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Early versus late tracheostomy in critically ill patients: an umbrella review of systematic reviews of randomised clinical trials with meta-analyses and trial sequential analysis

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ABSTRACT

Objective This study conducts an umbrella review of systematic reviews and meta-analyses of randomised clinical trials (RCTs) to evaluate the outcomes of early vs late tracheostomy, focusing on potential biases and the coherence of the evidence.

Data sources Searches were conducted in the MEDLINE, Embase, Lilacs and Cochrane Library databases up to November 2024.

Study selection Our analysis included studies meeting the following criteria: Population: patients admitted to intensive care units and receiving mechanical ventilation. Intervention: early tracheostomy, as defined by the respective study. Control: late tracheostomy, as defined by the respective study. Primary outcomes: mortality and incidence of ventilator-associated pneumonia (VAP). Study design: systematic reviews and meta-analysis of RCTs.

Data extraction Two reviewers performed article inclusion, with consensus resolution by a third reviewer in case of disagreement. The quality of studies was assessed using the AMSTAR 2 tool. A random-effects meta-analysis was conducted with an algorithm based on the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) classification

Data synthesis Out of 7664 articles identified, 60 articles were considered eligible for full-text reading, and 22 were included in the review. Most studies were rated as critically low quality. Our meta-analysis update with 19 RCTs showed a decrease in VAP (OR 0.65 (0.47 to 0.89), 95% CI; p=0.007) among early tracheostomy patients compared with late tracheostomy patients, but no significant difference in terms of mortality (OR 0.85 (0.70 to 1.03), 95% CI; p=0.09). A trial sequential analysis indicated that the current data are insufficient to reach a definitive conclusion.

Conclusion In summary, despite extensive research on tracheostomy timing and its outcomes, as well as a correlation in our study between early tracheostomy and reduced VAP incidence, evidence remains weak. Besides that, no clear mortality benefits were observed. Further research using a different approach is crucial to identify the specific population that may derive benefits from early tracheostomy.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Over the past five decades, numerous randomised clinical trials (RCTs) and systematic reviews have examined the optimal timing of tracheostomy, particularly focusing on outcomes such as mortality and ventilator-associated pneumonia (VAP). However, the results remain inconsistent, and there is limited consensus on the optimal timing of tracheostomy. These discrepancies can be attributed to several factors, including heterogeneity in the populations studied, the absence of a standardised definition of early tracheostomy, the type and quality of studies included and variations in the outcomes assessed.

WHAT THIS STUDY ADDS

⇒ This umbrella review identifies critically low-quality evidence across most studies. An updated meta-analysis of 19 RCTs demonstrates a reduction in VAP with early tracheostomy (OR 0.65; p=0.007) but no significant effect on mortality (OR 0.85; p=0.09). Meta-regression revealed that neither neurological condition nor tracheostomy timing had a significant impact on mortality or VAP outcomes. Trial sequential analysis confirms that the current evidence remains insufficient for definitive conclusions.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study calls for more rigorous trials with standardised methodology to identify which subgroups of patients may benefit most from early tracheostomy, emphasising a well-designed RCT with a carefully selected population is considered more beneficial than relying solely on systematic reviews with meta-analyses of the current available RCTs.

INTRODUCTION

Tracheostomy is a common procedure in critically ill patients who need prolonged mechanical ventilation, with a prevalence ranging from 10% to 20%.[1–3] The rationale of a tracheostomy is that it facilitates maintenance

of oral hygiene and pulmonary hygiene, improves the patient's overall comfort, simplifies the patient's mobilisation and reduces sedation.[4 5] Multiple randomised clinical trials (RCTs) regarding the ideal timing of tracheostomy have been conducted evaluating outcomes such as incidence of ventilator-associated pneumonia (VAP), mortality, length of stay (LOS) in the intensive care units (ICU) and days of mechanical ventilation, and in the last five decades, a myriad of systematic reviews were published with contradictory results, leaving decision-makers uncertain how to base their conclusions.[6–11]

Although a well-conducted systematic review of RCTs is considered a high rank in the evidence hierarchy, meta-analyses about tracheostomy in critically ill patients have yielded conflicting conclusions. While some meta-analyses suggest that early tracheostomy may reduce the incidence of mortality,[6 10 12–17] VAP,[6 7 18] the duration of mechanical ventilation[6 7 14 15 17 19–21] and ICU LOS,[6 7 13 14 17–22] others have found no significant differences in these outcomes.[23–30] These discrepancies can be attributed to several factors, including heterogeneity in the populations studied, the absence of a standardised definition of early tracheostomy, the type and quality of studies included and variations in the outcomes assessed.

