

## Review Article

## Impact of tracheostomy on ICU stay in adult patients with ARDS: A systematic review

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## ABSTRACT

**Objective:** To investigate the impact of tracheostomy on clinical outcomes in adults with acute respiratory distress syndrome (ARDS) who require mechanical ventilation (MV).

**Methods:** This systematic review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). Three electronic databases including PubMed, The Cochrane Library, and EMBASE to identify relevant studies on ARDS patients receiving MV were searched from inception to July 31, 2024. The reviewers assessed the risk of bias of included studies according to the Cochrane Risk of Bias 1 tool or JBI checklists, as appropriate. Two reviewers independently screened the literature and extracted the data. Outcomes among patients who underwent tracheostomy were compared and analyzed.

**Results:** Twenty studies involving 4,022 patients with ARDS who required tracheostomy were included, comprising 2 randomized controlled trials, 5 prospective studies, 12 retrospective studies, and 1 case series. On average, tracheostomized patients spent 30.2 days in the ICU and 44.8 days in the hospital, with an overall mean duration of MV of 27 days. Tracheostomy-related adverse events were reported in 15 studies and local bleeding was the most common complication. Of the 1,074 patients with tracheostomy, 626 (58.3%) were successfully weaned from the ventilator. Mortality outcomes were documented in 18 studies, indicating that 883 out of 2,302 (38.4%) of these patients died during hospitalization.

**Conclusion:** Tracheostomy in MV patients with ARDS does not have a clearly defined impact on ICU length of stay due to variability in study findings. However, it remains a safe intervention with generally minor complications. Future research should focus on standardized weaning protocols and multidisciplinary rehabilitation strategies to potentially improve patient outcomes.

**Implications for clinical practice:** Tracheostomy allows for a more controlled and gradual weaning process in patients with ARDS requiring prolonged MV. Moreover, although current evidence does not indicate a significant reduction in ICU length of stay, tracheostomy contributes to more effective patient management during the weaning by facilitating oral hygiene, improving mobility, and enabling both verbal communication and oral feeding.

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Introduction

Advances in mechanical ventilation (MV) techniques and improvements in respiratory management [1] have led to a continuous increase in survival rates among critically ill patients admitted to the intensive care unit (ICU) [2]. Tracheostomy is a widely used intervention that provides direct access to the trachea for respiratory support and secretion management in patients with acute respiratory failure [3], especially when clinicians predict a patient’s need for prolonged mechanical ventilation (PMV) [4], defined as at least 21 consecutive days of MV for at least six hours daily [5]. This intervention has been shown to facilitate earlier weaning, improve patient comfort, reduce the need for sedation [6], and enhance tracheobronchial toileting efficiency [7], as well as to support the transition from ICU to step-down units [8]. Tracheostomy requires daily nursing care to prevent stoma infection and cannula obstruction [9], as well as frequent suctioning, which is used to clear airway secretions and ensure patency of the artificial airway [10].

The use of tracheostomy has increased over the past decade, partly due to the introduction of a practical bedside percutaneous tracheostomy technique [11], compared to the surgical technique, which remains in use in specific situations (unfavorable anatomy or head and neck pathologies) [12]. On the other hand, tracheostomy can significantly affect the ICU length of stay (LOS) [13] and also have a considerable impact on patients’ functional recovery [14,15]. In particular, several authors report that tracheostomy does not improve long-term survival and is associated with worse outcomes after ICU discharge, particularly among older adults [16,17]. Furthermore, patients who underwent tracheostomy were also found to be four times more likely to be readmitted or to die within the first year following the hospitalization [18].

Acute respiratory failure is the primary reason for initiating mechanical ventilation [19], with approximately 67% of these patients fulfill the criteria for acute respiratory distress syndrome (ARDS) [20]. This syndrome is characterized by severe hypoxemia (define as  $PaO_2/FiO_2 < 150$  mmHg with  $PEEP \geq 5$  cmH<sub>2</sub>O despite optimization of ventilation settings), diffuse alveolar damage, non-cardiogenic pulmonary edema, and decreased lung compliance [21]. A large observational study investigating the global impact of severe acute respiratory failure found that tracheostomy was performed in 13% of patients with ARDS [22]. These patients were approximately four times more likely to require PMV compared to those without ARDS [23]. While various strategies (such as lung-protective ventilation, spontaneous breathing trials, and early mobilization) have been investigated to minimize the duration of MV [24,25], the characteristics of patients with ARDS and the severity of the disease pose challenges in establishing standardized weaning protocols, highlighting the need for individualized approaches. Early tracheostomy, generally defined as an intervention performed within the first ten days of MV initiation, has been suggested to offer several clinical benefits for patients requiring PMV [26]. These benefits include reduced sedation requirements, shorter ICU stays, a lower incidence of ventilator-associated pneumonia (VAP), and improved patient comfort [27,28]. A recent systematic review and meta-analysis of randomized controlled trials (RCTs) involving mechanically ventilated adult patients suggests that early tracheostomy shortens the duration of MV and ICU LOS but does not significantly impact the incidence of VAP, mortality, or overall hospital stay [29]. However, since these results included highly heterogeneous ICU patients (not only with ARDS but also cardiac, neurosurgical, trauma, and severe burn patients) the generalizability of these findings may be limited.

