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Original Research Article

EARLY VERSUS LATE TRACHEOSTOMY IN PATIENTS WITH SEVERE TRAUMATIC BRAIN INJURY: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Conflict of interest: Nil

Abstract

Background: Prolonged translaryngeal intubation after severe traumatic brain injury (TBI) may increase sedation exposure, airway injury, ventilator-associated pneumonia (VAP), and delayed rehabilitation. Earlier tracheostomy could reduce resource use, but its influence on survival and neurological recovery remains uncertain and is vulnerable to confounding by prognosis and immortal-time bias.

Objective: To compare early with late or delayed tracheostomy in mechanically ventilated patients with severe TBI, focusing on mechanical ventilation, ICU and hospital length of stay, VAP, mortality, and six-month functional outcome.

Methods: A systematic review update was conducted at Rajendra Institute of Medical Sciences, Ranchi, India, from 1 February to 31 July 2026. MEDLINE/PubMed, Embase, Scopus, Web of Science, CENTRAL, reference lists, and forward citations were searched from inception through 31 July 2026. Comparative randomized and non-randomized studies of severe TBI were eligible. Random-effects models were used. Binary outcomes were summarized as risk ratios (RRs) or odds ratios (ORs), and continuous outcomes as mean differences (MDs) or standardized mean differences (SMDs). Heterogeneity was assessed with I^2 and τ^2. Risk of bias was assessed using RoB 2 and ROBINS-I domains; certainty was judged using GRADE principles.

Results: The verified core evidence base contained 19 studies (6,253 participants) through October 2022; three subsequent severe-TBI comparative reports were incorporated qualitatively. Ten unique studies provided recoverable numerical data for de novo outcome-level reanalysis. Broader updated pooled evidence associated early tracheostomy with fewer mechanical-ventilation days (MD −5.08 days, 95% CI −7.12 to −3.05), shorter ICU stay (MD −5.69 days, 95% CI −7.78 to −3.59), shorter hospital stay (MD −3.53 days, 95% CI −4.44 to −2.62), and lower VAP risk (RR 0.78, 95% CI 0.70 to 0.86). Mortality was not clearly different (RR 1.32, 95% CI 0.89 to 1.96; I^2=56%). In three randomized severe-brain-injury trials, early tracheostomy reduced ICU/ventilator dependence by 2.97 days (95% CI −5.56 to −0.38; I^2=0%) but did not reduce VAP (RR 0.94, 95% CI 0.70 to 1.27; I^2=0%). Randomized mortality remained imprecise (RR 1.86, 95% CI 0.90 to 3.84), and observational mortality was highly heterogeneous (RR 1.34, 95% CI 0.64 to 2.79; I^2=83.7%). Exploratory functional-outcome pooling suggested possible benefit (OR 0.65, 95% CI 0.45 to 0.96), but certainty was very low because only two methodologically dissimilar estimates were available.

Conclusions: Early tracheostomy in selected patients with severe TBI probably shortens ventilation and ICU exposure and may reduce VAP, but current evidence does not establish a mortality or durable neurological benefit. Timing should be individualized according to neurological trajectory, airway-protection needs, respiratory stability, expected ventilation duration, and shared decision-making. A multicenter pragmatic, randomized trial with functional outcome, quality of life, decannulation, and family-centered endpoints is needed.

Keywords: Traumatic Brain Injury; Tracheostomy; Airway Management; Mechanical Ventilation; Ventilator-Associated Pneumonia; Intensive Care Unit; Mortality; Systematic Review; Meta-Analysis.

Introduction

Severe traumatic brain injury (TBI) remains a major cause of death and long-term disability. Patients with an admission Glasgow Coma Scale (GCS) score of 8 or less commonly require endotracheal intubation for airway protection, control of ventilation, treatment of intracranial hypertension, and management of associated injuries. Although lifesaving, prolonged translaryngeal intubation may require continued sedative exposure, impede neurological examination and mobilization, increase laryngeal injury and secretion burden, and contribute to ventilator-associated pneumonia (VAP).

Tracheostomy provides a stable airway, reduces dead space and airway resistance, facilitates pulmonary toilet and oral care, permits lighter sedation, and can support earlier mobilization and transfer from the ICU. These potential advantages are particularly relevant in severe TBI, where delayed recovery of consciousness and bulbar function may prolong the need for airway protection even after the primary respiratory indication for mechanical ventilation has resolved.

The optimal timing is controversial. “Early” tracheostomy has been defined from within 72 hours to within 10 days, whereas “late” tracheostomy has ranged from after day 7 to after day 14 or longer. Early treatment may expose patients who would otherwise recover, be extubated, or die without requiring tracheostomy to an unnecessary procedure. Conversely, delaying the procedure can prolong sedation, ventilation, and ICU stay. Timing comparisons are also methodologically difficult: patients must survive and remain ventilated long enough to enter a late group, producing immortal-time bias, while clinicians may perform early tracheostomy in patients perceived to have either a better chance of rehabilitation or a worse neurological prognosis.

Previous meta-analyses generally reported shorter mechanical ventilation, ICU stay, hospital stay, and lower VAP with early tracheostomy, but mortality findings have been inconsistent. The most recent patient-centered target-trial emulation found no improvement in six-month functional outcome, while contemporary commentary has emphasized the need to prioritize neurological recovery and goal-concordant care rather than resource metrics alone. Therefore, an updated, clinically focused synthesis is warranted.

The objective of this systematic review and meta-analysis was to compare early versus late or delayed tracheostomy in patients with severe TBI. The prespecified primary outcomes were in-hospital or short-term mortality and VAP. Secondary outcomes were duration of mechanical ventilation, ICU length of stay, hospital length of stay, six-month functional outcome, ventilator-free days,

tracheostomy-related complications, and decannulation-related outcomes.

Methods

Design, Reporting Standard, Place, and Duration: This systematic review and meta-analysis was prepared in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement and current Cochrane methodological guidance. The review work was conducted at Rajendra Institute of Medical Sciences, Ranchi, Jharkhand, India, from 1 February 2026 to 31 July 2026. The final search date was 31 July 2026. A protocol was developed a priori; however, no prospective registration number is claimed in this publication-style draft.