The umbrella review can reach intuitive conclusions by conducting systematic reviews with a consistent approach to variables, allowing for comprehensive analysis integrating previously published systematic reviews or meta-analyses.[31 32] In this umbrella review, in order to enhance the overall quality of evidence, we focused on reviews that integrated randomised trials. Therefore, this study aims to offer a comprehensive overview of the outcomes associated with the timing of tracheostomy, while assessing potential biases and the coherence of the existing evidence base. This will be achieved through an umbrella review of systematic reviews and meta-analyses encompassing RCTs.

METHODS

Protocol and registration

We systematically searched, organised and evaluated existing data from systematic reviews and meta-analyses of RCT and quasi-randomised clinical trials (quasi-RCT) on early versus late tracheostomy outcomes. The protocol was registered on PROSPERO (Prospective Register of Systematic Reviews) 2021: CRD42021279855. This umbrella review followed the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions[33] and reported in accordance with the latest Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.[34]

Search strategy and eligibility criteria

Appropriate search strategies were elaborated and adapted for each of the following electronic databases: MEDLINE, EMBASE, LILACS and COCHRANE from database inception to November 2024 to identify systematic reviews and meta-analyses of RCT and quasi-RCT comparing early tracheostomy with late tracheostomy in critically ill patients receiving mechanical ventilation (online supplemental appendix 1). No limitations on the time of publications were established. We also manually searched reference lists of the retrieved articles. Two authors (AB and TAT) independently screened titles and abstracts to identify eligible studies using an online software (Rayyan, Qatar Computing Research Institute)[35] and then assessed the eligibility of identified publications, and duplicates were removed.

The studies included in our analysis met the following criteria: Population: patients admitted to intensive care units and receiving mechanical ventilation. Intervention: early tracheostomy, as defined by the respective study. Control: late tracheostomy, as defined by the respective study. Outcomes: mortality, incidence of VAP, LOS in the ICU, length of hospital stay, duration of mechanical ventilation and complications of tracheostomy. Study types: systematic reviews and meta-analyses specifically based on randomised clinical trials or quasi-RCTs. We excluded the following types of reviews: studies focused on paediatric and neonatal patients, systematic reviews based on observational studies, meta-analyses that did not distinguish between data from randomised studies and observational studies, meta-analyses that did not assess the quality of evidence. Additionally, only articles written in English, Portuguese or Spanish were included, as there was no translator available for other languages.

Data extraction

Two reviewers (AB and TAT) independently extracted data and methodological characteristics from the included studies using a standard form and cross-checked by a third reviewer (MVV). If an article included both RCT and non-randomised clinical trials, we extracted data from RCT or quasi-RCT only. The definition of early or late tracheostomy was according to each study. When data were incomplete, the corresponding author was contacted and asked to send additional information.

Quality appraisal and strength of evidence

Two reviewers (AB and TAT) independently assessed the quality of the included systematic reviews. Disagreement was resolved by a third reviewer (MVV). We evaluated the methodological quality and strength of all included meta-analyses using the AMSTAR 2 tool, which includes 16 items, being a reliable and validated tool in assessing the quality of systematic reviews and meta-analyses.[36] The overall confidence in the results of a systematic review was rated as high, moderate, low or critically low. For each outcome, we classified the evidence of the associations in accordance with previous umbrella reviews: convincing (class I) when the number of cases was >1000, $p<10^{-6}$, $I^2<50\%$, 95% prediction interval excluding the null, no small-study effects, and no excess significance bias; highly suggestive (class II) when the number of cases was >1000,

$p<10^{-6}$, largest study with a statistically significant effect, and class I criteria not met; suggestive (class III) when the number of cases was >1000, $p<10^{-3}$, and class I–II criteria not met; weak (class IV) when $p<0.05$ and class I–III criteria not met; non-significant when $p>0.05$.[32]

Outcomes and data synthesis

Primary outcomes were all-cause mortality and incidence of VAP. Secondary outcomes were LOS in the ICU, duration of mechanical ventilation, length of hospital stay and complications of tracheostomy.

