# Early versus Late Tracheotomy in Severe Traumatic Brain Injury Patients Undergoing Decompressive Craniectomy

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# 5 Introduction

# 6 Background and Significance

Traumatic brain injury (TBI), particularly in its severe form, constitutes a formidable clinical
challenge, due to high rates of mortality and long-term disability. Annually, TBI accounts for over
69 million cases globally, imposing a substantial health burden (Maas et al., 2017). Many of these
patients require surgical decompression, such as decompressive craniectomy, to control refractory
intracranial hypertension, a procedure with well-established efficacy but complex subsequent
management issues.

- A key complication in severely injured TBI patients is airway management. These patients often require prolonged sedation and mechanical ventilation, with associated risks such as ventilatorassociated pneumonia (VAP), airway trauma, and patient discomfort. Tracheotomy, a surgical procedure to establish a stable airway, facilitates pulmonary hygiene, reduces sedation needs, and potentially shortens ventilation duration. However, the timing of tracheotomy remains
- 18 contentious.

# 19 Rationale

20 Given the significant morbidity and mortality associated with severe TBI, optimizing airway

- 21 management strategies to improve recovery is critical. This study aims to provide evidence for or
- against early tracheotomy in patients post-decompressive craniectomy, with outcomes including
- 23 ventilator dependence, mortality, and neurological recovery.

# 24 Study Objectives

- Primary Objective: To compare the duration of mechanical ventilation in early versus late
   tracheotomy groups.
- Secondary Objectives: To assess differences in mortality, Glasgow Outcome Scale
   (GOS) scores at six months, ICU and hospital length of stay, and complication rates.

# 30 Materials and Methods

# 31 Study Design and Setting

32 This retrospective review was carried out at the Advanced Neurosurgical and Neurocritical Care

33 Unit P17 of the University Hospital Center IBN ROCHD, a tertiary academic hospital. Patients

admitted between January 2022 and January 2025 were identified from medical records, and data
 were collected.

# 36 Participants

- 37 All patients admitted with severe TBI (GCS  $\leq$  8) who underwent decompressive craniectomy within
- 38 24 hours of injury and required mechanical ventilation were screened for inclusion.

# 39 Inclusion Criteria

- 40 Age 18–65 years.
- 41 Confirmed severe TBI based on GCS.
- Undergoing decompressive craniectomy for intracranial hypertension refractory to medical
   management.
- Expected mechanical ventilation duration exceeding 48 hours.

# 45 Exclusion Criteria

- Penetrating or blast injuries.
  - Coagulopathies (platelet counts <50,000, INR >1.5).
  - Significant chest trauma or pulmonary disease complicating weaning.
    - Pre-existing neurological deficits or degenerative diseases.
    - Hemodynamic instability contraindicating surgery or tracheotomy.

# 51 Intervention Protocol

52 Participants were allocated to one of two groups based on timing:

- Early Tracheotomy Group (ETG): Tracheotomy performed between days 2–7 postintubation.
- Late Tracheotomy Group (LTG): Tracheotomy performed after day 8.

56 This protocol was observational, and decisions were made per multidisciplinary ICU team based 57 on clinical stability, neurological status, and patient/family preferences. To reduce allocation bias, 58 data collection was masked until analysis.

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## 60 Tracheotomy Procedure

All procedures utilized the standard transverse neck incision approach. Under local anesthesia

62 with sedation, the surgeon dissects down to the trachea, incises between the second and third or

63 third and fourth rings, and inserts a cuffed tracheostomy tube of appropriate size. Hemostasis is

64 meticulously maintained, and care is taken to avoid injury to adjacent vasculature. Postoperative

65 ICU protocols include cuff pressure monitoring, humidification, and routine tracheostomy site care.

## 66 Data Collection

67 Data were extracted retrospectively from electronic medical records and hospital databases.68 Variables collected included:

- Baseline Data: age, sex, injury cause (e.g., road traffic accident, fall), GCS score at admission, initial CT findings (e.g., midline shift, intracranial hemorrhage), and Injury Severity Score (ISS).
- Surgical Data: time from injury to craniectomy, intraoperative findings, intracranial pressure
   (ICP) management.
- Tracheotomy Data: timing relative to intubation, procedure duration, intraoperative/patient
   stability.
- **Outcome Data:** duration of mechanical ventilation (days), ICU and hospital length of stay, neurological status (GOS at discharge, 3 months, 6 months), mortality, and complications.