Despite increasing interest in the timing of tracheostomy for critically ill patients, current evidence remains inconclusive. Retrospective studies have produced conflicting results: some suggest that early tracheostomy may significantly reduce the risk of VAP, the duration of MV, and the ICU LOS [30–33]. However, a Cochrane systematic review reported inconsistent outcomes, indicating that early tracheostomy may offer little or no significant advantage in reducing the time to liberation

from MV compared to late tracheostomy [34]. Furthermore, the 2021 ARDS Clinical Practice Guidelines emphasize that the optimal timing of tracheostomy in patients with ARDS continues to rely largely on clinical judgment [35]. Given this variability and the limited evidence, the present systematic review aims to specifically evaluate the impact of tracheostomy on ICU LOS in adult patients with ARDS, regardless of disease severity. Additionally, the secondary aims include assessing other clinically relevant outcomes such as the duration of MV, adverse events, and mortality.

Materials and Methods

The Protocol of systematic review was registered in the International Prospective Register of Systematic Reviews (PROSPERO registration number: CRD42024555351) and conducted according to the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) statement [36].

Search strategy

A literature search was performed across three databases: PubMed, The Cochrane Library, and EMBASE, from inception to July 2024. No restrictions were placed on the publication dates to ensure a thorough review of the evidence. The search strategy was developed using Medical Subject Headings (MeSH) and relevant text-words, which were then tailored to each specific database.

The research question guiding this systematic review was structured using the PICO framework, as outlined in Table 1. The following MeSH terms and text-words were used for condition, context, and population/patient: (“Respiratory Distress Syndrome” [MeSH Terms]) AND (“Tracheostomy” [Mesh Terms]) AND (“Ventilator Weaning” [MeSH Terms]) OR (“Airway Extubation” [MeSH Terms])). Additional articles were identified by hand-searching through citation chasing. A detailed description of the search strategy is presented in the supplementary materials (Table S1).

Eligibility criteria

Studies including adult patients with ARDS admitted to ICU requiring tracheostomy during MV were eligible for inclusion. Articles written in languages other than English were excluded, as well as studies without full texts. Only RCTs, prospective and retrospective cohort studies, and case series were considered. Articles in which the presence of tracheostomy was not clearly assessed, and case series with fewer than 10 participants were also excluded to minimize the risk of bias and enhance data reliability while maintaining inclusivity [37]. Full-text publications and preprint articles were considered. Abstracts, clinical trials registry entries, results published in trial registries, and personal communications with investigators were also excluded.

Study selection

The initial phase of the study selection process was performed blindly based on titles and abstracts. All the results from the search

Table 1  
PICO criteria used in the systematic review.

| PICO         | Description                                                                                                               |
|--------------|---------------------------------------------------------------------------------------------------------------------------|
| Population   | Adults patients with ARDS                                                                                                 |
| Intervention | Ventilator weaning strategies<br>Tracheostomy                                                                             |
| Comparisons  | Any other intervention or no intervention                                                                                 |
| Outcomes     | ICU and hospital length of stay<br>Duration of mechanical ventilation<br>Mortality<br>Tracheostomy-related adverse events |

strategies were imported using the tool Rayyan [38]. Three authors (VR, ST, SC) were responsible for independently screening the titles and abstracts and selecting potential articles for inclusion based on the inclusion and exclusion criteria. Each article was assessed by two of these three authors. Finally, all relevant articles were retrieved as full-text and subsequently reviewed by two of these three investigators (VR, ST, SC), who independently applied the inclusion and exclusion criteria to determine final eligibility. In both phases (screening and full-text analysis), a third researcher (AF) resolved any disagreements regarding article eligibility. All reviewers responsible for study selection were nurses or physiotherapists with over 10 years of experience in critical care and respiratory management, as well as expertise in research methodology, ensuring a rigorous and informed selection process. In cases of overlapping populations (i.e., different papers reporting data from the same patients), the article with the larger sample size or greater data granularity was selected for inclusion in the review.

### Data extraction

Two reviewers (VR, FM) independently extracted general characteristics (first author, publication year, country, study design, sample size, participants characteristics, and comorbidities), interventions, and outcome data into a Microsoft Excel spreadsheet. Any differences in opinion about the study characteristics were resolved with a third reviewer (ST). When the information was not directly available, it was calculated if possible. When this occurred, the authors were contacted (following a standard procedure of two e-mail attempts) to obtain more details about the use of tracheostomy or to acquire data specific to patient characteristics.

### Critical appraisal

The risk of bias in the studies included in our systematic review was assessed by utilizing the Cochrane Risk of Bias 1 (RoB1) or JBI Critical Appraisal tools [39] for observational studies and case series [40] as appropriate. Two reviewers (VR and FM) independently evaluated the study quality, resolving discrepancies through discussion. Any unresolved disagreements were arbitrated by a third reviewer (FB). A detailed description of risk of bias evaluation is available in the [Supplementary materials](#) (Tables S2, S3 and S4).

