Original Article

Incidence, timing, and outcomes of tracheostomy in COVID-19 acute respiratory distress syndrome patients across three nations—an individual patient data analysis

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Background: Tracheostomy is often performed to facilitate weaning in invasively ventilated patients. There are studies regarding tracheostomy in acute respiratory distress syndrome (ARDS) patients, but its practice in ARDS patients due to coronavirus disease 2019 (COVID-19) remains uncertain. The aim of the study was to compare incidences of tracheostomy among three nations and to analyze outcomes associated with tracheostomy in COVID-19 ARDS patients.

Methods: Post hoc analysis of patient-level data on tracheostomy in patients with COVID-19 ARDS from nationwide ventilation studies in Argentina, Spain, and the Netherlands. The primary endpoint was incidence and timing of tracheostomy. A propensity matched analysis was used to correct for factors with a known association with mortality, and a sensitivity analysis was performed to correct for the risk of death and the chance of receiving a tracheostomy. All three studies included patients that were admitted to a participating intensive care unit (ICU); aged >18 years; receiving ventilatory support; confirmed to have

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COVID-19 pneumonia. Patients were excluded from participation when there was an alternate cause for pneumonia. For the current analysis, we additionally excluded patients not having ARDS.

Results: The analysis included 5,781 invasively ventilated patients: 1,469 (25%) patients from Argentina, 3,349 (58%) patients from Spain, and 963 (17%) patients from the Netherlands. Tracheostomies were performed 24% in Argentina {median 20 [16–24] days}, 40% in Spain {median 16 [12–21] days}, and 18% in the Netherlands {median 21 [17–27] days}. In unmatched and matched analyses 60-day mortality was lower in patients that received a tracheostomy.

Conclusions: Both the incidence and timing of tracheostomy in COVID-19 ARDS patients differed among the three nations. Tracheostomy was associated with lower mortality rates.

Keywords: Tracheostomy; acute respiratory distress syndrome (ARDS); coronavirus disease 2019 (COVID-19); incidence; timing

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Introduction

Tracheotomy is often performed to facilitate weaning in invasively ventilated patients (1-3). While randomized clinical trials have failed to show outcome benefit (4), tracheostomy offers patient comfort, e.g., by allowing a patient to speak and eat, reducing sedation requirements, improving pulmonary hygiene, and potentially decreasing the risk of laryngotracheal stenosis (5). Tracheostomy incidence in patients with acute respiratory distress syndrome (ARDS) was previously examined in a global observational study (6). This study showed that up to one in eight ARDS patients received a tracheostomy within 2 weeks of the start of invasive ventilation, with notable variations among nations. In non-ARDS patients, the incidence is lower but still significant, with up to one in ten patients weaned from ventilation with a tracheostomy (7,8).

The role of tracheostomy in care of patients with ARDS due to coronavirus disease 2019 (COVID-19) remains uncertain. A comparative analysis of global COVID-19 tracheostomy protocols revealed how the global community made critical decisions when faced with a lack of substantial scientific data; wide variations in tracheostomy protocols were observed across geographies and resource levels (9). Several clinical factors may have led to differences in tracheostomy practice for patients with COVID-19 ARDS, compared to patients with classic ARDS and other critically ill patients receiving invasive ventilation. For example, COVID-19 ARDS patients often experience profound and refractory hypoxemia (10). This may require more frequent use of prone positioning (11), which could increase the risks associated with tracheostomy (12). Furthermore, concerns relating to viral transmission to healthcare personnel may have hindered an early tracheostomy (12). Studies on the right timing of tracheostomy show conflicting results, in patients with stroke early tracheostomy does not seem to improve outcome whereas in patients with traumatic brain injury early tracheostomy is associated with better outcome (13,14). Lastly, it remains unclear whether tracheostomy impacts outcomes in COVID-19 ARDS patients, similar to those with ARDS resulting from other causes.

Although acute pandemic surges have subsided (15), healthcare crises will continue to induce resource capacity

Highlight box

Key findings

- Incidence of tracheostomy was different among the three nations compared; timing of tracheostomy was also different among the three nations; mortality rates were lower in patients that received tracheostomy compared to patients that did not receive tracheostomy.

