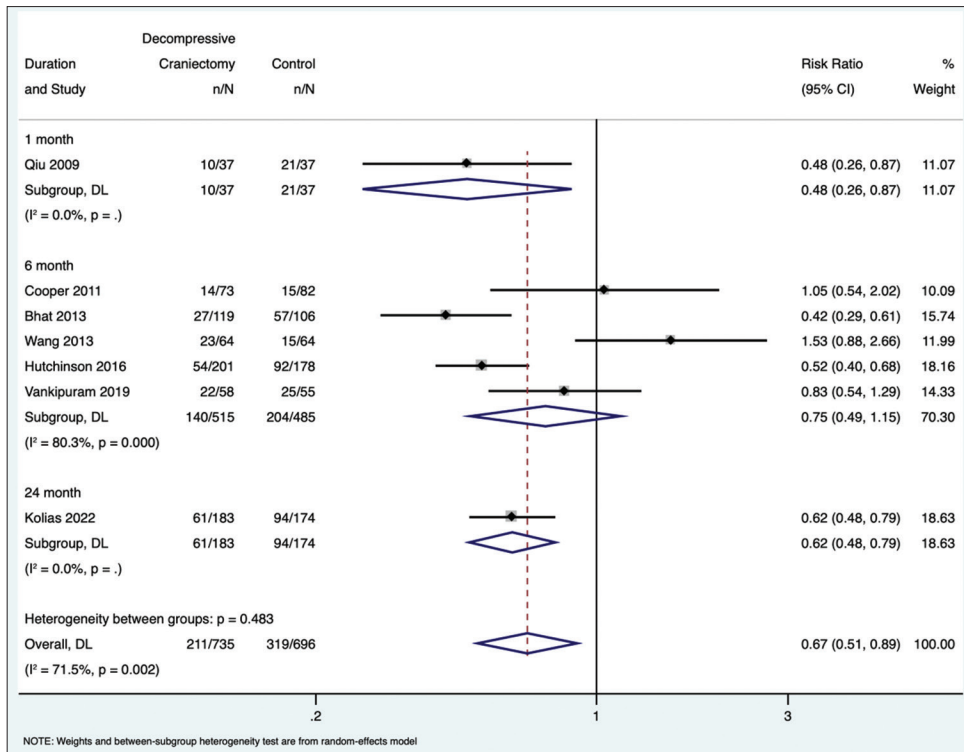
Survival

Randomised control trial

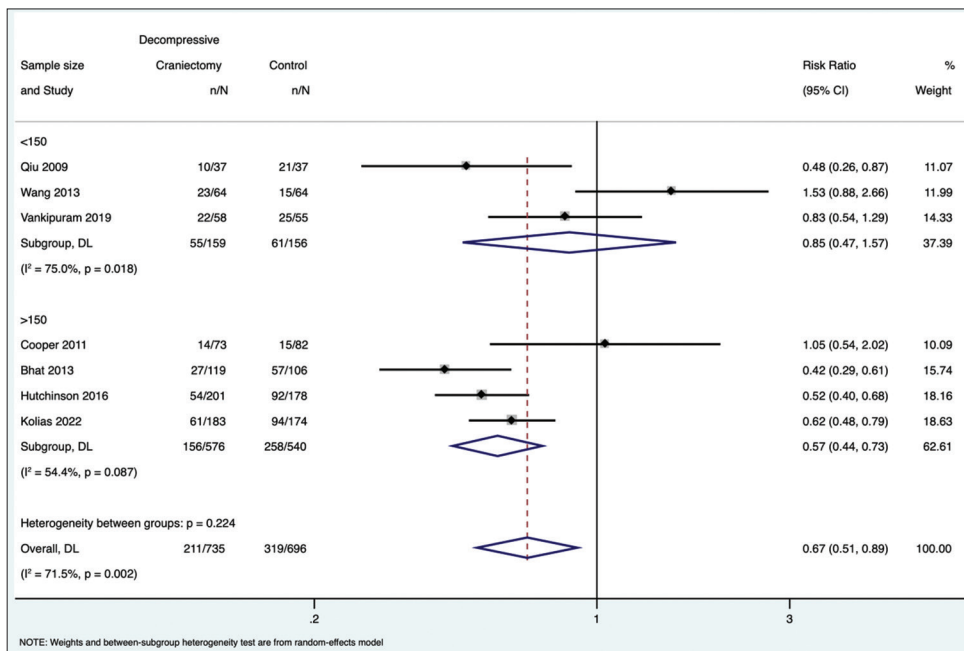
ICU stay

**COCHRANE:**

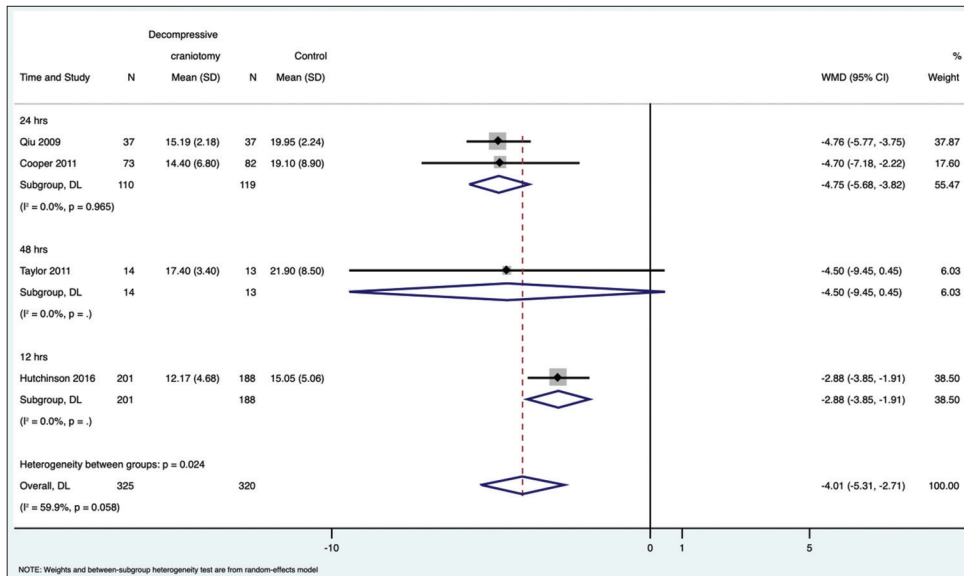
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#1	Traumatic brain injury	259
#2	Intensive care unit patients	2226
#3	Decompressive craniectomy	177
#4	Glasgow outcome scale	164
#5	Intracranial pressure	1911
#6	ICU stay	6869
#7	Mortality	99871
#8	Randomized control trial	706148
#10	#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11	817625
#11	#1 AND #10	23



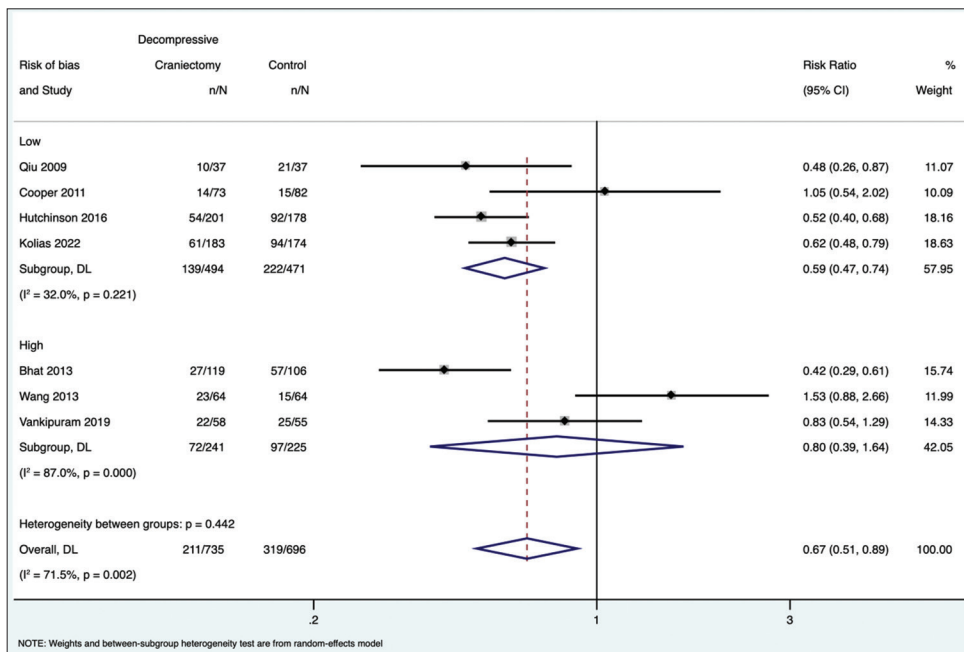
**Supplementray File 2:** Forest plot showing subgroup analysis (follow-up duration) of pooled risk ratio of mortality between the intervention and control group



**Supplementray File 3:** Forest plot showing subgroup analysis (respect to sample size) of pooled risk ratio of mortality between the intervention and control group



**Supplementary File 4:** Forest plot showing the subgroup analysis (time of assessment) of pooled mean difference of IOP between the intervention and control group



**Supplementary File 5:** Forest plot showing the sensitivity analysis (ROB tool) of the pooled risk ratio of mortality between the intervention and control group