For the primary outcome, we extracted data directly from individual studies included in the highest AMSTAR-rated review, specifically those focusing on mixed ICU populations. In addition, we incorporated data from individual studies identified through recent reviews and updated research that were not covered in the highest-rated AMSTAR review. We did not rely on synthesised data from previous meta-analyses to perform a new meta-analysis, as doing so would violate the independence assumptions required for meta-analysis. A random-effects meta-analysis was conducted using the metaumbrella package, using an algorithm based on the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) classification.[37] Heterogeneity was assessed using I^2, and classification followed Cochrane recommendations.[33] In order to evaluate publication bias, we employed Egger's test. Furthermore, we aimed to investigate whether the timing of tracheostomy had varying impacts on specific subgroups of critically ill patients, such as those with traumatic injuries, neurological conditions and COVID-19. Additionally, we conducted a meta-regression analysis to evaluate the influence of timing and neurological conditions on patient outcomes, using the metafor package. The regression coefficient from the meta-regression describes how the outcome variable (intervention effect) changes with a unit increase in the explanatory variable (potential effect modifier). The statistical significance of the regression coefficient tests whether a linear relationship exists between the intervention effect and the explanatory variable.[33] A trial sequential analysis was performed using the RTSA package for the primary outcome. Parameters were set for a two-sided test with equal group sizes, a type I error of 0.05 and a type II error of 0.2. All analyses were conducted in R V.4.3.1 (2023, The R Foundation for Statistical Computing).

Patient and public involvement

This umbrella review did not involve patients or the public in the design, conduct, reporting or dissemination plans of the research. As a synthesis of existing systematic reviews and meta-analyses, it relied solely on previously published data.

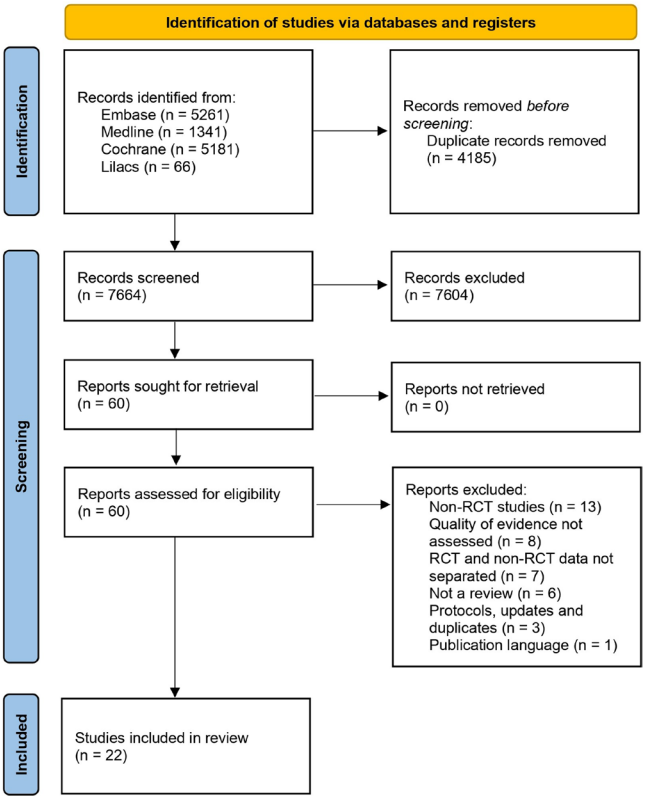

Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram.

RESULTS

We identified 7664 citations from searches of electronic bibliographies, and 60 articles were considered eligible for full-text reading. Thereafter, only 22 systematic reviews were finally included for quality assessment and data synthesis. In total, we included 28 RCTs comprising 4146 patients. Moreover, the complete process of studies' identification and selection is provided in figure 1.

