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Original Article

Complications and Clinical Outcomes of Percutaneous Dilatational Tracheostomy in COVID-19 Versus Non-COVID-19 Critically Ill Patients: A Retrospective Cohort Study

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Background: Percutaneous dilatational tracheostomy (PDT) is commonly performed in critically ill patients requiring prolonged mechanical ventilation. Comparative data regarding PDT-related complications and outcomes in patients with and without COVID-19 remain limited. This study compared procedural complications and selected intensive care unit (ICU) outcomes between these groups.

Methods: This single-center retrospective cohort study included all adult patients who underwent PDT in the medical ICU of Ayatollah Rouhani Hospital between March 2019 and March 2021. Patients were classified as COVID-19 or non-COVID-19. Demographic and clinical variables, including age, sex, Glasgow Coma Scale score, APACHE II score, interval from intubation to tracheostomy, procedure duration, duration of mechanical ventilation, ICU length of stay, ventilator weaning, procedure-related complications, and ICU mortality, were compared.

Results: Seventy-nine patients were included: 37 with COVID-19 and 42 without COVID-19. COVID-19 patients were younger (66.38 ± 14.36 vs 72.71 ± 10.13 years; *P*=0.030). Mechanical ventilation was longer (36.05 ± 12.04 vs 30.62 ± 10.55 days; *P*=0.039), and successful weaning was less frequent (32.4% vs 57.1%; *P*=0.028). Complications occurred in 24.3% versus 7.1% (*P*=0.036), and ICU mortality was 62.2% versus 38.1% (*P*=0.033), respectively.

Conclusion: Critically ill patients with COVID-19 undergoing PDT had higher observed complication and ICU mortality rates, longer mechanical ventilation, and lower weaning success. Larger, adequately adjusted multicenter studies are needed to confirm whether these differences are independently associated with COVID-19.

Keywords: COVID-19; percutaneous dilatational tracheostomy; critically ill patients; mechanical ventilation; complications; mortality

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Introduction

Coronavirus (COVID 19) was first reported in Wuhan, China in 2019. The virus spread rapidly, infecting millions of people and killing thousands around the world. According to initial reports, at least 10% of patients with COVID-19 require ICU admission. About 5% of patients have severe respiratory involvement and 3% of patients require long-term invasive mechanical ventilation (1-3). However, approximately a quarter of patients are hospitalized and are the most common cause of prolonged mechanical ventilation in the ICU (4,5).

Tracheostomy is a common procedure in critically ill ICU patients who require prolonged mechanical ventilation. Compared with endotracheal intubation, tracheostomy results in lower respiratory resistance, less oral and laryngeal injury, easier discharge , less need for suction, reduced likelihood of VAP, greater patient comfort, and reduced need for sedatives (6, 7) .

Some studies have recommended that tracheostomy in acute viral disease be delayed for at least 14 days to determine the patient's prognosis and also to reduce virus loading (8, 9).

According to the recommendation of the American Academy of Otolaryngology, tracheostomy in patients with COVID-19 who are positive or suspected because of the risk of spreading the virus to ICU personnel should not be performed before 2-3 weeks after intubation, and preferably after the COVID-19 test is negative(9, 10). Tracheostomy should be performed surgically and some guidelines recommend a tracheostomy after 21 days (10-12).

The American College of Chest Physicians' guidelines for tracheostomy in patients with COVID-19 include the following: tracheostomy in patients with COVID-19 with long-term mechanical ventilation is recommended, the exact time of tracheostomy is not specified, both open surgical tracheostomy (OST) or percutaneous dilatational tracheostomy (PDT) is acceptable, but still recommends that the least risk of aerosolization and contamination be posed to personnel, and that personnel be provided with maximum protection against contamination. Because the tracheostomy procedure has the highest risk of aerosolization and infection transmission, it should be performed inside the ICU and in a room with negative pressure(13) .

Evidence from a study by Murthy et al. Shows that patients with COVID 19 who had lung disease and no radiological evidence of improvement within the first 10 days developed pulmonary disease, leading to prolonged mechanical ventilation and sometimes death(14).

Chen et al. Showed that in most patients with a positive COVID test, the test remains positive for at least 2 to 3 weeks (15).

Various studies have determined the appropriate time for tracheostomy (PDT or open surgery) and its indications and complications in patients admitted to the ICU. The most common complication is bleeding (mild to severe); other complications include: wound infection, subcutaneous emphysema, pneumothorax, hypoxia during the procedure, hypotension, and airway loss (16-19).