### Outcome measure

The primary outcome was the ICU LOS (days). Other comparative results, designated as secondary outcomes, included hospital LOS (days), in-hospital and long-term mortality, duration of invasive MV (days), and tracheostomy-related adverse events. ICU and hospital LOS were measured in days from ICU admission to discharge, while ventilator weaning success was defined as sustained spontaneous breathing for at least 48 h after extubation or decannulation. Mortality rates were recorded as in-hospital death. Adverse events were reported as absolute numbers, percentages relative to the study population, and categorized by type and timing. Early complications included bleeding, severe hypoxia, subcutaneous emphysema, pneumothorax, and accidental decannulation [41]. Late complications included stoma infection, tracheal stenosis, tracheomalacia, and fistula formation [41]. Where possible, results have been categorized based on the timing of tracheostomy: early tracheostomy, performed within the first 10 days after endotracheal intubation, and late tracheostomy, conducted on or after the tenth day of MV [26].

### Statistical analysis

A random-effects model *meta-analysis* was planned to pool similar studies regarding participants, interventions, comparisons, and outcomes if the data were available. Mean differences (MDs) for continuous

outcomes measured with the same metrics or standardized mean differences (SMDs) for outcomes measured with different metrics with 95% CIs were calculated, as well as risk ratios (RRs) with 95% CIs for adverse events and mortality. Statistical heterogeneity was assessed through visual inspection of the forest plot and the  $\chi^2$  statistic (with statistical significance defined as  $p < 0.1$ ); and the  $I^2$  statistic. Following the guidance provided in the Cochrane Handbook for Systematic Reviews of Interventions [42],  $I^2$  values were interpreted as follows: 0% to 40% may indicate unimportant heterogeneity, 30% to 60% moderate heterogeneity, 50% to 90% substantial heterogeneity and 75% to 100% considerable heterogeneity. In the case of 10 or more studies included in the *meta-analysis*, publication bias was assessed via visual inspection of funnel plots [43]. Sensitivity analyses were planned by removing studies if they were assessed as having low methodological quality in any item or as having high or unclear RoB in the blinding of outcome assessors (detection bias) domain. Sensitivity analyses were also planned on comparisons with high heterogeneity ( $I^2 > 75\%$ ) by removing the studies responsible for the high levels of heterogeneity. All the *meta-analyses* and graphical outputs, including forest and funnel plots, were conducted using Review Manager (RevMan) 5.4.1 software. In cases where *meta-analysis* was inappropriate, a narrative synthesis with descriptive statistics and frequency reporting was planned. Where possible, weighted means and standard deviations were calculated either by aggregating available data or, when only medians and interquartile ranges (IQRs) were reported and sample sizes were available, by applying the formula proposed by Wan et al. [44]. To facilitate this process and ensure consistency, a specific tool called Meta-Analysis Accelerator was used [45].

## Results

### Study selection

The PRISMA flow diagram summarizing the study selection process is reported in [Fig. 1](#). After removing duplicates, 2,814 records were screened for title and abstract, of which 2,719 were discarded. Ninety-one records were retrieved for full-text screening, and those not meeting the inclusion criteria were excluded. Finally, 18 studies were included, and two additional publications were identified via citation searching. Details of the article selection are available in [supplementary materials](#) (Table S5). To obtain more details about the use of tracheostomy, authors were contacted: two of them responded providing useful data for the quantitative analysis.

### Study characteristics

The characteristics of the included studies are summarized in [Table 2](#). All studies, published between 2004 and 2023, were conducted in various countries, including Canada, several European nations, Kuwait, India, United Kingdom, and North America. Among the eligible studies, two were RCTs involving a total of 270 patients, one was a case series, 12 were retrospective studies, and five were prospective studies. Additionally, five of the studies were multicentre, while 15 were conducted at a single centre. Overall, the 20 studies reviewed involved a total of 4,022 adults, with individual study sample sizes ranging from 24 to 1,168 participants. The studies reviewed included participants aged 48 to 66 years, with a gender distribution across groups showing a major prevalence of males (2883/4022, 71.7%). All the studies, except two [46,47], included adult patients with COVID-19 ARDS. Of the 20 studies included, 14 specifically provided comorbidity data on ARDS patients who underwent tracheostomy, although only five studies showed data on obesity, arterial hypertension, and diabetes. Thirteen studies reported the presence of chronic obstructive pulmonary disease (COPD) in patients, accounting for 9.4% (380/4,022) of the total cohort. The main characteristics of patients with tracheostomy are presented in [Table 3](#).

Eleven studies reported the type of tracheostomy procedures. Of these, six included participants with both surgical and percutaneous