All studies included surgical or percutaneous tracheostomy techniques, with the exception of four studies which did not describe this type of information.[15–17 29]

Carrie Liu *et al*, Hosokawa *et al* and Kishihara *et al* analysed three different definitions of early tracheostomy.[13 16 22] Although Siempos *et al* report two quasi-RCTs in their analysis due to allocation bias, these studies are treated as RCTs in other analyses that have included them.[7] Figure 2 highlights the variability in how intervention and control groups are defined based on tracheostomy timing. Panel A depicts the definitions of early and late tracheostomy (or prolonged intubation) groups used in the systematic reviews and meta-analyses included in this study. Most studies define early tracheostomy as occurring within 10 days or less (dashed line). Six studies evaluated early tracheostomy only according to each RCT included, and were not included in figure 2A.[15 19–21 24 29] Panel B focuses on the timing of randomisation and the definitions of early and late tracheostomy (or prolonged

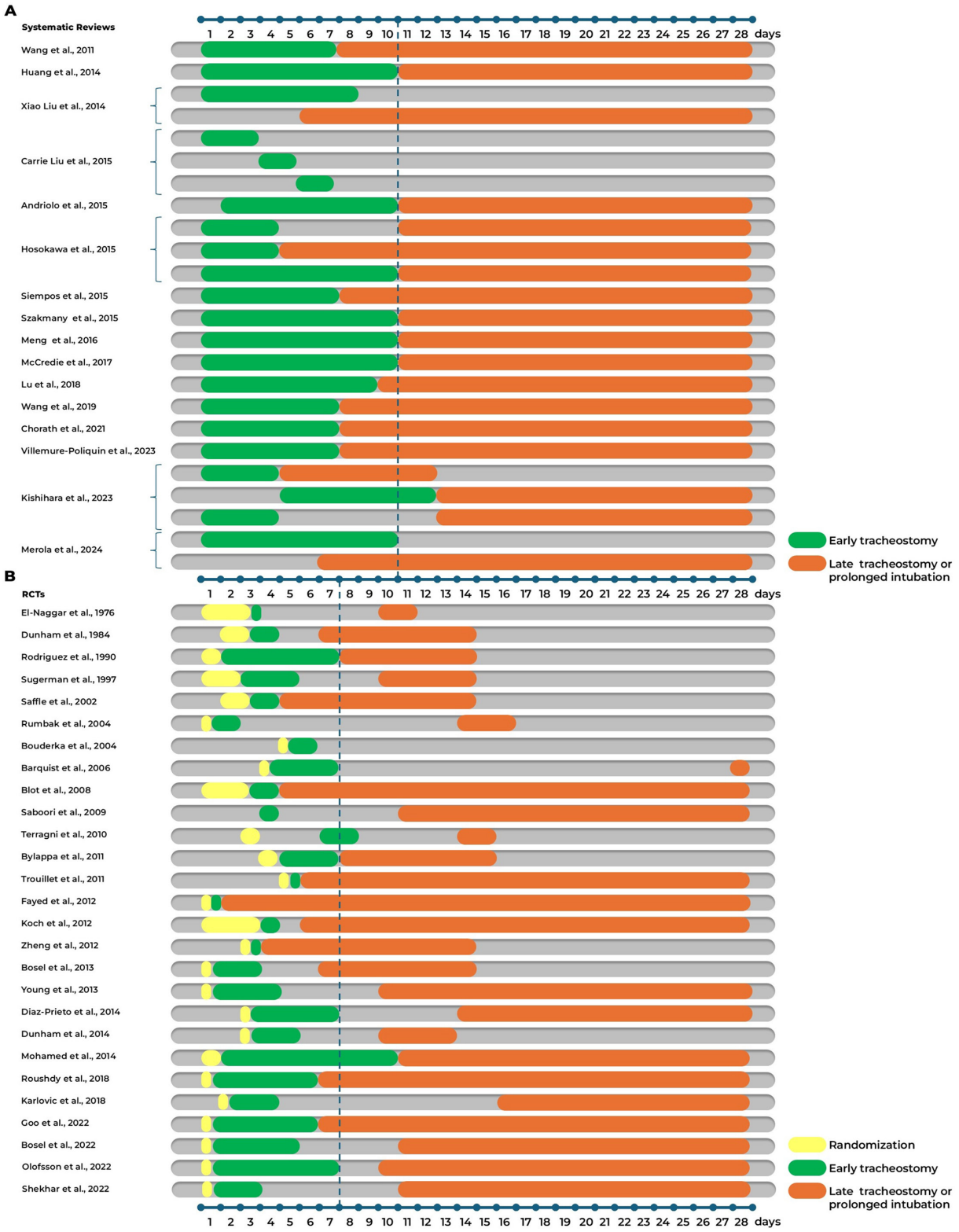

Figure 2 Definition of early and late tracheostomy (or prolonged intubation). (**A**) Definitions used in the systematic reviews and meta-analyses included in this study. Most studies define early tracheostomy as occurring within 10 days or less (dashed line). Definitions used in the systematic reviews and meta-analyses included in this study. Most studies define early tracheostomy as occurring within 10 days or less (dashed line). (**B**) Definitions used in the RCTs included in these meta-analyses, with the majority of studies defining early tracheostomy as occurring within 7 days or less (dashed line).

intubation) groups in the RCTs included in these meta-analyses, with the majority of studies defining early tracheostomy as occurring within 7 days or less (dashed line). Filaire *et al*'s RCT was not included in figure 2B, as the intervention was prophylactic tracheotomy on the day of lung cancer resection.[38] A detailed list of all the RCTs included in each systematic review and meta-analysis is provided in online supplemental material etable 1.

Overall characteristics of the systematic reviews and meta-analysis are available in online supplemental material etable 2. The comprehensive summary of the results for each outcome across all reviews can be found in the online supplemental material etable 3.

Outcomes

Primary outcomes

Mortality