What is known and what is new?

- It is unclear whether tracheostomy impacts outcomes in acute respiratory distress syndrome (ARDS) patients due to coronavirus disease 2019 (COVID-19).
- The timing and incidence of tracheostomy in COVID-19 ARDS patients differed among the three nations compared. Tracheotomy is associated with a lower mortality.

What is the implication, and what should change now?

- There is a need for future investigations considering patient centered outcomes.

strain (16). Furthermore, the potential of viral pathogens to induce ARDS underscores the ongoing relevance of pandemic experience to contemporary tracheostomy practice (17). Therefore, we reanalyzed a pooled database that merged the individual data of patients in national studies of ventilation in COVID-19 patients. We wished to compare incidences of tracheostomy among three nations and to analyze outcomes associated with tracheostomy in COVID-19 ARDS patients. We hypothesized that the incidence and timing were different among the three nations. To create comparable groups of patients, we used propensity matching to correct for factors with a known association, and we performed a sensitivity analysis to correct for immortal time bias. We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-2025-104/rc).

Methods

Study design and participants

This is a post hoc analysis of a pooled database that merged the individual data of patients included in three national studies of ventilation in COVID-19 patients, named 'sociedad Argentina de Terapia Intensiva-COVID-19' (SATI-COVID-19) in Argentina (18), 'Centro de Investigación Biomédica en Red Enfermedades Respiratorias COVID-19' (CIBERESUCICOVID) in Spain (19), and 'Practice of VENTilation in COVID-19 patients' (PRoVENT–COVID) in the Netherlands (11). All studies were conducted during the COVID-19 pandemic, ranging from March 2020 to 2021.

The original studies were conducted following study protocol approval from a central Institutional Review Board. Comprehensive information about the studies can be found in the original publications (11,18,19). Additional ethical approval was neither needed for the creation of the pooled database nor for this current analysis. The three original studies are registered at clinicaltrials.gov (NCT04611269, NCT04457505 and NCT04346342).

The funding of studies used for this analysis has been reported with the original publications of the three national studies. This analysis was performed without additional funding.

Inclusion and exclusion criteria

Inclusion and exclusion criteria used in the original studies can be found in the original publications (11,18,19). All three studies included patients that were (I) admitted to a participating intensive care unit (ICU); (II) aged >18 years; (III) receiving ventilatory support; for (IV) confirmed to have COVID-19 pneumonia. Patients were excluded from participation when there was an alternate cause for pneumonia. PRoVENT-COVID additionally excluded transferred patients that had started with invasive ventilation in a non-participating center.

For the current analysis, we additionally excluded patients with missing data on tracheostomy and not having ARDS according to the Berlin definition of ARDS on the first 2 days of the study (20).

Data available for each study

The investigators of the three studies captured the following demographic characteristics and data at baseline—age, sex, height, weight, home medication, and comorbidities, and a severity of illness score like Sequential Organ Failure Score (SOFA) (21), Simplified Acute Physiology Score (SAPS) 3 (22), or Acute Physiology and Chronic Health Evaluation (APACHE) II score (23,24). Ventilation characteristics were recorded for day 1 and day 2, and the day of tracheostomy. Follow up data included the last day of invasive ventilation; last day in ICU and in hospital; and survival at 28 and 60 days after initiation of invasive ventilation.

Definitions

For this analysis, the first calendar day a patient was receiving invasive ventilation was merged with the second day. This day was named 'Day 1'. The following days were numbered successively. Timing of tracheostomy was defined as the day that the tracheostomy was performed and counted from the day of start of invasive ventilation. VFD-28 and 60 were calculated as the amount of days free from ventilation until day 28 or day 60, if a patient died on day 28 or day 60 they would be assigned 0 VFD-28 or VFD-60 respectively.

Tidal volume (V_T) was expressed in mL/kg predicted body weight (PBW) using standard formulas for females and males. Driving pressure (ΔP) was calculated by subtracting positive end-expiratory pressure (PEEP) from the plateau pressure with volume-controlled ventilation, or from the maximum airway pressure with pressure-controlled ventilation, and only for timepoints with evidence of absence of spontaneous breathing (25). We also calculated respiratory system compliance (C_{RS}) by dividing V_T by ΔP, and absolute mechanical power of ventilation (MP) by using standard formulas (26,27).