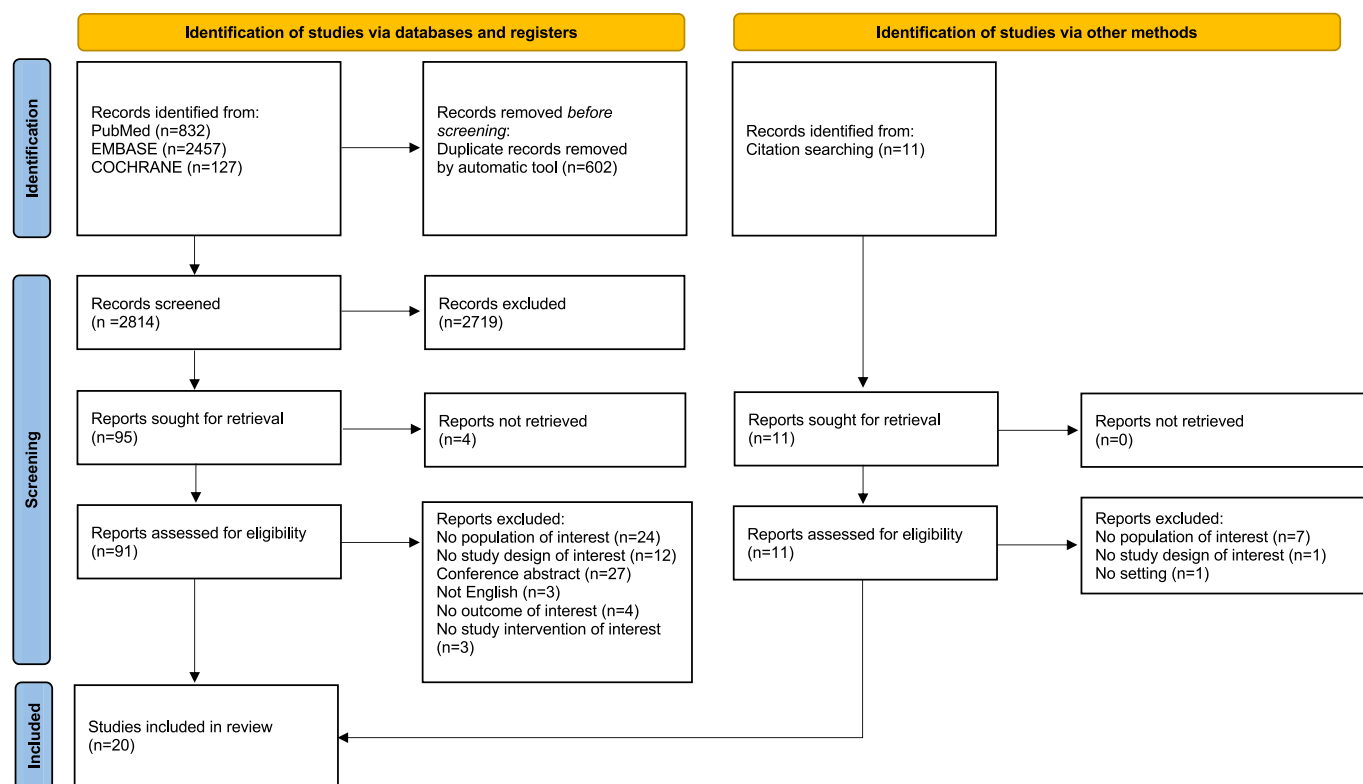


Fig. 1. Diagram of the study selection process for the systematic review.

Table 2  
Characteristics of included studies.

| Study               | Study design                   | Country | Sample size | Age (years)      | Sex (male) (%) | Patients with tracheostomy/<br>Patients on mechanical ventilation |
|---------------------|--------------------------------|---------|-------------|------------------|----------------|-------------------------------------------------------------------|
| Alshukry (2022)*    | Retrospective                  | Kuwait  | 377         | 56.2 (15.3)      | 222 (58.9%)    | 377/377                                                           |
| Arnold (2023)       | Retrospective                  | USA     | 72          | 66 (58 – 71)     | 51 (70.8%)     | 72/72                                                             |
| Botti (2021)        | Retrospective                  | Italy   | 44          | 64 (34 – 79)     | 32 (72.7%)     | 44/44                                                             |
| Bui (2023)          | Retrospective                  | USA     | 219         | 56.7 (NR)        | 139 (63.5%)    | 219/219                                                           |
| Cankar Dal (2022)   | Retrospective                  | Turkey  | 33          | 65.2 (14.0)      | 25 (75.8%)     | 33/33                                                             |
| Cardasis (2022)     | Case series                    | USA     | 24          | 61.1 (36 – 76)   | 19 (79.2%)     | 24/24                                                             |
| Carmichael (2021)   | Retrospective                  | USA     | 26          | 55 (12)          | 21 (80.8%)     | 26/26                                                             |
| Eeg-Olofsson (2022) | Randomized<br>Controlled Trial | Sweden  | 150         | 64.6 (11.4)      | 118 (78.7%)    | 118/150                                                           |
| Faure (2022)        | Retrospective                  | France  | 43          | 61 (48 – 66)     | 35 (81.4%)     | 43/43                                                             |
| Gamberini (2020)*   | Prospective                    | Italy   | 470         | 66 (18.3)        | 366 (77.9%)    | 267/470                                                           |
| Guarnieri (2021)    | Retrospective                  | Italy   | 151         | 59 (11.0)        | 116 (76.8%)    | 73/151                                                            |
| Long (2021)         | Prospective                    | USA     | 67          | 66 (52 – 72)     | 48 (71.6%)     | 67/67                                                             |
| Mahmood (2021)      | Retrospective                  | USA     | 118         | 54 (42.5 – 65.0) | 75 (63.6%)     | 118/118                                                           |
| Plečas Đurić (2023) | Retrospective                  | Serbia  | 73          | 63.7 (10.4)      | 48 (65.8%)     | 73/73                                                             |
| Prats-Urbe (2021)   | Prospective                    | UK      | 696         | 63 (10.2)        | 481 (69.1%)    | 696/696                                                           |
| Rumbak (2004)       | Randomized<br>Controlled Trial | USA     | 120         | 63 (9.9)         | 65 (54.2%)     | 120/120                                                           |
| Saraf (2023)        | Prospective                    | India   | 60          | 55.9 (2.3)       | 49 (81.7%)     | 60/60                                                             |
| Schmidt (2021)      | Retrospective                  | France  | 1168        | 48 (16)          | 894 (76.5%)    | 530/1168                                                          |
| Staibano (2023)     | Retrospective                  | Canada  | 24          | 49.4 (7.3)       | 18 (75%)       | 24/24                                                             |
| Takhar (2020)       | Prospective                    | UK      | 87          | 54 (26 – 72)     | 61 (70.1%)     | 87/87                                                             |