All 22 studies included mortality as an outcome. The systematic reviews evaluated mortality using various definitions and follow-up periods, including short-term, long-term, hospital and ICU mortality. Among the eight studies that reported a significant reduction in mortality with early tracheostomy, the evidence supporting the association was weak (class IV).[6 10 12–17] In six studies, early tracheostomy was associated with decreased mortality depending on the defined follow-up period.[6 10 13 14 16 17] Wang *et al* identified a decrease in mortality with early tracheostomy in 28-day mortality, whereas Hosokawa *et al* and McCredie *et al* demonstrated a significant benefit of the intervention in long-term mortality (defined as more than 2 months), but not in short-term mortality.[6 13 14] McCredie *et al* demonstrated a reduction in long-term mortality and ICU mortality, without a difference in short-term and hospital mortality.[14] However, when the analysis of long-term mortality was performed without including a study with an unclear risk of bias, the statistical significance was lost. Kishihara *et al* classified the timing of tracheostomy into three groups: ≤4 versus 5–12 days, 5–12 versus ≥13 days and ≤4 versus ≥13 days.[16] A significant difference was observed only in the last group. Andriolo *et al* reported a reduction in mortality at any time point, including in-hospital mortality, ICU mortality or post-discharge, with weak evidence of associations (class IV).[10] The study by Quinn *et al* demonstrated a reduction in short-term mortality when early tracheostomy was performed.[15] Merola *et al* reported a reduction in mortality comparing early tracheostomy versus control and early tracheostomy versus late tracheostomy, but the statistical analysis is controversial, as the risk reduction was negative.[17]

Among the four articles focused on neurological patients,[14 20 28 29] only one[14] demonstrated a reduction in long-term mortality (defined as associated 6 to 12 months) with early tracheostomy. No significant differences were observed in short-term, ICU and hospital mortality.

Ventilator-associated pneumonia (VAP)

Among all the studies, only one[16] did not incorporate VAP in their analyses and two[10 22] studies did not provide the pooled effect in the meta-analysis. Early tracheostomy was associated with a reduction in VAP incidence in three studies, all demonstrating weak evidence of associations (class IV).[6 7 18] Meng *et al* did not conduct a meta-analysis due to significant heterogeneity among the included studies.[27] In systematic reviews specifically focusing on neurological patients, no significant difference was found in the incidence of VAP.[14 28 29]