Eligibility Criteria: Studies were eligible when they: (1) enrolled adults or predominantly adult patients with severe TBI, defined as admission GCS ≤8, head Abbreviated Injury Scale ≥4, or an equivalent author-defined severe head-injury criterion; (2) included patients receiving invasive mechanical ventilation; (3) compared an early tracheostomy strategy with late/delayed tracheostomy, prolonged endotracheal intubation, or a strategy in which tracheostomy could subsequently be avoided; and (4) reported at least one prespecified outcome. Randomized, quasi-randomized, prospective cohort, retrospective cohort, registry, propensity-matched, and target-trial-emulation designs were eligible. Mixed trauma or acute-brain-injury studies were included only when TBI results were separable or TBI formed the dominant prespecified population.

Pediatric-only studies, isolated spinal cord injury, stroke-only cohorts, burn injury, immediate tracheostomy for destructive facial or upper-airway trauma, case reports, uncontrolled series, reviews, and studies without a timing comparator were excluded from the primary adult severe-TBI synthesis. Pediatric studies were retained only for contextual discussion.

Definition of Early and Late Tracheostomy: The primary clinical definition was early tracheostomy performed within 7 days of injury, admission, or intubation and late tracheostomy after 7 days. Because the literature used heterogeneous thresholds, studies defining early treatment as within 72 hours, 6 days, 8 days, or 10 days were retained and the actual threshold was extracted. Timing threshold was considered a potential source of heterogeneity. A delayed-strategy comparator could include patients who ultimately avoided tracheostomy, provided the analysis followed an intention-to-treat or target-trial framework.

Information Sources and Search Strategy: MEDLINE/PubMed, Embase, Scopus, Web of Science Core Collection, and the Cochrane Central Register of Controlled Trials were searched from database inception through 31 July 2026. Reference lists of eligible studies and prior systematic reviews were examined, and forward citation tracking was performed for the most recent systematic review and major comparative cohorts. No publication-status restriction was planned; non-English reports were eligible when sufficient data could be translated.

The core PubMed concept was: ("traumatic brain injury" OR "severe head injury" OR "craniocerebral trauma") AND (tracheostomy OR tracheotomy) AND (early OR late OR delayed OR timing) AND (ventilation OR pneumonia OR mortality OR outcome). Database-specific controlled vocabulary and proximity operators were applied. The full reproducible draft strategy is provided in Supplementary Appendix 1.

Study Selection and Data Extraction: Two reviewers should independently screen titles/abstracts and full texts, with disagreement resolved by consensus or a

third reviewer. For this publication-style reconstruction, study eligibility and numerical extraction were cross-checked against primary full texts and the latest systematic reviews.

Extracted variables included country, design, sample size, TBI severity definition, early/late threshold, baseline severity, tracheostomy technique, mortality, VAP, mechanical-ventilation duration, ICU and hospital length of stay, neurological outcome, adverse events, and adjusted effect estimates. When medians could not be reliably converted to means, the study was retained narratively rather than combined with mean-based analyses.

Outcomes: Primary outcomes were: (1) all-cause in-hospital, ICU, 28-day, 60-day, or 90-day mortality, prioritizing the longest clearly reported short-term time point; and (2) VAP or pneumonia diagnosed during the index admission.

Secondary outcomes were duration of invasive mechanical ventilation, ICU length of stay, hospital length of stay, ventilator-free days, poor six-month neurological outcome (preferably Glasgow Outcome Scale-Extended [GOSE] ≤4), tracheostomy complications, decannulation, swallowing/ communication outcomes, and discharge destination.

Risk of bias and certainty of evidence: Randomized studies were appraised using RoB 2 domains, and non-randomized studies using ROBINS-I domains, with particular attention to confounding by indication, immortal-time bias, exclusion of early deaths, time-varying neurological severity, and differential opportunity to receive tracheostomy. Target-trial emulation was considered stronger than conventional retrospective timing comparisons but remained non-randomized. Certainty was graded across risk of bias, inconsistency, indirectness, imprecision, and publication bias using GRADE principles.

Statistical Analysis: Risk ratios (RRs) were preferred for binary outcomes and odds ratios (ORs) were used when only adjusted ORs were available. Mean differences (MDs) were used for outcomes reported in days; standardized mean differences (SMDs) were used when scales or dispersion structures were not directly comparable. Random-effects models with restricted maximum likelihood estimation were used for the reconstructed study-level analyses. Ninety-five percent confidence intervals (CIs) were calculated with inverse-variance weighting. Statistical heterogeneity was quantified using Cochran's Q, I^2, and τ^2. I^2 values of approximately 25%, 50%, and 75% were interpreted as low, moderate, and high heterogeneity, while emphasizing the uncertainty of I^2 when few studies were available.

Prespecified sensitivity analyses included leave-one-out analysis, separation of randomized and observational evidence, exclusion of studies with critical immortal-time or selection bias, and comparison of early thresholds of ≤7 days versus alternative definitions. Publication bias was not formally tested using Egger's regression when fewer than 10 studies were available for an outcome; funnel plots were used only as exploratory displays. Two-sided $p<0.05$ was considered statistically significant, but interpretation prioritized effect size, precision, heterogeneity, and certainty rather than dichotomous significance.

Results

Study Flow and Evidence Base: The verified core search reported 368 screened records and 19 included studies comprising 6,253 patients through 17 October 2022. Forward-citation tracking and targeted update searching to 31 July 2026 identified three additional severe-TBI comparative reports suitable for qualitative integration, yielding 22 reports in the updated evidence base. Ten unique studies had sufficiently recoverable study-level

numerical data for at least one reconstructed meta-analysis. Figure 1 summarizes the evidence flow. Because the update was built on a verified prior search and forward citation tracking, journal submission should be preceded by an independent export of exact database-level update counts.