Note: Data are expressed as mean (SD); median (IQR) or count and percentage (%); (\*) information retrieved from the author.

tracheostomies, whereas four studies enrolled exclusively patients with a percutaneous tracheostomy. Only six studies reported the timing of the procedure, comparing early versus late tracheostomy. The primary outcome analyzed was ICU LOS, reported in 12 studies. Table 4 offered a detailed description of the secondary outcomes examined in this review. Hospital LOS and MV duration were reported by 10 and 17 studies, respectively. Other outcome measures, such as in-hospital and long-term mortality, and tracheostomy-related adverse events, were not systematically reported across all studies.

### Critical appraisal

Findings from the critical appraisal are summarized in supplementary materials (Tables S2, S3 and S4). Based on the results, articles were grouped into three categories: low risk of bias (result 75%-100%), moderate risk of bias (50%-74%), and high risk of bias (0%-49%). The single case series was assessed as having a low risk of bias, as most items on the JBI checklist received positive evaluations, except for the criterion addressing completeness of participant inclusion. Among the other

**Table 3**

Characteristics of the patients with tracheostomy included in systematic review.

| Study               | Comorbidities |              |          |      | Tracheostomy time |      | Tracheostomy type |              |
|---------------------|---------------|--------------|----------|------|-------------------|------|-------------------|--------------|
|                     | Obesity       | Hypertension | Diabetes | COPD | Early             | Late | Surgical          | Percutaneous |
| Alshukry (2022)*    | NR            | 180          | 187      | 60   | NR                | NR   | 0                 | 377 (100.0%) |
| Arnold (2023)       | 24            | 44           | 36       | 5    | NR                | NR   | 0                 | 72 (100.0%)  |
| Botti (2021)        | NR            | NR           | NR       | NR   | NR                | NR   | 29 (66.0%)        | 15 (34.0%)   |
| Bui (2023)          | NR            | NR           | NR       | NR   | 50                | 169  | NR                | NR           |
| Cankar Dal (2022)   | 0             | 2            | 7        | 1    | 18                | 15   | 0                 | 33 (100.0%)  |
| Cardasis (2022)     | 8             | 14           | 10       | NR   | NR                | NR   | 24 (100.0%)       | 0            |
| Carmichael (2021)   | 8             | 11           | 12       | NR   | NR                | NR   | 0                 | 26 (100.0%)  |
| Eeg-Olofsson (2022) | NR            | 85           | 46       | 8    | 72                | 78   | 82 (55.0%)        | 19 (13.0%)   |
| Faure (2022)        | NR            | 24           | 13       | 3    | NR                | NR   | NR                | NR           |
| Gamberini (2020)*   | NR            | 268          | 102      | 38   | NR                | NR   | NR                | NR           |
| Guarnieri (2021)    | NR            | NR           | NR       | NR   | NR                | NR   | NR                | NR           |
| Long (2021)         | 29            | 41           | 18       | 12   | NR                | NR   | 32 (48.0%)        | 35 (52.0%)   |
| Mahmood (2021)      | NR            | 53           | 49       | 2    | 9                 | 109  | 26 (22.0%)        | 92 (78.0%)   |
| Plečas Đurić (2023) | NR            | NR           | NR       | NR   | NR                | NR   | NR                | NR           |
| Prats-Urbe (2021)   | NR            | 324          | 150      | 50   | 142               | 554  | NR                | NR           |
| Rumbak (2004)       | NR            | NR           | 9        | 66   | 60                | 60   | NR                | NR           |
| Saraf (2023)        | NR            | 23           | 35       | 6    | NR                | NR   | NR                | NR           |
| Schmidt (2021)      | NR            | NR           | NR       | 124  | NR                | NR   | 262 (49.0%)       | 268 (51.0%)  |
| Staibano (2023)     | NR            | 6            | 3        | 5    | NR                | NR   | 4 (17.0%)         | 20 (83.0%)   |
| Takhar (2020)       | NR            | NR           | NR       | NR   | NR                | NR   | NR                | NR           |

Abbreviations: MV = mechanical ventilation; ICU = intensive care unit; COPD = chronic obstructive pulmonary disease; NR = not reported.

Note: Data are expressed as mean (SD); median (IQR) or count and percentage (%); (\*) information retrieved from the author.