Endpoints

The primary endpoint was incidence and timing of tracheostomy. The secondary endpoints were mortality at day 28 and day 60, mortality in ICU and hospital, duration of ventilation in survivors, and ICU and hospital length of stay (LOS).

Power calculation

We did not perform a formal power calculation. Instead, the available number of patients in the three studies served as the sample size.

Statistical analysis

Categorical variables were expressed as counts (proportions) and continuous variables as median and interquartile range (IQR). Categorical variables were compared using Chi-squared test or Fisher's exact test when indicated. Two-group comparisons of continuous variables were performed with the Mann-Whitney *U* test.

The incidence of tracheostomy was compared among the three countries using a Kruskall Wallis test. Timing of tracheostomy was compared using a shared frailty model that was visualized using Kaplan-Meier curves.

Hazard ratios for 28- and 60-day mortality rates were compared using Cox proportional hazards model. ICU and hospital LOS were compared through a clustered Fine Gray competing risk model, with death before discharge treated as competing risk with study as a gamma frailty.

Propensity score matching was performed using nearest-neighbor matching with a maximum caliper of 0.1 and a ratio of 1:3 using the following predefined variables with a known or suspected association with tracheostomy: (I) demographic characteristics [age, gender, body mass index (BMI), comorbidities]; (II) ventilatory and oxygenation variables (PEEP, C_{RS}, and PaO_2/FiO_2, and use of prone positioning); (III) use of vasopressors; and (IV) use of renal replacement therapy (RRT); (V) use of prone positioning. The amount of missing data for variables included in propensity matching was <5%, except for BMI (Table S1), for matching BMI was imputed using multiple imputation using predictive mean matching in the Multivariable Imputation by Chained Equations (MICE) package.

As a sensitivity analysis, 60-day mortality was compared in the unmatched and in the matched cohort using a time dependent Cox proportional hazards model to correct for immortal time bias, in the entire cohort and in the three national cohorts separately.

We used R statistics version 4.0.3 (R Foundation for Statistical Computing, Vienna, Austria). A P value <0.05 was considered significant.

Results

Patients

From the 8,374 COVID-19 patients included in the studies from Argentina, Spain, and the Netherlands, 2593 patients were excluded. Main reasons for exclusion were not having ARDS according to the Berlin definition of ARDS, or not having received invasive ventilation (*Figure 1*). The majority of the included 5,781 COVID-19 ARDS patients were male, overweight, and had a history of pulmonary disease, cardiac failure, or diabetes mellitus (*Table 1* and Table S2). Compared to patients that did not receive a tracheostomy, patients receiving a tracheostomy were more often male and had higher ARDS severity. Patients who received a tracheostomy were ventilated in the first days of ventilation with a higher median FiO_2. Incidence of prone positioning was 82% in the group that received tracheostomy and 70% in the group that did not (P<0.001). This was 80% and 75% after propensity matching (P<0.001). After matching (Figure S1), groups were well balanced (Table S3).

Tracheostomy incidence and timing

The overall incidence of tracheostomy was 32%. In the unmatched analysis tracheostomies were performed on 24% in Argentina {median 20 [16–24] days}, 40% in Spain {median 16 [12–21] days}, and 18% in the Netherlands {median 21 [17–27] days} (*Figure 2*). In matched analysis, differences in incidence and timing among nations did not change (*Figure 2*).

Outcomes

In unmatched analysis, compared to patients that did not receive a tracheostomy, patients that received a tracheostomy had lower mortality rates, a longer duration of ventilation in survivors, and a longer ICU and hospital LOS (*Table 2* and Figure S2). In matched analysis, differences in clinical outcomes did not change (Table S4 and Figure S3).