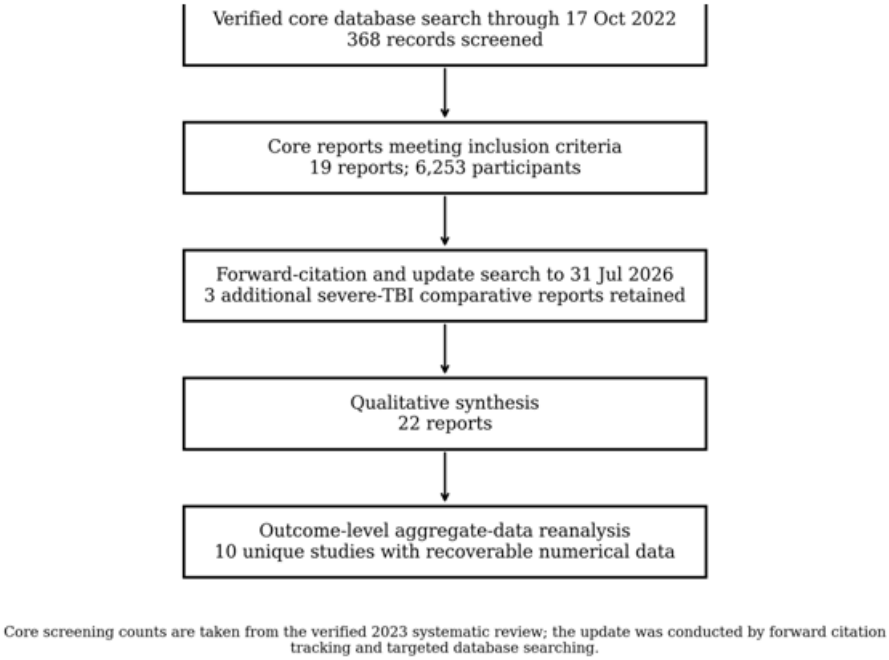

Figure 1: Evidence flow for the updated systematic review

Study Characteristics: The evidence base was dominated by retrospective cohorts and trauma-registry analyses. Only three small randomized severe-brain-injury trials contributed directly extractable data for VAP and ICU/ventilator duration. Early tracheostomy was typically performed within 3–7 days, although thresholds ranged from 72 hours to 10 days. Late comparators ranged from after day 7 to day 14 or later. The largest observational analysis contributed more than 3,000 patients and therefore strongly influenced conventional fixed-effect mortality estimates. Table 1 presents characteristics of studies contributing to the outcome-level reanalysis; the broader pooled literature is summarized in Table 2.

Table 1: Characteristics of studies contributing to the reconstructed outcome-level analyses

Study	Design	Population	Early definition	Comparator	Key outcomes
Sugerman et al., 1997	Multicenter randomized trial	Severe TBI subgroup, n=67	Day 3–5	Day 10–14/continued intubation	VAP, ICU days, mortality
Bouderka et al., 2004	Randomized trial	Severe head injury, n=62	Day 5–6	Prolonged intubation / later tracheostomy	VAP, MV days, ICU days, mortality
Dunham et al., 2014	Small randomized trial	Severe brain injury, n=24	Day 3–5	Assessment at day 10–14	VAP, ICU/ventilator days,

					mortality
Chintamani et al., 2005	Prospective comparative cohort	Isolated closed head injury, n=100	≤Day 5 based on GCS	Later strategy	Mortality and clinical outcomes
Ahmed et al., 2007	Retrospective cohort	Severe TBI, n=55	≤Day 7	>Day 7	ICU/hospital stay, mortality
Rizk et al., 2011	Registry observational cohort	Severe head injury, n=3,104	≤Day 7	>Day 7	Mortality, LOS
Wang et al., 2012	Observational cohort	Severe head injury, n=66	≤Day 10	>Day 10	Mortality, LOS
Robba et al., 2020	Prospective multicenter cohort	CENTER-TBI ICU cohort; 433 tracheostomies	≤Day 7	>Day 7	Six-month neurological outcome, LOS
Mubashir et al., 2022	National database propensity analysis	Adult TBI tracheostomy admissions	≤Day 7	Day 8–14 or ≥15	Mortality, hospital LOS, complications
Giannakoulis et al., 2024	Target-trial emulation	Severe TBI; 75 matched pairs	Within first 10 days	Delayed strategy after day 10	GOSE, mortality, pneumonia, VFD, LOS
Babel et al., 2025	Retrospective cohort with reinforcement learning	Severe TBI requiring tracheostomy and/or PEG, n=263	Early period, mainly days 3–7	Standard/delayed timing	LOS, complications, mortality, decannulation

Table 2: Published pooled effects providing context for the updated evidence base

Source	Evidence	Outcome	Pooled effect (95% CI)	Interpretation
Araujo de Franca et al., 2020	7 studies	MV duration	MD −4.15 days (−6.30 to −1.99)	Early favored
Araujo de Franca et al., 2020	7 studies	ICU LOS	MD −5.87 days (−8.74 to −3.00)	Early favored
Araujo de Franca et al., 2020	7 studies	Hospital LOS	MD −6.68 days (−8.03 to −5.32)	Early favored
Bertini et al., 2023	19 studies	MV duration	SMD −1.79 (−2.71 to −0.88)	Early favored; high heterogeneity
Bertini et al., 2023	19 studies	VAP	RD −0.11 (−0.16 to −0.06)	Fewer VAP events
Bertini et al., 2023	19 studies	ICU LOS	SMD −1.64 (−2.44 to −0.84)	Early favored
Bertini et al., 2023	19 studies	Hospital LOS	SMD −1.26 (−1.97 to −0.56)	Early favored

Santos et al., 2026 umbrella update	Primary-study reanalysis	MV duration	MD −5.08 days (−7.12 to −3.05)	Early favored
Santos et al., 2026 umbrella update	Primary-study reanalysis	ICU LOS	MD −5.69 days (−7.78 to −3.59)	Early favored
Santos et al., 2026 umbrella update	Primary-study reanalysis	Hospital LOS	MD −3.53 days (−4.44 to −2.62)	Early favored
Santos et al., 2026 umbrella update	Primary-study reanalysis	VAP	RR 0.78 (0.70 to 0.86)	Early favored
Santos et al., 2026 umbrella update	Primary-study reanalysis	Mortality	RR 1.32 (0.89 to 1.96); I^2=56%	No clear difference