**Table 4**

Characteristics of the outcome measures.

| Study               | Length of stay (days) |               | MV (days)      | Mortality   | Tracheostomy decannulation | Ventilator weaned |
|---------------------|-----------------------|---------------|----------------|-------------|----------------------------|-------------------|
|                     | ICU                   | Hospital      |                |             |                            |                   |
| Alshukry (2022)*    | NR                    | NR            | 12.9 (1 – 58)  | 236 (63.0%) | 53 (38.0%)                 | 156 (41.0%)       |
| Arnold (2023)       | 38 (32 – 44)          | 42 (35 – 56)  | 35.0 (31 – 44) | 28 (39.0%)  | 39 (54.0%)                 | 42 (58.0%)        |
| Botti (2021)        | NR                    | NR            | 35 (18 – 79)   | 15 (34.0%)  | 29 (65.9%)                 | 29 (65.9%)        |
| Bui (2023)          | NR                    | NR            | 17.2 (18.5)    | 75 (34.0%)  | 75 (34.0%)                 | 124 (56.6%)       |
| Cankar Dal (2022)   | 33 (25 – 37)          | NR            | 27 (18 – 33.5) | 22 (66.7%)  | NR                         | NR                |
| Cardasis (2022)     | 27.6                  | 43.5          | NR             | 3 (12.5%)   | 16 (67.0%)                 | 20 (83.0%)        |
| Carmichael (2021)   | NR                    | 49 (13)       | NR             | 4 (15.0%)   | 14 (42.0%)                 | 21 (81.0%)        |
| Eeg-Olofsson (2022) | 23.9 (15.1)           | NR            | 20.4 (13.2)    | 49 (32.7%)  | NR                         | NR                |
| Faure (2022)        | 30 (21 – 46)          | 71 (46 – 101) | 34 (24 – 52)   | 1 (2.0%)    | 40 (93.0%)                 | 40 (93.0%)        |
| Gamberini (2020)*   | 22.4 (8.5)            | 35.1 (8.5)    | 19 (8.5)       | 188 (40.0%) | NR                         | NR                |
| Guarnieri (2021)    | 27 (17 – 39)          | 45 (27 – 58)  | 25 (15 – 36)   | 25 (16.6%)  | NR                         | NR                |
| Long (2021)         | 10 (2 – 29)           | 22 (14 – 38)  | 15 (13 – 19)   | 5 (7.5%)    | 25 (37.0%)                 | 52 (78.0%)        |
| Mahmood (2021)      | 35.5 (28 – 46)        | 49 (37 – 61)  | 34.7 (9.3)     | 18 (15.3%)  | 40 (33.9%)                 | 78 (66.1%)        |
| Plečas Đurić (2023) | NR                    | NR            | 10.5 (7.9)     | NR          | NR                         | NR                |
| Prats-Urbe (2021)   | NR                    | NR            | 30.2 (14.9)    | NR          | NR                         | NR                |
| Rumbak (2004)       | 10.5 (2.9)            | NR            | 12.5 (4.7)     | 56 (46.7%)  | NR                         | NR                |
| Saraf (2023)        | NR                    | NR            | NR             | 5 (8.3%)    | 55 (91.6%)                 | 55 (91.6%)        |
| Schmidt (2021)      | 38.0 (18.5)           | 45.8 (23.0)   | 32 (16.4)      | 138 (26.0%) | NR                         | NR                |
| Staibano (2023)     | 69.1 (30.9)           | 118.7 (49.4)  | 60.2 (24)      | 8 (33.3%)   | 9 (37.5%)                  | 9 (37.5%)         |
| Takhar (2020)       | NR                    | NR            | 30 (25 – 36)   | 7 (8.0%)    | NR                         | NR                |

Abbreviation: ICU = intensive care unit; NR = not reported.

Data are expressed as mean (SD); median (IQR) or count and percentage (%); (\*) information retrieved from the author.

17 observational studies, nine were classified as low risk of bias and eight as moderate risk. The main methodological limitations were the lack of clear identification of confounding factors and inadequate reporting of strategies to address them. Finally, the risk of bias assessment of the two included RCTs indicated a high risk of performance and detection bias due to the absence of blinding for study personnel and outcome assessors.

#### Evidence synthesis

Due to the clinical heterogeneity of PICO elements and the lack of data to perform the meta-analysis, the results were synthesized narratively.

#### ICU length of stay

The overall mean ICU LOS was 22.3 (11.7) days, as shown in Table 4. Only four studies [46–49] directly reported the primary outcome data as means and SD. To increase the available data, we also included seven studies [50–56] in which means and SDs were estimated from medians and interquartile ranges (IQR) using the method described by Wan et al. [44]. With these additional studies, the estimated mean ICU LOS increased to 30.2 (16.8) days. Moreover, when including the study by Cardasis et al. [57], which did not report an SD, the mean ICU LOS remained similar at 30.1 days. Among the 20 studies, only four [47,49,52,56] specifically compared ICU LOS between early and late tracheostomy, defined as procedure performed before or after 10 days of MV, respectively. The mean duration of ICU LOS in early tracheostomy group was 15.1 (11.3) versus 20.7 (11.5) days in two studies [47,49]. Considering another two studies where means and SD were estimated

from medians and IQR, the mean duration of ICU LOS was found to be 17.4 (11.8) days in early tracheostomy versus 27.9 (22.2) days in late tracheostomy [52,56]. However, these four studies varied in terms of ARDS severity and etiology, comorbidities, and study design. Three of them included a higher proportion of critically ill patients with COVID-19 ARDS, and stratify the severity of ARDS using the Horowitz index [49,52,56]. In contrast, the other study was conducted in a non-COVID-19 cohort and did not report data about the severity of ARDS [47].