Meta-analysis, meta-regression analysis and trial sequential analysis

Figure 3 presents the forest plot summarising the results of prior meta-analyses alongside our synthesis findings. For mortality, no significant difference was identified (OR 0.85 [0.70–1.03]), whereas a significant reduction was observed for VAP (OR 0.65 (0.47–0.89)). According to the GRADE classification, the evidence quality was rated as weak for mortality and very weak for VAP. Data from Beritini *et al* and Merola *et al* were excluded from the forest plot as their effect measures were not expressed as ratios. The analysis included 18 studies and 3421 patients for mortality and 15 studies and 2128 patients for VAP, totalising 19 different RCTs. Egger's test did not show significant publication bias for both outcomes (p=0.210 and 0.955 for mortality and pneumonia, respectively). A meta-regression with mortality as the outcome and the definition of early tracheostomy as the moderator was not significant (coefficient −0.09 (−1.6 to 0.27), 95% CI; p=0.33). Similarly, a meta-regression with mortality as the outcome and neurological condition as the moderator was not statistically significant (coefficient −0.49 (−1.57 to 0.58), 95% CI; p=0.372). The same analysis was performed for VAP, and no significant difference was found for the definition of early tracheostomy (coefficient 0.002 (−0.09 to 0.09), 95% CI; p=0.964) or neurological condition (coefficient −0.43 (−0.93 to 0.07), 95% CI; p=0.09). Hence, neither the neurological condition nor the timing of tracheostomy significantly influenced the outcomes related to mortality or VAP.

The secondary outcomes of our study showed a higher rate of heterogeneity in previous meta-analyses; for this reason, we decided against updating the meta-analysis.

A trial sequential analysis using a random-effects model for mortality indicated that an additional 169 100 patients across 19 trials are needed, assuming a minimum clinically relevant effect size of 0.85 and a 30% event probability. Repeating the analysis for VAP revealed that 403 686 patients across 82 trials would be required to achieve a more definitive conclusion.

Secondary outcomes

Hospital length of stay

Hospital LOS was included in eight studies.[7 19–21 23 28–30] Only two studies[20 21] showed a reduction in the hospital LOS, one[20] of them in traumatic brain injury patients.