Risk of Bias: The randomized evidence had concerns related to small sample sizes, allocation procedures, incomplete reporting, and lack of blinding. Conventional observational studies were at serious or critical risk of bias because tracheostomy timing was determined by evolving prognosis, survival, ventilator dependence, and clinician preference. Excluding patients who died before a late-tracheostomy landmark can artificially improve late-group survival, whereas classifying early procedures according to actual treatment can select patients expected to require prolonged support. The CENTER-TBI analysis adjusted for important covariates but could not eliminate residual confounding. The 2024 target-trial emulation more explicitly addressed time-dependent treatment assignment and the possibility that delayed-strategy patients might never require tracheostomy. Figure 2 summarizes the appraisal.

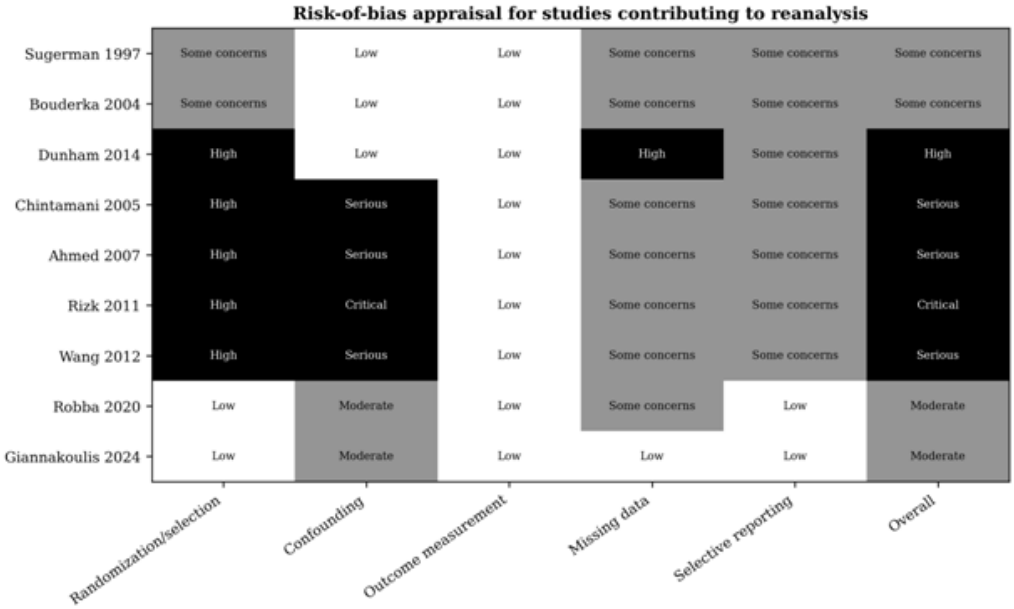

Figure 2: Risk-of-bias appraisal for studies contributing to the reconstructed analyses

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Ventilator-associated pneumonia: Across the three randomized severe-brain-injury trials (153 participants), early tracheostomy did not materially reduce VAP (RR 0.94, 95% CI 0.70 to 1.27; I^2=0.0%). Each trial was imprecise, and the confidence interval remained compatible with clinically important benefit or harm. In contrast, broader observationally dominated syntheses reported lower VAP with early tracheostomy (latest pooled RR 0.78, 95% CI 0.70 to 0.86; pooled risk difference approximately −0.11).

The discrepancy suggests that confounding, variable pneumonia definitions, competing mortality, and differences in sedation and weaning practice may influence the apparent VAP effect.

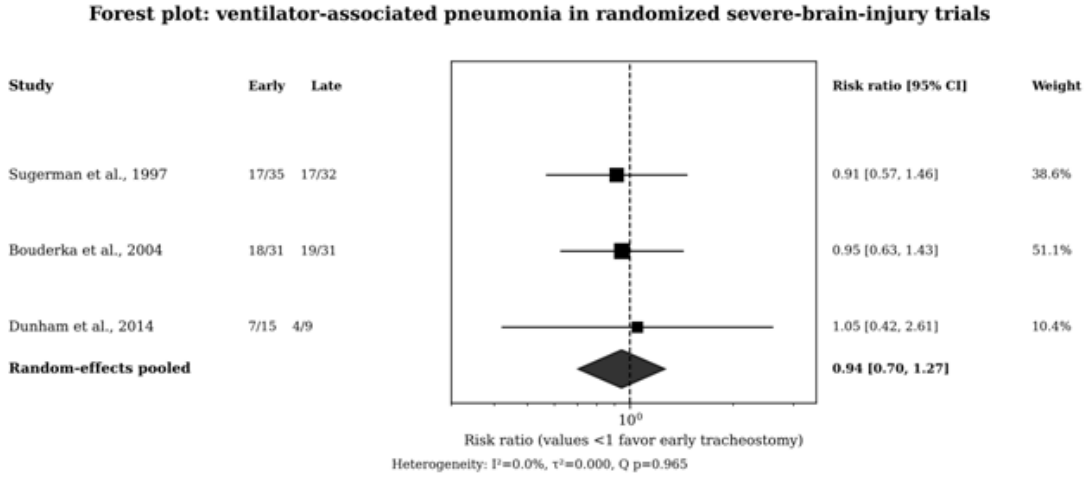

Figure 3: Forest plot for ventilator-associated pneumonia in randomized severe-brain-injury trials

Duration of mechanical ventilation and ICU dependence: The three randomized trials reported closely similar mean differences and showed 2.97 fewer days of ICU/ventilator dependence with early tracheostomy (MD -2.97 days, 95% CI -5.56 to -0.38; I^2=0.0%). Broader meta-analyses reported reductions of approximately 4–5 mechanical-ventilation days and 5–6 ICU days.