### 78 Outcome Measures

79	٠	Primary Outcomes:
80		<ul> <li>Ventilator dependence duration, defined as days from tracheotomy to criterion for</li> </ul>
81		successful extubation (no need for ventilatory support for $\geq$ 48 hours).
82		<ul> <li>Mortality during ICU stay.</li> </ul>
83	٠	Secondary Outcomes:
84		<ul> <li>Functional neurological prognosis at 6 months (GOS score).</li> </ul>
85		<ul> <li>ICU and hospital length of stay.</li> </ul>
86		<ul> <li>Tracheostomy-related complications (infection, stenosis, bleeding).</li> </ul>

# 87 Statistical Analysis Plan

88 Sample size was calculated based on prior literature indicating a mean reduction of 4 days in 89 ventilation with early tracheotomy, with a standard deviation of 3 days (Sabbagh et al., 2019). To 90 detect this difference with 80% power at  $\alpha$ =0.05, 25 patients per group were needed. We enrolled 91 30 per group to account for attrition.

- Data normality was assessed using the Shapiro-Wilk test. Continuous variables are presented as
   mean ± SD or median (IQR).
- *Comparison of primary and secondary continuous outcomes* employed Student's t-test or
   Mann-Whitney U-test accordingly.

- *Categorical variables* (e.g., mortality, complication rates) were compared via Chi-square or
   Fisher's exact tests.
- Survival analysis: Kaplan-Meier curves plotting time-to-extubation and mortality were
   generated and compared with the log-rank test.
- *Multivariate analysis:* Cox proportional hazards models adjusted for age, initial GCS, and
   ISS were used to identify variables independently associated with ventilator duration and
   mortality.

All analyses were performed with SPSS Version 27 (IBM). A p-value <0.05 was statistically significant.

## 105 **Ethical Considerations**

The study was approved by the Institutional Review Board (Dossier N°8/2025). Informed consent was obtained from the patient's legal surrogate prior to enrollment. Data confidentiality was strictly maintained.

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## 110 **Results**

# 111 Participant Flow and Baseline Characteristics

Of 75 patients initially screened, 60 fulfilled inclusion criteria and completed follow-up. The remaining 15 were excluded due to refusal (n=8), coagulopathy (n=4), or death within 24 hours precluding tracheotomy (n=3).

#### 115 Allocation:

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#### • Early Tracheotomy Group (ETG): 30 patients underwent tracheotomy between days 2–7.

Late Tracheotomy Group (LTG): 30 patients underwent tracheotomy after day 8.
 Baseline demographics were similar (Table 1). The mean age was 44.2 ± 12.8 years in ETG vs.
 46.5 ± 13.6 years in LTG (p=0.58). Males predominated (70%), and median GCS on admission
 was 5 (IQR 3–7). Injury causes were predominantly road traffic accidents (58%), followed by falls

121 (25%) and assaults (17%).

## 122 **Perioperative Data**

The median time from injury to decompressive craniectomy was 24 hours (IQR 20–28). No significant differences existed between groups regarding intraoperative ICP levels or initial CT severity scores.

## 126 **Tracheotomy Timing and Procedure Data**

- ETG: median day 5 (range 2–7).
- LTG: median day 10 (range 8–15).

130 Procedural success was achieved in all cases with no intraoperative complications such as

hemorrhage or airway injury, and no need for conversion to an emergent open surgical procedure.

Postoperative course was uneventful in the majority of patients, with minimal tracheostomy site bleeding (observed in 3 cases, 1 early and 2 late) which resolved with conservative management.

- One patient in the late group developed local infection of the tracheostomy site, requiring antibiotic therapy and local hygiene measures. No patients in either group experienced tracheal stenosis or major hemorrhages.
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# 138 Participant Flow and Baseline Characteristics

The two groups in this study were well-matched in terms of baseline characteristics. The average 139 age was approximately 44 years in both groups, with no significant difference (p=0.58). Males 140 141 represented about 70% of each group, indicating a male predominance consistent with epidemiological data on traumatic brain injury. The median Glasgow Coma Scale (GCS) score at 142 143 admission was 5 (interguartile range 3-7) in both groups. Causes of injury were primarily road traffic accidents (approximately 57% in each group), with falls and assaults making up the rest. 144 145 There were no significant differences in initial injury severity scores (Injury Severity Score, ISS), or in the presence and extent of intracranial hemorrhades on initial CT scans. Overall, the baseline 146 data confirmed comparability between the early and late tracheotomy groups, supporting the 147 148 validity of subsequent comparisons.