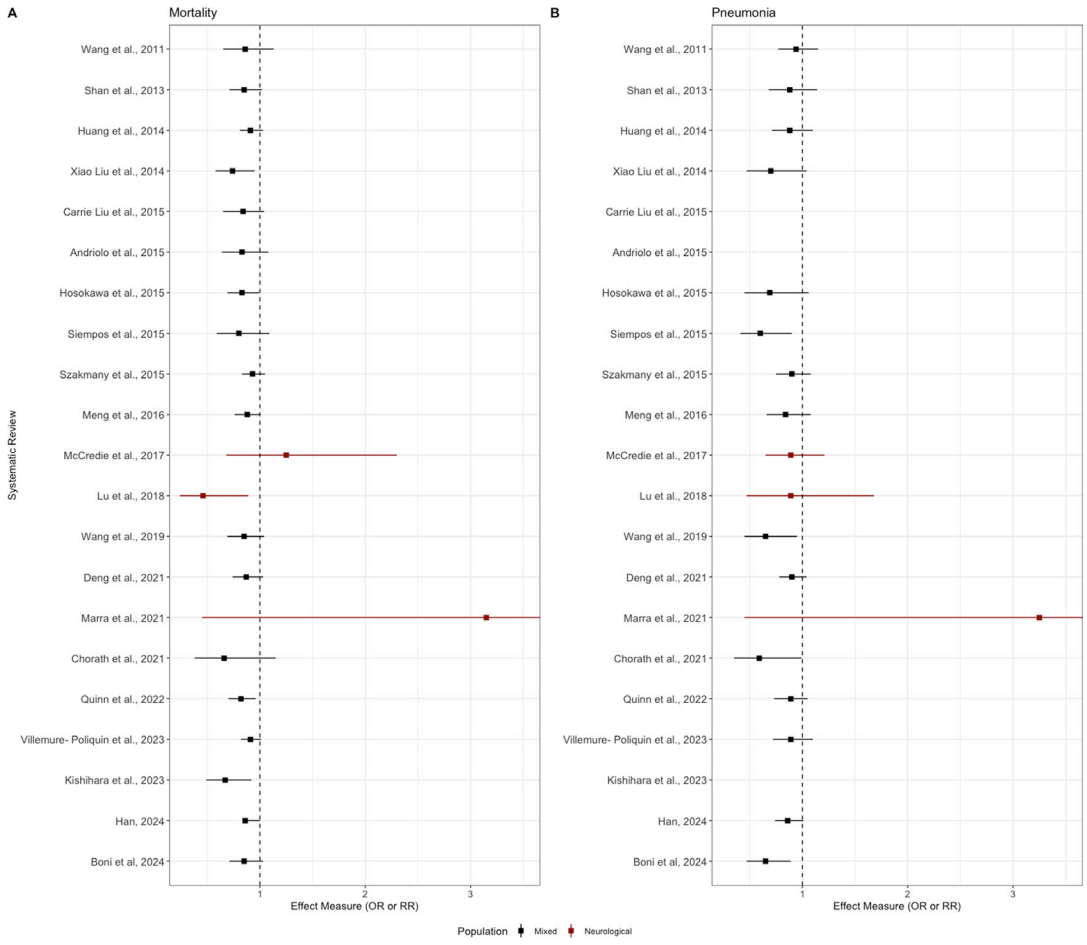

Figure 3 The figure displays the overall estimates and CIs for each meta-analysis across various systematic reviews, with those focusing on patients admitted with neurological conditions highlighted in red. The final entry (Boni *et al*) represents the updated meta-analysis conducted as part of this study. RR, risk relative.

Two studies did not separate RCT data from non-RCT data for hospital LOS, precluding their inclusion in our review.[28 29] The remaining four studies found no association in hospital LOS and early versus late tracheostomy.[7 19 23 30]

ICU length of stay

Of the 22 reviews included in our study, two studies[12 16] did not include the outcome of ICU LOS, two[28 29] did not separate RCT data from non-RCT data and one[10] did not provide the pooled effect. Early tracheostomy was associated with a reduction in the ICU LOS in 10 studies: six[7 13 14 18 20 22] with weak evidence of association (class IV) and four[6 17 19 21] with suggestive evidence of association (class III).

Duration of mechanical ventilation

Of the total 22 reviews included in our study, two studies[12 16] did not include the outcome of duration of mechanical ventilation, one[10] did not provide the pooled effect and one[29] did not separate RCT data from non-RCT data. The early tracheostomy group demonstrated a reduction in the duration of mechanical ventilation in eight studies: six[7 15 17 19–21] with weak evidence of association (class IV) and two[6 14] with suggestive evidence of association (class III). Liu *et al* conducted a subgroup analysis based on the timing of early tracheostomy (less than 3 days, 4 to 5 days and 7 to 8 days) and the aetiology of critical illness (trauma, neurological, medical and surgical); no difference was found between early tracheostomy and late tracheostomy.[22]

Complications

Complications were evaluated in eight studies.[7 10 14 16 20 22 23 26] The most common complications included stoma inflammation or infection,[10 14 16 22] postoperative and intraoperative minor and major bleeding,[7 16 26] pneumothorax,[14 26] tracheoesophageal fistula[14 26] and tracheal stenosis.[10 22 26]

AMSTAR 2

Based on the AMSTAR 2 quality assessment tool, most studies were rated as critically low quality. McCredie *et al*[14] was rated as high quality, Siempos *et al*[7] as moderate quality and Andriolo *et al*,[10] Kishihara *et al*[16] and Chorath *et al*[18] as low quality (online supplemental appendix 2).

DISCUSSION

The current umbrella review provides a critical analysis and summary of previous systematic reviews of RCTs investigating the timing of tracheostomy in critically ill patients. Our findings indicate a decrease in VAP among early tracheostomy patients compared with late-tracheostomy patients, but no significant difference in mortality. It is noteworthy that despite the inclusion of several trials and reviews, the overall quality of evidence remains low.

The results of our meta-analysis regarding mortality are in line with most reviews included.[7 22–30] However, the reduction in VAP was only supported by three other reviews, indicating less consensus among the included studies.[6 7 18] The meta-regression we conducted to investigate potential sources of heterogeneity and assess the influence of tracheostomy timing and neurological admission did not yield additional insights regarding the observed results. Notably, the secondary outcomes reported in the included reviews varied, with some indicating no difference while others suggested a weak benefit for early tracheostomy compared with late tracheostomy. Regarding the incidence of tracheostomy complications, only seven evaluated the incidence of tracheostomy complications and mostly short-term complications.[7 10 14 16 22 23 26]