#### *Hospital length of stay*

Three studies reported a mean hospital LOS of 42.6 (15.9) days [46,50,58]. When six studies were included, and means and SDs were estimated from medians, the overall mean hospital LOS was 44.8 (24.7) days [48,51,53–56]. This data remained 44.8 days even after including the study by Cardasis et al. [57], which did not report the SD. For further details, see Table 4.

#### *Duration of mechanical ventilation*

Duration of MV was reported in 17 out of 20 studies. Of these, six studies provided the data as mean and SD [46–49,59,60], with the mean duration of MV being 18.7 (10.2) days. When eight studies were included [51–55,61–63], where means and SDs were estimated from medians, the mean duration of MV was 28.0 (15.3) days. Adding the three studies that did not report the SD [50,56,64], the overall mean duration of MV was 27 days (see Table 4 for further details). Ten studies also collected data on ventilator weaning, as shown in Table 4. Among the studies included, 626 out of 1,074 patients with tracheostomy were successfully weaned from MV.

#### *Long-term mortality*

Mortality outcomes were reported in 18 studies, with 883 out of 2,302 ventilated tracheostomy patients dying. Only two studies [59,60] did not provide any data about this outcome. Rates of mortality in these studies varied markedly, ranging from 2% [53] to 66.7% [52]. Five studies reported mortality outcome by stratifying patients into early versus late tracheostomy groups. The results of the four studies that included patients with COVID-19 ARDS showed no statistically significant difference in mortality [49,52,56,64]. However, in the pre-pandemic study, mortality was significantly higher in the late tracheostomy group (31.7% versus 61.7%,  $p < 0.005$ ) [47].

#### *Tracheostomy-related adverse events*

Complication rates related to tracheostomy were specifically reported in 15 studies, ranging from 4% [64] to 76% [49]. Local bleeding was the most frequently reported early complication, described in 14 studies that exclusively enrolled patients with COVID-19 ARDS [48–52,54–56,58–62,64]. Episodes of bleeding occurred in 369 out of 2,530 patients included in the 15 studies that describe the complications. Other common complications included pneumothorax and subcutaneous emphysema, reported in 6 [49–51,56,59,61] and 5 [52,60–62,65] studies, respectively. Among the late complications, stoma infections were noted in six studies, while more severe adverse events such as tracheal stenosis and bronchopleural fistula were observed in a limited number of studies.

### **Discussion**

This systematic review examined the impact of tracheostomy on ICU LOS in patients with ARDS, synthesizing data from 20 studies that included a total of 4,022 participants. The findings suggest that tracheostomy in this population is associated with prolonged ICU stay, often exceeding an average of 30 days, and duration of MV, likely reflecting the severity of their underlying condition.

The included studies predominantly focused on adult patients with COVID-19 ARDS, highlighting the increased research interest in this topic during the pandemic [66]. COVID-19 has been a leading cause of

respiratory failure, with a significant proportion of hospitalized patients developing ARDS. Tracheostomy practices underwent a significant shift during the pandemic, with a higher procedure rate among COVID-19 ARDS patients compared to those without [67]. Considering timing, some studies included in this systematic review [47,49,56,60,68] reported that early tracheostomy facilitated ventilator weaning and reduced ICU LOS by an average of six days. These findings also highlight that tracheostomy was employed during the pandemic to facilitate weaning from MV and expedite ICU discharge, thereby increasing ICU bed availability during the healthcare crisis [69]. Conversely, delayed tracheostomy, performed two weeks or later the initiation of MV, was associated with prolonged ICU stay, thereby extending the overall duration of hospitalization. Most studies included in this review reported similar ICU LOS (ranging from 10 to 38 days), except for the paper by Staibano et al. [48], which included only patients receiving ECMO support and reported an average ICU stay of 69.1 days. This prolonged ICU LOS may reflect the severity of ARDS in this cohort, often requiring additional advanced therapies such as prone positioning, ECMO or continuous renal replacement therapy [70,71]. Similarly, a study conducted in a medical intensive care setting involving 1,570 ICU patients further supports this association, demonstrating that early tracheostomy was significantly associated with a shorter ICU LOS (median of 36 days versus 45 days), reduced duration of MV (median of 21 days versus 31 days), and lower mortality rate (32.3% versus 40.6%) [72]. While these results reinforce the potential benefits of early tracheostomy, the variability in weaning strategies limits generalizability, highlighting the need for further investigations.

MV is the most frequently reported outcome in this systematic review, reflecting its relevance in the treatment of ARDS patients with tracheostomy. These findings are consistent with the international, multicenter, prospective WEANSafe study, conducted across 481 ICUs worldwide, which reported in the subgroup of patients requiring PMV a similar duration of MV [73]. Patients requiring PMV may benefit from a tracheostomy, as it facilitates a slow and gradual weaning process by allowing for the progressive reduction of pressure support ventilation, implementation of spontaneous breathing trials, and the use of tracheostomy capping in conjunction with non-invasive ventilation [74]. Although detailed data on the use of tracheostomy as a facilitator of weaning were provided, significant variability across studies in weaning parameters, criteria, and management protocols (often influenced by local institutional and team practices) complicated comparisons [75]. In this context, Rose et al. [76] demonstrated that patients requiring PMV benefit from specialized approach that prioritizes rehabilitation pathway, symptom management, and discharge planning, underscoring the importance of comprehensive care strategies for these patients. Importantly, PMV in these patients often delays functional recovery, such as active sitting position, occurs only after two weeks of ICU stay [77].