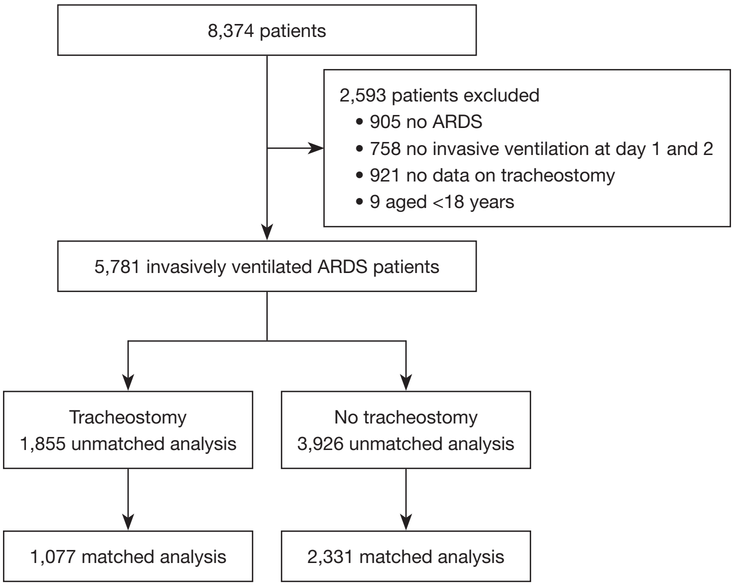

Figure 1 Flowchart of the three included studies. ARDS, acute respiratory distress syndrome.

Sensitivity analysis

After correcting for immortal time bias, 60-day mortality remained lower in tracheotomized patients compared to patients that did not receive a tracheostomy (Figure S4).

Discussion

The findings of this analysis can be summarized as follows: (I) the incidence of tracheostomy was different among the three nations compared, with a lower incidence of tracheostomy in the Netherlands compared to Argentina and Spain; (II) timing of tracheostomy was also different among the three nations, with Spain having the shortest time from start of invasive ventilation to tracheostomy. In addition, (III) mortality rates were lower in patients that received tracheostomy compared to patients that did not receive tracheostomy; (IV) this difference remained statistically significant after correcting for immortal time bias. Propensity matched analysis did not change the findings.

Our study has strengths. We had access to the individual patient data of three large nationwide studies early in the pandemic. The datasets could be merged easily, and the individual databases were rich, both in respect to incidence and timing of tracheostomy and follow-up. The amount of missing data was low in all three studies. The original studies enrolled patients in various types of hospitals, including university-affiliated centers, and teaching and non–teaching hospitals, increasing the generalizability of the findings. We restricted the analysis to patients that had ARDS according to the Berlin definition, to minimize heterogeneity, and performed an additional propensity score matched analysis to correct for factors with known associations with tracheostomy practice and outcome. Lastly, we strictly followed a predefined analysis plan, and we included one sensitivity analysis to correct for immortal time bias.

Our findings enhance our understanding of global tracheostomy incidence in critically ill patients in recent years. A secondary analysis of LUNG SAFE showed an incidence of tracheostomy of 13% in ARDS patients (6). This study also showed differences by nation, with a higher incidence in European high-income countries than in non-European high-income countries and middle-income countries. In non-ARDS patients, tracheostomy incidence is around 7% (7,8). The overall incidence in our cohort is remarkably higher, but nation differences differed from what has been found in ARDS patients before the COVID-19 pandemic.

We can only speculate on the reasons for the variance in incidence. One potential factor could be perceived differences between countries in indications for tracheotomy (28). Apart from the potential positive outcomes for weaning, communication, or reduced sedation associated with tracheostomy, tracheostomy

Table 1 Baseline characteristics and demographics, and ventilation characteristics