The strength of this umbrella review lies in its comprehensive assessment and synthesis of the best available evidence on the timing of tracheostomy in critically ill patients, while also highlighting the ongoing controversies in this field. We evaluated the impact of early tracheostomy across mixed patient populations and those specifically admitted to the ICU for neurological conditions. However, we were unable to identify a consistent pattern or clear benefit for any particular group. We identified significant variability in the definition of early tracheostomy, which complicates the interpretation of the findings. Systematic reviews typically defined early tracheostomy as occurring within 10 days of mechanical ventilation, while randomised clinical trials often used a limit of 7 days. This discrepancy is surprising, given that systematic reviews rely on secondary data derived from primary studies. Additionally, we observed discrepancies across studies in the timing of mortality assessments and secondary outcomes, which added complexity to the synthesis and interpretation of the results.

There are certain limitations that need to be addressed in this review. First, it is important to acknowledge that most data for the meta-analyses and meta-regression were extracted from systematic reviews[6 7 10 12–30] rather than directly from original studies. Although we do not believe that this influenced the overall results, it is worth noting that potential biases or variations in the methodologies of the included systematic reviews may have impacted the findings to some extent. Second, since this study is an umbrella review, the quality assessment of the individual randomised trials was not performed. Instead, we relied on the quality evaluations conducted within the included systematic reviews. However, it is important to emphasise that we excluded any systematic reviews that did not assess the quality of the studies they included. Third, we should acknowledge that our umbrella review did not include a systematic review specifically focused on COVID-19 patients. This is primarily due to the limited availability of RCTs addressing the timing of tracheostomy in this particular population. However, it must be pointed out that a recent systematic review and meta-analysis of observational data in COVID-19 patients reported findings consistent with our umbrella study. Specifically, this study demonstrated no significant difference in mortality rates between early and late tracheostomy groups, along with a reduction in VAP associated with early tracheostomy.[39]

The intricacies surrounding the controversy in tracheostomy timing can be attributed to the fundamental challenges embedded within the research question. Studies have consistently highlighted the difficulty in accurately predicting patients who necessitate prolonged mechanical ventilation and, consequently, stand to benefit most from tracheostomy interventions.[11 40] The TracMan study exemplifies this challenge, revealing that a mere 45% of patients in the late tracheostomy group underwent the procedure. The absence of validated tools for accurately assessing the need for prolonged mechanical ventilation further compounds this complexity.[11] A pivotal first step in advancing this research paradigm involves a more discerning approach to population selection.

A thorough review of the existing literature on tracheostomy timing in critically ill patients reveals insufficient evidence to support a definitive recommendation for or against early tracheostomy. Most outcomes reported in previous systematic reviews fail to demonstrate significant benefits, and the definition of early tracheostomy varies widely, often referring to procedures performed within the first 7 days of mechanical ventilation. These gaps in evidence underscore the need for rigorous research to better inform policymakers and guideline developers.

The findings of our trial sequential analysis further emphasise the need for new trials to address this unresolved question. To advance the field, we propose a novel methodological approach. Initially, the focus should be directed towards the development and validation of a comprehensive scoring system aimed at identifying patients who derive optimal benefit from tracheostomy. Subsequently, multicentre randomised trials should be meticulously conducted, with patient selection guided by this newly developed score. This approach aims to definitively establish whether the timing of tracheostomy holds substantial significance. Finally, once this novel dataset is available, a comprehensive systematic review and meta-analysis can be conducted to assimilate the latest insights and further refine our understanding of this critical aspect of patient care.

CONCLUSIONS

Despite extensive exploration, the evidence for the benefits of early tracheostomy remains very weak concerning VAP, and there is weak evidence indicating no benefit for mortality. Emphasising a well-designed RCT with a carefully selected population is considered more beneficial than relying solely on systematic reviews with meta-analyses of the current available RCTs.

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Contributors AB, TAT, MFR and MVV have made substantial contributions to the conception and design of the study and to acquisition of data; AB, TAT and MVV performed the analysis and the interpretation of data. All authors read and approved the final manuscript. MVV is the guarantor of the data. AI was used solely for reviewing and refining the English language, as none of the authors are native speakers.

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Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval Ethics approval was not required for this umbrella review as it exclusively utilizes published data. However, the study was assessed and approved by the *Diretoria de Pesquisa* at Hospital de Clínicas de Porto Alegre under registration number 2021-0448.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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