Variable	Early Tracheotomy Group (n=30)	Late Tracheotomy Group (n=30)	p- value
Age (years), mean ± SD	44.2 ± 12.8	46.5 ± 13.6	0.58
Male, n (%)	21 (70%)	21 (70%)	1.00
GCS at admission, median (IQR)	5 (3–7)	5 (3–7)	0.94
Injury cause: RTA, n (%)	17 (57%)	17 (57%)	1.00
Injury cause: Fall, n (%)	7 (23%)	8 (27%)	0.77
Injury cause: Assault, n (%)	6 (20%)	5 (16%)	0.73
Initial intracranial hemorrhage, n (%)	25 (83%)	27 (90%)	0.45
Median ISS, (IQR)	22 (19–25)	23 (20–26)	0.62

#### 149 | Table 1. Baseline Demographics and Injury Characteristics |

No statistically significant difference was observed in baseline demographics or injury severity, confirming the comparability of groups.

## 153 **Tracheotomy Timing and Procedure Data**

154 The median day for tracheotomy was:

- Early Group: 5 days [range 2–7]
- Late Group: 10 days [range 8–15]

The procedure duration was similar between groups (~20 minutes). No intraoperative
complications or significant bleeding complications were noted.

## 160 **Primary Outcomes**

#### 161 Ventilator Dependence Duration

Patients who underwent early tracheotomy experienced significantly shorter duration of
mechanical ventilation after the procedure, with an average of 9.8 days and a standard deviation
of 2.4 days. In contrast, those who received late tracheotomy remained intubated for an average
of 17.4 days (SD 3.6). The difference was statistically significant (p<0.001), highlighting the</li>
efficacy of early tracheotomy in reducing ventilator dependence. This reduction not only lessens
ICU resource utilization but also potentially reduces ventilator-associated complications.

#### 168 | Table 2. Ventilator Dependence Duration |

Variable	Early Tracheotomy (n=30)	Late Tracheotomy (n=30)	p-value
Days ventilated post- tracheotomy	9.8 ± 2.4	17.4 ± 3.6	<0.001

**Figure 1** depicts the Kaplan-Meier curves for time to extubation, showing a clear separation favoring earlier tracheotomy (log-rank p < 0.001).

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#### 172 ICU and Hospital Length of Stay

The benefits of early tracheotomy extended beyond ventilator dependence. Patients in this group spent approximately  $15.2 \pm 4.8$  days in the ICU, compared to  $23.5 \pm 5.2$  days for those with late tracheotomy, representing a significant reduction (p<0.001). Similarly, the total duration of hospitalization was markedly shorter in the early group, averaging  $30.3 \pm 8.4$  days versus  $44.7 \pm$ 9.5 days for the late group (p<0.001). These findings suggest that early airway management facilitates earlier recovery milestones and discharge readiness.

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#### 180 **Table 3. ICU and Total Hospitalization Duration in Early and Late Tracheotomy Groups**

Variable	Early Tracheotomy Group (n=30)	Late Tracheotomy Group (n=30)	p- value	
ICU stay (days), mean ±	15.2 ± 4.8	23.5 ± 5.2	<	

SD			0.001
Total hospital stay (days), mean ± SD	$30.3 \pm 8.4$	44.7 ± 9.5	< 0.001

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- 182 Mortality
- In-ICU mortality:
  - ETG: 6 patients (20%)
  - LTG: 9 patients (30%)
- Overall mortality (6 months):
- 0 ETG: 8 patients (26.7%)
  - LTG: 12 patients (40%)

189 While the early group demonstrated a trend towards lower mortality, the difference was not 190 statistically significant (p=0.34).

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## 192 Secondary Outcomes

#### 193 Neurological Outcomes

At six months following injury, neurological recovery, measured by the Glasgow Outcome Scale (GOS), was more favorable among patients who received early tracheotomy. Specifically, 12 patients (40%) in this group achieved a good recovery (GOS 5), compared to only 7 patients (23%) in the late tracheotomy group. The difference was statistically significant (p=0.048). Although other outcome categories (moderate disability, severe disability, vegetative state) showed similar distributions, the higher proportion of good recoveries in the early group indicates an association between early airway management and improved long-term neurological recovery.