Characteristics	Tracheostomy (N=1,855)	No tracheostomy (N=3,926)	P
Age (years), median [IQR]	65 [57–71]	64 [55–71]	0.17
Sex (male), n [%]	1,391 [75]	2,708 [69]	<0.001
BMI (kg/m^2), median [IQR]	29 [26–33]	29 [26–32]	0.44
SOFA score[a], median [IQR]	6 [4–8]	6 [4–8]	0.51
Comorbidities, n [%]			
Cardiac failure[b]	189 [10]	356 [9]	0.17
COPD[c]	223 [12]	408 [10]	0.06
Diabetes mellitus	505 [27]	1,035 [26]	0.49
Chronic kidney disease[d]	108 [6]	221 [6]	0.77
Liver disease[d]	50 [3]	67 [2]	0.24
Cancer[e]	58 [3]	126 [3]	0.87
No comorbidity	1,025 [55]	2,287 [58]	0.03
ARDS severity, n [%]			0.02
Mild	321 [17]	756 [19]	
Moderate	929 [50]	2,025 [52]	
Severe	605 [33]	1,145 [29]	
V_T (mL/kg PBW), median [IQR]	6.7 [6.0–7.5]	6.7 [6.0–7.4]	0.62
PEEP (cmH_2O), median [IQR]	12 [10–14]	12 [10–14]	<0.001
P_{MAX} (cmH_2O), median [IQR]	25 [22–28]	25 [22–28]	0.27
ΔP (cmH_2O), median [IQR]	12 [10–15]	13 [10–15]	0.002
C_{RS} (mL/cmH_2O), median [IQR]	35 [28–45]	34 [27–44]	<0.001
MP (J/min), median [IQR]	17 [14–21]	17 [14–21]	0.30
FiO_2 (%), median [IQR]	70 [50–100]	65 [50–100]	<0.002
Total RR (breaths per min), median [IQR]	22 [20–25]	22 [20–25]	0.23

[a], SOFA score at baseline; [b], cardiac failure as defined by NYHA; [c], COPD according to GOLD classification; [d], different definitions could have been used between the cohorts; [e], cancer defined as active solid or hematologic malignancy. ARDS, acute respiratory distress syndrome; BMI, body mass index; COPD, chronic obstructive pulmonary disease; C_{RS}, respiratory system compliance; ΔP, driving pressure; FiO_2, fraction of inspired oxygen; IQR, interquartile range; MP, mechanical power of ventilation; PBW, predicted bodyweight; PEEP, positive end-expiratory pressure; P_{MAX}, maximum airway pressure; RR, respiratory rate; SOFA, Sequential Organ Failure Assessment; V_T, tidal volume.

may also present a more stable airway option for patients. In situations involving a large number of patients and a concurrent shortage of healthcare professionals (e.g., staff with airway expertise), it may prove difficult to re-intubate patients following accidental extubation. This shortage was notably apparent in the early stages of the pandemic. Additionally, given that COVID-19 ARDS patients typically require invasive ventilation for a longer duration compared to critically ill patients before the pandemic, a higher incidence of tracheostomy is not surprising. This pattern aligns with guidelines favoring tracheostomy in patients necessitating prolonged ventilation.

Several studies (29-35) and meta-analyses (36-40) have explored the optimal timing for tracheostomy in critically ill patients, with conflicting evidence on the advantages of an early versus a late tracheostomy (41-46). One meta-

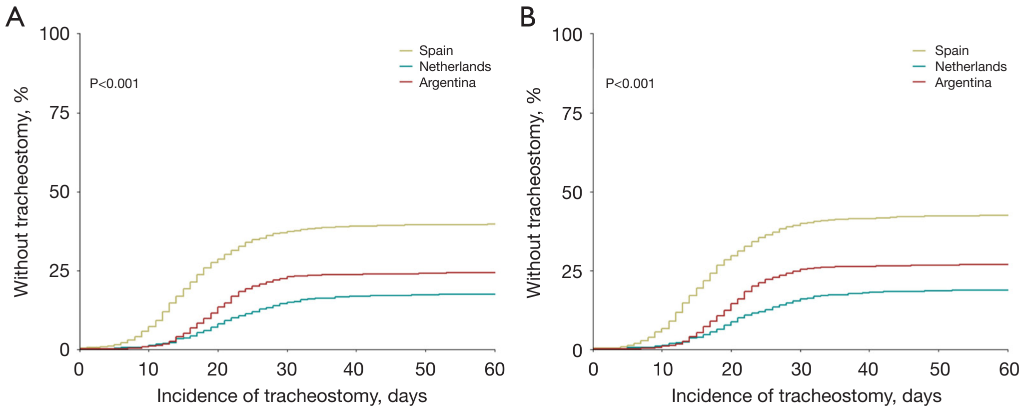

Figure 2 Incidence and timing of tracheostomy in unmatched analysis (A) and in matched analysis (B).