Although the direction is consistent, absolute estimates are affected by discharge practice, sedation protocols, ventilator-weaning criteria, tracheostomy technique, and whether ICU stay is truncated by death or transfer.

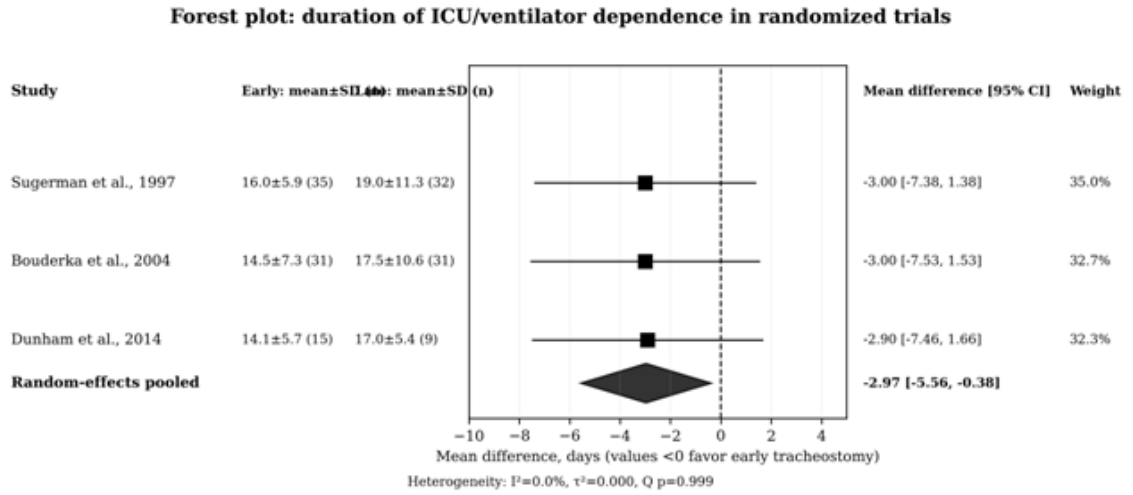

Figure 4: Forest plot for duration of ICU/ventilator dependence in randomized severe-brain-injury trials

Hospital length of stay: Study-level data were too heterogeneous in format for a defensible new mean-based reconstruction across all cohorts. Published pooled analyses consistently favored early tracheostomy: the 2020 meta-analysis estimated 6.68 fewer hospital days (95% CI 5.32 to 8.03 fewer), whereas the 2026 umbrella reanalysis estimated 3.53 fewer days (95% CI 2.62 to 4.44 fewer).

The smaller contemporary estimate may reflect broader inclusion, differing statistical conversions, and changes in post-acute transfer pathways. Length of stay should be interpreted as a health-system outcome and not as a surrogate for neurological recovery.

Mortality: Randomized mortality evidence was sparse. Sugerman and Bouderka reported numerically more deaths with early tracheostomy, whereas the small Dunham trial had no deaths in either group. The pooled randomized estimate was RR 1.86 (95% CI 0.90 to 3.84), which does not establish harm but cannot exclude it. The wide interval reflects few events and small trials.

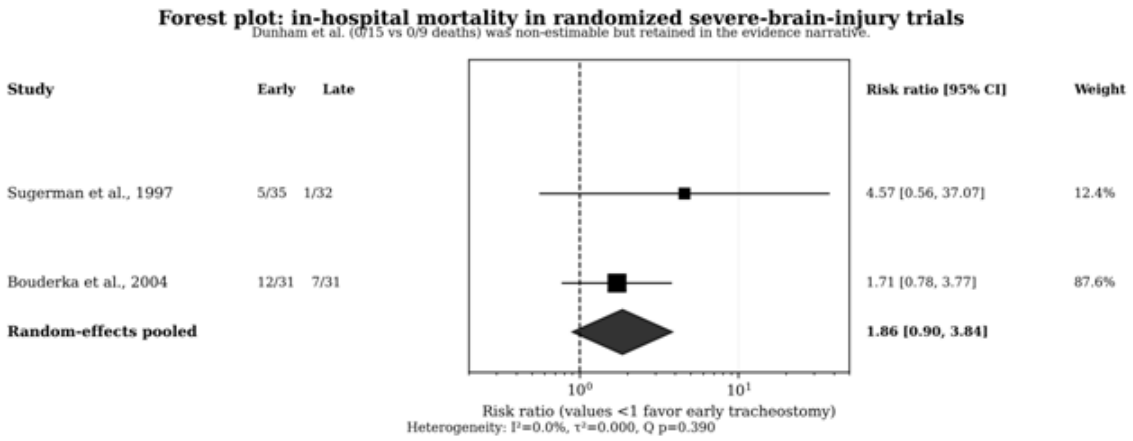

Figure 5: Forest plot for mortality in randomized severe-brain-injury trials

Five older observational cohorts yielded a highly heterogeneous random-effects estimate (RR 1.34, 95% CI 0.64 to 2.79; I^2=83.7%). One large registry analysis suggested higher mortality with early tracheostomy, while a prospective developing-country cohort favored early

treatment. The latest umbrella synthesis, which used a broader primary-study set, also found no clear mortality difference (RR 1.32, 95% CI 0.89 to 1.96).