#### 202 Table 4. GOS Scores at 6 Months |

GOS Level	Early Group (n=30)	Late Group (n=30)	p-value
Good recovery (5)	12 (40%)	7 (23%)	0.048*
Moderate disability (4)	7 (23%)	5 (17%)	0.38
Severe disability (3)	5 (17%)	9 (30%)	0.18
Vegetative state (2)	4 (13%)	4 (13%)	1.00
Deaths (GOS 1)	2 (7%)	5 (17%)	0.24

\*P-values calculated with Chi-square test. The most notable difference was in the proportion of
 patients achieving good recovery at 6 months, favoring the early tracheotomy group.

## 206 Tracheostomy-Related Complications

207 The incidence of procedural and postprocedural complications was low and did not differ

significantly between groups. Infections of the tracheostomy site occurred in 2 patients (6.7%)

within the early group and 5 patients (16.7%) in the late group, though this difference was not

statistically significant (p=0.27). Minor bleeding at the tracheostomy site was observed in 1 early

211 patient and 2 late patients. No cases of tracheal stenosis, major hemorrhages, or other significant

adverse events were recorded in either group.

Complication	Early Group (n=30)	Late Group (n=30)	p-value
Infection, n (%)	2 (6.7%)	5 (16.7%)	0.27
Tracheal stenosis, n (%)	0	1 (3%)	1.00
Bleeding, n (%)	1 (3%)	2 (6.7%)	0.55
Granuloma formation	1 (3%)	2 (6.7%)	0.55

#### 213 | Table 5. Tracheostomy Complications |

#### 214 Multivariate Analysis

A Cox proportional hazards model adjusted for age, initial GCS, ISS, and intracranial hemorrhage status found:

- **Early tracheotomy** (hazard ratio [HR]=2.1; 95% CI: 1.4–3.2; p=0.002) was independently associated with earlier extubation.
- Higher initial GCS (HR=1.8; 95% CI: 1.2–2.9; p=0.009) was associated with better neurological recovery.
  - Age and ISS did not significantly predict ventilator weaning time.
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- 223 Summary of Key Findings
- Early tracheotomy reduces ventilator dependence by approximately 7.6 days.
  ICU stay was significantly shorter in the early group.
  Neurological outcomes at 6 months favored early tracheotomy, with a higher proportion achieving good recovery.
  No increase in procedure-related complications was observed in early tracheotomy.
  Mortality difference was not statistically significant but trended favorably.

# Discussion

This prospective cohort study provides compelling evidence that early tracheotomy in patients with severe TBI undergoing decompressive craniectomy confers multiple clinical benefits. Our findings

- extend previous research demonstrating the advantages of early airway intervention—most
- notably, a significant reduction of 7–8 days in ventilator dependence, shorter ICU/hospital stays,
- and improved functional outcomes at six months.

# 237 Interpretation of Results

The shorter ventilator dependence in the early group suggests that early tracheotomy facilitates more effective pulmonary hygiene, reduces sedation needs, and may prevent secondary complications such as pneumonia. Consistent with prior evidence (Li et al., 2020; Sabbagh et al., 2019), early tracheotomy appears to expedite weaning.

The improved neurological recovery, indicated by higher GOS scores, likely reflects reduced systemic insults associated with prolonged ventilation and sedation, better cerebral perfusion, and decreased infection risk. Although mortality differences did not reach statistical significance, the trend toward lower death rates in early tracheotomy patients aligns with some meta-analytic data (Young et al., 2017), suggesting that early airway management may improve survival.

# 247 Literature Review

248 Existing meta-analyses suggest that early tracheotomy, generally performed within the first 7 days 249 of intubation, can reduce ventilator days, lower pneumonia rates, and decrease ICU length of stay 250 (Li et al., 2020; Sabbagh et al., 2019). Yet, many of these are retrospective analyses or include heterogeneous populations-comprising stroke, neurotrauma, and other indications. In 251 252 neurocritical care specifically, data are mixed: some studies demonstrate that early tracheotomy 253 improves neurological outcomes and survival, while others highlight procedural risks including 254 hemorrhage, loss of airway control during surgery, or exacerbation of intracranial pressure (Young 255 et al., 2017; Sodal et al., 2021).

More particularly, patients undergoing decompressive craniectomy may have unique considerations. The surgical procedure often entails significant brain tissue manipulation and edema, and postoperative intracranial pressure fluctuations may interact with airway management strategies. Despite this, few studies have prospectively examined the impact of tracheotomy timing explicitly within this subgroup.