The impact on mortality indicated a significant association between late tracheostomy and higher mortality [49,56,64]. The TracMan trial, the largest RCT to date with 909 mixed ICU patients, found no difference in survival between early and late tracheostomy, with both groups showing the same ICU discharge mortality rate of 29.7% ( $p > 0.99$ ) [78]. Furthermore, tracheostomy is typically performed in patients who are clinically stable but likely to require PMV [79]. Therefore, direct comparisons between patients who received a tracheostomy and those who did not might be affected by immortal time bias, an important source of confounding since patients who die early are less likely to undergo tracheostomy [79].

Several studies have reported tracheostomy-related complications, which were generally minor. The most frequent complication was local bleeding, defined as a blood loss ranging from 25 to 100 ml or as bleeding that could be controlled with digital pressure [80]. Acute bleeding during the tracheostomy procedure is mostly caused by injuries of cervical vessels and is generally unrelated to coagulation function [81]. Conversely, in patients with COVID-19 ARDS, the increased risk of

bleeding may be explained by the use of antithrombotic prophylaxis, which often involves elevated doses of low-molecular-weight heparin or unfractionated heparin to counteract the hypercoagulable state induced by COVID-19 [82]. These findings are also supported by previous COVID-19 literature [83], although the percutaneous technique is widely accepted as a low-complication procedure ensuring safe patient care in ICU, since it involves less tissue dissection and a smaller stoma compared to the surgical technique [84]. Among late complications, stoma infections [67] and ulcers [85] have been commonly reported following tracheostomy in patients with COVID-19, particularly due to the significant increase in the use of tracheostomy devices for long-term ventilation during the pandemic [86]. Notably, evidence from ARDS of other etiology also confirms the occurrence of tracheostomy-related complications, with bleeding (9.5%), accidental tube dislodgement (7.0%) and subglottic stenosis (4.5%) being the most frequently reported events [87]. These complication rates are comparable to those in COVID-19 ARDS cohorts, suggesting a consistent safety profile for tracheostomy across different ARDS etiologies.

Overall, the findings align with literature suggesting a favorable safety profile for tracheostomy, with risks being relatively low in incidence and minor in severity [88]. Although many of the included studies reflect the unique circumstances of the COVID-19 pandemic, the findings highlight that tracheostomy remains a key intervention in the management of patients requiring PMV and experiencing difficulties in weaning, regardless of ARDS etiology. Additional advantages in these patients are that the presence of tracheostomy improves nursing management by simplifying oral hygiene care [89], enhancing patient mobility, and facilitating both verbal communication and oral feeding [90]. The increasing number of patients requiring tracheostomy underscores the necessity for healthcare providers to acquire comprehensive knowledge in tracheostomy management. This includes expertise in tracheostomy weaning and conducting long-term follow-up evaluations of patients' rehabilitation after ICU discharge, particularly for those who are discharged still with the tracheostomy in place.

### Limitations and strengths

This systematic review has the strength of including a well-defined population, focusing exclusively on adult patients with ARDS who required MV. No other pathologies were included, and all patients were treated in medical ICUs. However, the nature and quality of the studies limit the generalizability of the conclusions regarding the non-superiority of tracheostomy compared to weaning with endotracheal tubes. Similarly, since most studies included only patients with ARDS related to COVID-19, a condition known for prolonged ICU and hospital stays, generalizing these findings to all ARDS patients should be done with caution.

### Conclusion

Our findings indicate that tracheostomy in MV patients with ARDS does not have a clearly defined impact on ICU LOS. This uncertainty arises from the variability in the reviewed studies, with some suggesting that tracheostomy facilitates weaning and reduces ICU LOS, while other studies do not. Nevertheless, tracheostomy remains a safe intervention, with a low prevalence of complications that are generally minor in severity. The implementation of standardized weaning protocols and a multidisciplinary approach that prioritizes rehabilitation may contribute to reducing the duration of MV and, consequently, improving ICU LOS.

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### Ethical approval

Not applicable.

### Declaration of Generative AI and AI-assisted technologies in the writing process

During the preparation of this work the authors used AI-assisted tool for language translation. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

### CRediT authorship contribution statement

**Veronica Rossi:** Writing – original draft, Project administration, Investigation, Data curation, Conceptualization. **Filippo Binda:** Writing – original draft, Visualization, Investigation, Data curation. **Claudio Cordani:** Writing – original draft, Methodology, Formal analysis, Conceptualization. **Federica Marelli:** Writing – original draft, Investigation, Data curation. **Serena Tammaro:** Writing – original draft, Investigation, Data curation. **Sabrina Colombo:** Investigation, Data curation. **Alice Fantini:** Investigation, Data curation. **Annalisa Carlucci:** Writing – review & editing, Supervision. **Giacomo Grasselli:** Writing – review & editing, Supervision.

### Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

### Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.iccn.2025.104076>.

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