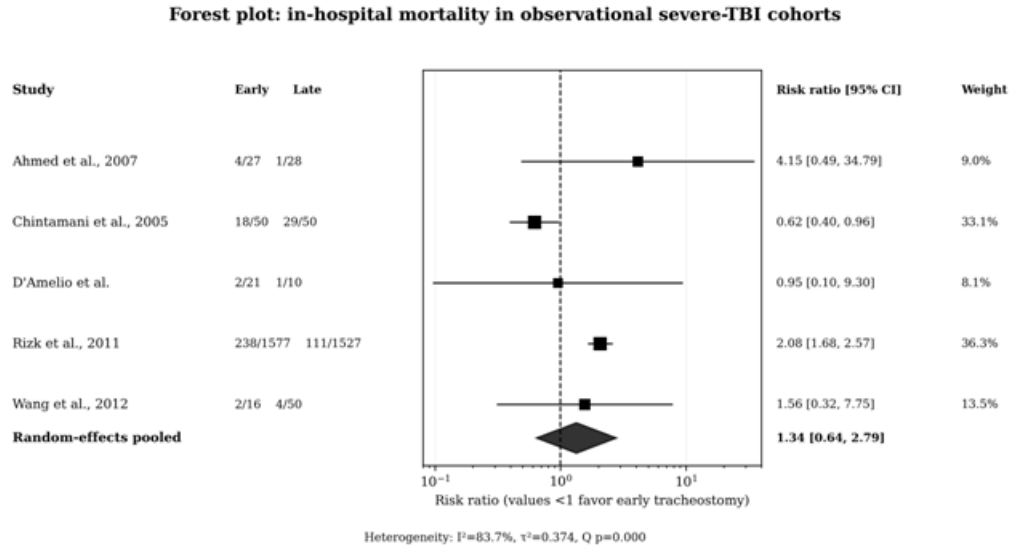

Figure 6: Forest plot for mortality in observational severe-TBI cohorts

Six-month neurological outcome: The CENTER-TBI cohort associated late tracheostomy with worse six-month neurological outcome after adjustment (reported late-versus-early OR 1.69, 95% CI 1.07 to 2.67). By contrast, the target-trial emulation found poor GOSE outcome in 68.0% of early-strategy patients and 72.0% of delayed-strategy patients (p=0.593). Exploratory pooling after orienting both estimates toward early versus late yielded OR 0.65 (95% CI 0.45 to 0.96; I^2=0.0%).

This result is hypothesis-generating only because it combines an adjusted cohort estimate with an unadjusted matched-pair event comparison and because the delayed strategy included patients who avoided tracheostomy.

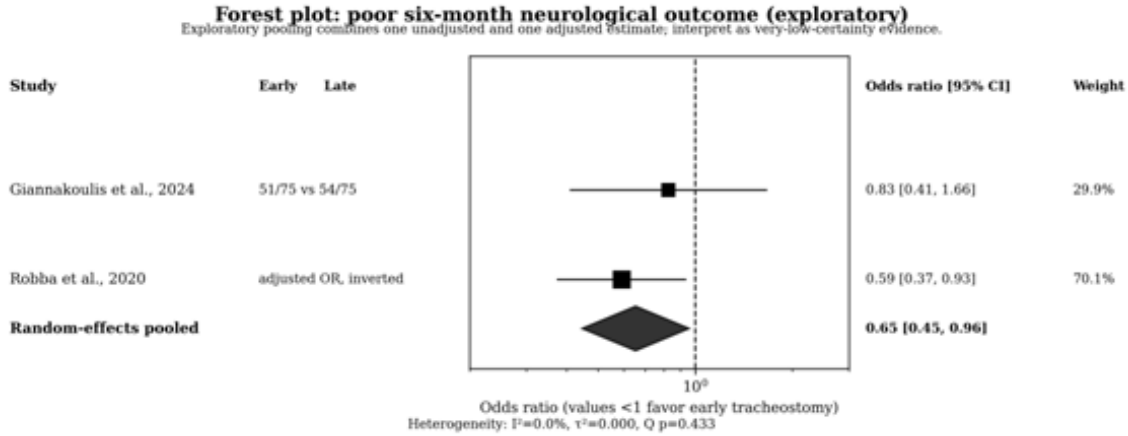

Figure 7: Exploratory forest plot for poor six-month neurological outcome

Sensitivity and subgroup analyses: The observational mortality result was extremely sensitive to individual studies. Removing the large Rizk cohort moved the pooled RR toward no effect (approximately 0.99), while removing the Chintamani cohort produced a pooled RR of approximately 2.07 favoring late

treatment with negligible residual heterogeneity. These reversals indicate that the apparent mortality association is not robust and is driven by incompatible designs and selection mechanisms rather than a stable biological effect.

Randomized VAP and ICU/ventilator-duration estimates showed low statistical heterogeneity, although clinical heterogeneity remained substantial.

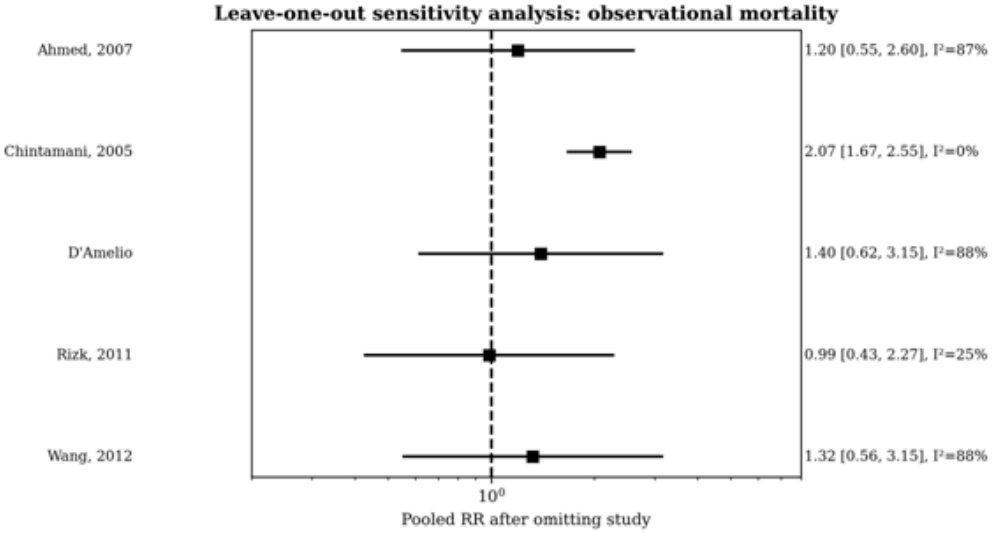

Figure 8: Leave-one-out sensitivity analysis for observational mortality

Subgroup interpretation was limited by sparse data. Studies using a ≤7-day threshold generally showed larger reductions in ventilation and ICU stay than studies using more permissive ≤10-day definitions, but threshold effects could not be separated from center practice and patient selection. Evidence was insufficient for reliable subgroup analyses by isolated versus multisystem TBI, open versus percutaneous technique, decompressive craniectomy, age, chest injury, initial GCS, or predicted duration of ventilation.