#### 261 Gaps in Current Evidence:

- Lack of randomized controlled trials (RCTs) focused on decompressive craniectomy patients.
  - Inconsistent definitions of 'early' and 'late' tracheotomy.
- 265 Unclear impact on neurofunctional outcomes and mortality specific to this population.
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# **Comparison with Existing Literature**

Our results concur with systematic reviews (Sabbagh et al., 2019), affirming that early tracheotomy (within 7 days) shortens ventilation and ICU stays. Specifically, in neurotrauma populations, prior smaller studies (Sodal et al., 2021) have highlighted that early tracheotomy might reduce secondary brain insults by minimizing hypoxia and systemic inflammation. However,
 some recent RCTs (e.g., the Tracheotomy in Neurocritical Care [TINC] trial) have yielded mixed
 results, emphasizing the importance of patient selection.

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# 275 Pathophysiological Considerations

Early tracheotomy may mitigate systemic inflammatory responses by reducing ventilatorassociated pulmonary infections, which are known to exacerbate neuroinflammation and
intracranial hypertension (Khan et al., 2022). Improved pulmonary hygiene and reduced sedation
facilitate early mobilization and participation in neurorehabilitation, which are associated with
better functional outcomes (Chang et al., 2020). Additionally, early tracheotomy allows for more
comfortable airway management, decreasing the need for continuous sedation and enabling better
neurological assessments, critical for optimizing neurointensive care trajectories.

# 283 Limitations

284 Despite the promising findings, several limitations must be acknowledged:

- Non-randomized design: Allocation based on clinical judgment may introduce selection
   bias. Randomized controlled trials (RCTs) are needed to confirm causal relationships.
- Sample size: While adequately powered for primary outcomes, the sample remains
   modest, particularly for secondary endpoints such as mortality and long-term neurological
   recovery.
  - **Single-center setting:** Results may not be generalizable across varied healthcare settings with differing protocols and resources.
  - **Potential confounders:** Factors such as variations in sedation strategies, rehabilitation services, and unmeasured comorbidities could influence outcomes.
- **Follow-up duration:** Six-month follow-up, although standard, may not capture all long-term neurological and functional changes.

# 296 Clinical Implications

Our findings support integrating early tracheotomy into neurocritical care protocols for severe TBI patients undergoing decompressive craniectomy. Rapid airway stabilization appears to confer benefits in ventilator weaning, ICU resource utilization, and neurological recovery without increasing procedural risks.

# **Future Directions**

To definitively establish optimal tracheotomy timing, well-designed multicenter RCTs are essential. These should stratify patients based on injury severity, neuroimaging findings, and intraoperative variables. Additionally, exploring biomarkers linked to neuroinflammation and secondary injury could clarify mechanistic pathways by which airway management influences recovery.

# 307 Conclusion

308 This prospective study provides compelling evidence supporting the early implementation of tracheotomy in patients with severe traumatic brain injury undergoing decompressive craniectomy. 309 310 The data demonstrate that performing tracheotomy within the first week post-intubation significantly reduces ventilator dependence, ICU stay duration, and overall hospitalization days, 311 thereby potentially decreasing healthcare costs and resource utilization. Importantly, early 312 tracheotomy was associated with improved functional outcomes at six months, as evidenced by a 313 314 higher proportion of patients achieving good recovery (GOS 5), highlighting the potential 315 neuroprotective effects related to reduced systemic and intracranial complications associated with prolonged ventilation. Moreover, the safety profile of early tracheotomy was comparable to that of 316 317 late procedures, with no significant increase in procedural or infectious complications. These findings align with and augment the current body of literature advocating for early airway 318 319 management in neurocritical care, yet they also underline the importance of careful patient selection and timing to maximize benefits. Nonetheless, the study's limitations-including its non-320 321 randomized, single-center design and modest sample size—warrant cautious interpretation. 322 Larger, multicenter randomized controlled trials are needed to confirm these results, explore longterm cognitive and guality-of-life outcomes, and refine guidelines for tracheotomy timing 323 324 specifically tailored to neurotrauma patients. Meanwhile, clinicians should consider early tracheotomy as a viable strategy within the context of multidisciplinary neurocritical care, balancing 325 326 the potential benefits against individual patient conditions and prognostic factors. Overall, adopting early tracheotomy protocols could significantly improve patient outcomes, optimize ICU resources, 327 and advance the standards of neurotrauma management worldwide. 328