Table 2 Outcomes—unmatched analysis

Outcomes	Tracheostomy (N=1,855)	No tracheostomy (N=3,926)	P
28-day mortality, n [[%]	243 [13]	1,777 [45]	<0.001
60-day mortality, n [%]	531 [29]	1,907 [49]	<0.001
VFD-28, median [IQR]	11 [0–19]	0 [0–15]	<0.001
VFD-60, median [IQR]	18 [0–47]	38 [0–50]	<0.001
LOS ICU (days), median [IQR]	37 [27–51]	13 [8–19]	<0.001
LOS hospital (days), median [IQR]	50 [35–70]	20 [13–29]	<0.001

ICU, intensive care unit; IQR, interquartile range; LOS, length of stay; VFD, ventilator-free days.

analyses (36) showed lower mortality rates in patients that received an early tracheostomy, but with divergent results on time under invasive ventilation. We observed significant variations in tracheostomy timing among nations. Delayed tracheostomy is favored when prone positioning is necessary (47), while early tracheostomy is favored for potential benefits like earlier rehabilitation, reduced risk of laryngeal injury, and less use of sedatives (5). The COVID-19 pandemic introduced an additional consideration, with concerns about viral transmission during the procedure (5,48-52). An international survey across 26 countries showed that there were some country differences on timing. In Argentina, timing of tracheostomy in our analysis is in line what was reported in the international survey, but timing in Spain and in the Netherlands was not. The above-mentioned international survey indicated a preference for performing the tracheostomies in negative-pressure ICU rooms, although some guidelines supported standard or negative-pressure operating room (9). Issues related to personal protective equipment have also been prominent (53-55). Timing decisions may be influenced by the availability of negative-pressure rooms and personal protective equipment, which can vary between institutions and countries (56).

The direct effects of tracheostomy on outcomes remain uncertain. A secondary analysis of LUNG SAFE showed that tracheotomized patients had the highest survival probability, but no significant increase in 60- or 90-day survival compared to patients without a tracheostomy (6). However, there is a risk of immortal time bias when the exposure group, i.e., tracheotomized patients, includes a follow-up period during which the event of interest, i.e., death, cannot occur. To address this bias, we employed a time-dependent Cox proportional hazards model. Further investigation may be warranted.

Our study has limitations. First, we do not have access to the tracheostomy protocols used within the hospitals that participated in the national investigations included in our analysis, if there were any. The studies captured neither information regarding the tracheostomy techniques used, i.e., whether open or percutaneous techniques were used, nor the indications and contraindications, both at an ICU level and a patient level. While a tracheostomy could reduce the risk of ventilator–associated pneumonia, the individual studies did not capture this important complication of invasive ventilation. We can only speculate on resource constraints, which may not only be different between the nations compared, but also within a country and depending on data collection. Indeed, very early in the pandemic, resource constraints could be more present then at later time points. Additionally, our propensity score matching sought to include all relevant confounding variables; however, unobserved, or unmeasured confounders could have introduced bias. Different definitions for some comorbidities could have been used between the cohorts, this could have introduced bias in this analysis. Also, withdrawal of life sustaining support was not collected, this could have introduced bias in the analysis. The timeline studied also did not permit analysis of longer-term survivorship outcomes. Finally, we could only use data from three nations, and differences could be much larger when comparing incidence, timing, and outcomes amongst nations with more differences in resource constraints, i.e., high-income countries versus middle–income countries and low-income countries. Lastly, only time until first extubation was known, therefore, reintubation was not taken into account in the calculation of VFDs.

Conclusions

In conclusion, the timing and incidence of tracheostomy in COVID-19 ARDS patients differed among the three nations compared. Tracheotomy is associated with a lower mortality. These observations highlight the need for future investigation beyond mortality, LOS, or short-term complications to consider patient centered outcomes including comfort, communication, and survivorship, including avoiding laryngeal injury and stenosis.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-2025-104/rc

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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