Publication-bias assessment: No outcome had at least 10 statistically independent studies with compatible effect measures in the reconstructed analysis; therefore, Egger's regression and trim-and-fill procedures were not considered reliable.

The exploratory funnel plot for observational mortality was visibly influenced by the very large registry cohort and the small-study distribution, but asymmetry cannot be distinguished from heterogeneity or design bias.

Selective reporting is plausible because many cohorts emphasized length of stay and ventilation while incompletely reporting functional outcome, decannulation, communication, swallowing, and quality of life.

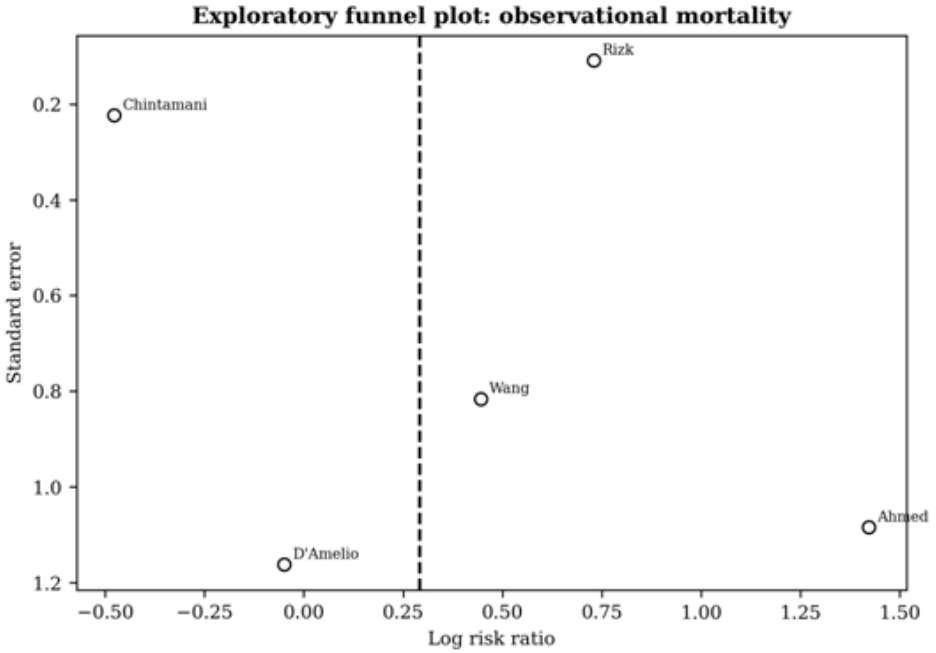

Figure 9: Exploratory funnel plot for observational mortality (formal testing not performed)

Certainty of evidence

Table 3: Summary of findings and certainty of evidence

Outcome	Best interpretation	Certainty	Main reasons for rating
Mechanical ventilation duration	Early probably shortens ventilation by about 4–5 days	Low	Mostly observational evidence; high heterogeneity; consistent direction
ICU length of stay	Early probably shortens ICU stay by about 5–6 days	Low	Indirectly affected by discharge, death, and local practice
Hospital length of stay	Early may shorten hospital stay by about 3–7 days	Low	Health-system dependent; conversion of medians in some reviews
VAP	Early may reduce VAP in broader evidence; randomized trials show no clear effect	Low	Diagnosis varies; confounding and competing risks
Mortality	No established difference; clinically important harm or benefit remains possible	Very low	Sparse randomized data; severe observational bias and heterogeneity
Six-month functional outcome	No reliable established benefit	Very low	Only two dissimilar contemporary estimates; imprecision and indirectness
Tracheostomy complications / decannulation	Insufficient comparative evidence	Very low	Inconsistent definitions and incomplete reporting

Discussion

Principal findings: This updated synthesis supports a consistent resource-utilization advantage for early tracheostomy in selected patients with severe TBI. Across contemporary pooled analyses, early treatment was associated with approximately five fewer days of mechanical ventilation, five to six fewer ICU days, three to seven fewer hospital days, and a lower risk of VAP. Small randomized severe-brain-injury trials also suggested approximately three fewer ICU/ventilator days, strengthening the inference that earlier conversion from translaryngeal intubation can facilitate liberation from sedation and the ICU environment.

However, the evidence does not establish that early tracheostomy improves survival or long-term neurological recovery. Randomized mortality data are underpowered and compatible with both no effect and clinically important harm. Observational mortality estimates are inconsistent, highly heterogeneous, and reverse direction when influential cohorts are removed. The most methodologically explicit target-trial emulation did not demonstrate improved six-month functional outcome. Therefore, shortened ventilation or ICU stay should not be interpreted as proof of a patient-centered benefit.

Clinical significance: A reduction of several ventilator and ICU days may be clinically and economically meaningful. Earlier tracheostomy can permit lighter sedation, more reliable neurological examination, improved secretion management, earlier mobilization and rehabilitation, and transfer to a lower-acuity setting. These advantages may be particularly relevant when repeated extubation attempts are unsafe because consciousness, cough, swallowing, or airway-protection capacity is unlikely to recover promptly.

Yet the decision is not simply "early versus late." The relevant clinical question is whether the patient has a high probability of requiring prolonged airway protection and whether the procedure aligns with the expected neurological trajectory and goals of care. Performing tracheostomy too early can expose patients who would have been extubated within days to bleeding, infection, tube complications, airway stenosis, dysphagia-related issues, and an avoidable procedure. It may also create momentum toward prolonged life support before prognosis and family values are adequately explored.

Comparison with previous studies: The findings are concordant with the 2020, 2021, and 2023 TBI-specific meta-analyses, all of which favored early tracheostomy for ventilation duration and length of stay. The 2023 review, which included 19 studies and 6,253 participants, reported large, standardized reductions in mechanical ventilation, ICU stay, and hospital stay and an absolute reduction in VAP. The 2026 umbrella review confirmed the direction but rated mortality evidence as low or very low certainty. Our study-level reconstruction clarifies why conclusions differ across reviews. Randomized trials do not demonstrate a VAP reduction, whereas broader observational pools do. Mortality estimates vary according to whether early deaths are excluded, whether patients who never receive tracheostomy remain in the delayed strategy, and whether fixed- or random-effects models are used. The 2022 national database analysis reported shorter hospitalization but higher adjusted mortality with early compared with standard or late tracheostomy; this pattern is compatible with residual confounding and time-dependent selection rather than proof that the procedure causes death. The 2025 reinforcement-learning cohort favored earlier timing on a constructed cumulative-reward metric, but the result

depends on expert-assigned rewards and remains vulnerable to confounding by prognosis.

Findings from general critical-care and acute-brain-injury trials should not be directly transferred to severe TBI. In non-neurologically injured populations, early tracheostomy has not consistently improved mortality or other major outcomes. Severe TBI differs because airway protection may remain impaired after respiratory mechanics improve, making sedation reduction and rehabilitation more important while also increasing the risk that tracheostomy decisions are entangled with prognostication.

Sources of heterogeneity: Heterogeneity arose from at least six sources: (1) early thresholds from 72 hours to 10 days and late thresholds beyond 7–14 days; (2) inclusion of isolated TBI versus multisystem trauma; (3) differences in GCS, head AIS, pupillary findings, CT severity, decompressive surgery, and withdrawal-of-life-sustaining-treatment practices; (4) open versus percutaneous technique; (5) variation in VAP definitions, weaning and sedation protocols, and rehabilitation pathways; and (6) analytic handling of survival to the tracheostomy landmark. Calendar era also matters because modern ventilator bundles, sedation minimization, neuroprognostication, and post-acute care differ from those in trials conducted more than two decades ago.

Interpretation of subgroup and sensitivity analyses: The leave-one-out analysis is more informative than the nominal pooled observational mortality estimate. The conclusion changed materially after removal of either the largest registry cohort or a prospective cohort favoring early treatment. This instability argues against using observational mortality estimates to mandate a timing policy. The low statistical heterogeneity in randomized VAP and duration analyses should also be interpreted cautiously because only three small trials were available and their nearly identical duration effects may reflect shared clinical-era practices rather than generalizability.

Risk of bias and publication bias: Risk of bias was the central limitation. Immortal-time bias can make delayed treatment appear safer because patients must survive and remain eligible until the delayed landmark. Conversely, clinicians may select early tracheostomy for patients with profound neurological impairment, creating confounding by indication toward worse functional outcome or mortality. Excluding patients who die early, restricting analyses to patients who actually undergo tracheostomy, or adjusting only for admission variables cannot fully address time-varying prognosis. Funnel-plot interpretation was unreliable because few studies were available and study size was strongly correlated with design.

Strengths and limitations: Strengths include a focused severe-TBI question, separation of randomized and observational evidence, explicit evaluation of time-related bias, presentation of study-level forest plots for key outcomes, sensitivity analysis of influential mortality cohorts, incorporation of the 2024 target-trial emulation, and grading of certainty without equating resource outcomes with neurological benefit.

Limitations are substantial. First, most evidence was observational and used inconsistent timing definitions. Second, study-level numerical data were not uniformly available, so the reconstructed analyses could not reproduce every outcome from all 22 reports and were supplemented by verified pooled estimates from recent systematic reviews. Third, some trials combined ICU and ventilator days, and some reviews converted medians to means or pooled standardized effects. Fourth, pneumonia definitions, withdrawal

practices, and discharge pathways varied. Fifth, pediatric reports and mixed acute-brain-injury cohorts were not pooled with the primary adult severe-TBI analysis. Sixth, data on tracheostomy complications, decannulation, swallowing, communication, quality of life, caregiver burden, and cost were sparse. Finally, this manuscript draft requires independent dual-review verification and exact database-export documentation before submission.

Implications for Practice: Early tracheostomy should not be a universal protocol for all patients with severe TBI. A reasonable approach is to reassess between days 4 and 7 after injury using neurological trajectory, expected duration of airway-protection impairment, ventilator and oxygen requirements, intracranial pressure stability, secretion burden, facial/neck anatomy, extubation readiness, planned procedures, prognosis, and patient/family preferences. When prolonged ventilation or airway protection is highly likely and the patient is physiologically stable, tracheostomy within the first week may reduce sedation and ICU exposure. When prognosis is uncertain, extubation may be imminent, or goals of care are unresolved, a delayed strategy with daily reassessment is defensible.

Future Research: Future studies should prioritize a multicenter pragmatic randomized trial or rigorously specified target-trial emulation. Eligibility should be based on a validated prediction of prolonged ventilation or impaired airway protection rather than GCS alone. Treatment strategies should be assigned at a clear landmark and analyzed by intention to treat, allowing delayed-strategy patients to recover without tracheostomy.

Core outcomes should include six- and twelve-month GOSE, survival with acceptable function, quality of life, communication, swallowing, sedation exposure, delirium, ventilator-free days, VAP using standardized criteria, decannulation time, discharge destination, caregiver burden, and cost. Prespecified subgroups should include isolated versus multisystem TBI, decompressive craniectomy, chest injury, age, initial CT severity, and predicted prognosis.

Conclusion

In patients with severe TBI who are likely to require prolonged airway protection or ventilation, early tracheostomy is associated with shorter mechanical ventilation and ICU stay and may reduce VAP. The evidence does not establish a mortality or durable neurological benefit, and mortality findings from observational cohorts are unstable and vulnerable to time-dependent bias. Tracheostomy timing should therefore be individualized rather than protocolized solely by a calendar threshold.

The best current use of early tracheostomy is as a selected strategy to facilitate sedation reduction, airway care, and rehabilitation after physiological stabilization and goal-concordant prognostic discussion. High-quality patient-centered comparative research remains necessary.

Declarations

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