The indications and timing of tracheostomy in patients with COVID-19 in the ICU remain unclear. There are few studies on the side effects of PDT in patients with COVID-19 (20, 21) and there are a few studies comparing the side effects of PDT in COVID 19 and non- COVID 19 patients. There is no study examining the complications of tracheostomy in COVID-19 patients and comparing them with non-COVID patients in northern of Iran.In this retrospective study, we compared the complications of PDT in patients with COVID-19 and COVID-19.

Material and Methods

Study Design and Participants

This single-center retrospective cohort study included adult patients admitted to the medical intensive care unit (ICU) of Ayatollah Rouhani Hospital, Babol, northern Iran, who underwent percutaneous dilatational tracheostomy (PDT) between March 2019 and March 2021. Patients were divided into COVID-19 and non-COVID-19 groups.

Patients aged ≥18 years who required prolonged invasive mechanical ventilation with endotracheal intubation for more than 14 days and subsequently underwent PDT were eligible for inclusion. Patients requiring emergency tracheostomy and those with anterior neck infection, thyroid enlargement, coagulation disorders, hemodynamic instability, multiple organ failure, or positive end-expiratory pressure (PEEP) >8 cmH_2O were excluded. Covid PDT Article.

Percutaneous Dilatational Tracheostomy Procedure

All PDT procedures were performed at the bedside in the ICU by the same intensivist, who had 8 years of experience in performing tracheostomy, assisted by a trained ICU nurse. A TRACOE single-dilator technique was used for all procedures.

Anticoagulant therapy was discontinued 12–24 hours before tracheostomy. During the procedure, patients received assist-control mechanical ventilation with an inspired oxygen fraction of 1.0 and were continuously monitored using electrocardiography, non-invasive blood pressure measurement, and pulse oximetry. Sedation was achieved with fentanyl and propofol, and atracurium was administered when neuromuscular blockade was considered necessary.

After sterile preparation and draping, the patient was positioned supine with the neck extended. Local anesthesia was achieved by subcutaneous infiltration of 3 mL of 2% lidocaine at the planned tracheostomy site. A 1–2 cm skin incision was made over the upper trachea. Tracheal access was obtained using a 14-gauge catheter, and correct intratracheal positioning was confirmed by aspiration of air. A guidewire was subsequently advanced into the tracheal lumen, followed by dilation using the single-dilator system. The tracheostomy tube was then inserted over the guidewire and secured in position. Covid PDT Article.

A chest radiograph was obtained after the procedure to confirm tracheostomy tube position and assess for procedure-related thoracic complications. Covid PDT Article.

Data Collection and Study Outcomes

Demographic and clinical data were retrospectively extracted from the patients' medical records. Recorded variables included age, sex, Glasgow Coma Scale (GCS) score, Acute Physiology and Chronic Health Evaluation II (APACHE II) score, interval between endotracheal intubation and PDT, procedure duration, duration of mechanical ventilation, ICU length of stay, successful ventilator weaning, and ICU outcome.

Procedure-related complications included bleeding, hypotension, hypoxemia, pneumothorax, pneumomediastinum, subcutaneous emphysema, and stoma infection. The occurrence of PDT-related complications was compared between the COVID-19 and non-COVID-19 groups. Clinical outcomes, including successful ventilator weaning, duration of mechanical ventilation, ICU length of stay, and ICU mortality, were also compared between groups. Covid PDT Article.

Statistical Analysis

Statistical analyses were performed using SPSS software, version 16.0. Continuous variables were expressed as mean ± standard deviation and compared between the two groups using the independent-samples *t* test. Categorical variables were presented as numbers and percentages and compared using the chi-square test or Fisher's exact test, as appropriate.

Receiver operating characteristic (ROC) curve analysis was performed separately in the COVID-19 and non-COVID-19 groups to evaluate the discriminative performance of the APACHE II score for ICU mortality. The area under the ROC curve (AUC) and corresponding 95% confidence interval were calculated. All statistical tests were two-sided, and a *P*value <0.05 was considered statistically significant. Covid PDT Article.

Ethical Considerations

The study protocol was approved by the Ethics Committee of Babol University of Medical Sciences (approval code: MUBABOL.REC.1394). Written informed consent for the tracheostomy procedure was obtained from the patients' legal guardians.

Results

Study Population

During the 2-year study period, from March 1, 2019, to March 1, 2021, a total of 84 patients were assessed for eligibility. Five patients were excluded according to the predefined exclusion criteria, and 79 patients were included in the final analysis. Of these, 37 patients were assigned to the COVID-19 group and 42 to the non-COVID-19 group. No patients were lost to follow-up. The study flow is presented in (Figure 1).

All patients in the COVID-19 group required prolonged mechanical ventilation because of acute respiratory failure. In the non-COVID-19 group, prolonged mechanical ventilation was required because of either acute or chronic respiratory failure.

Baseline Demographic and Clinical Characteristics

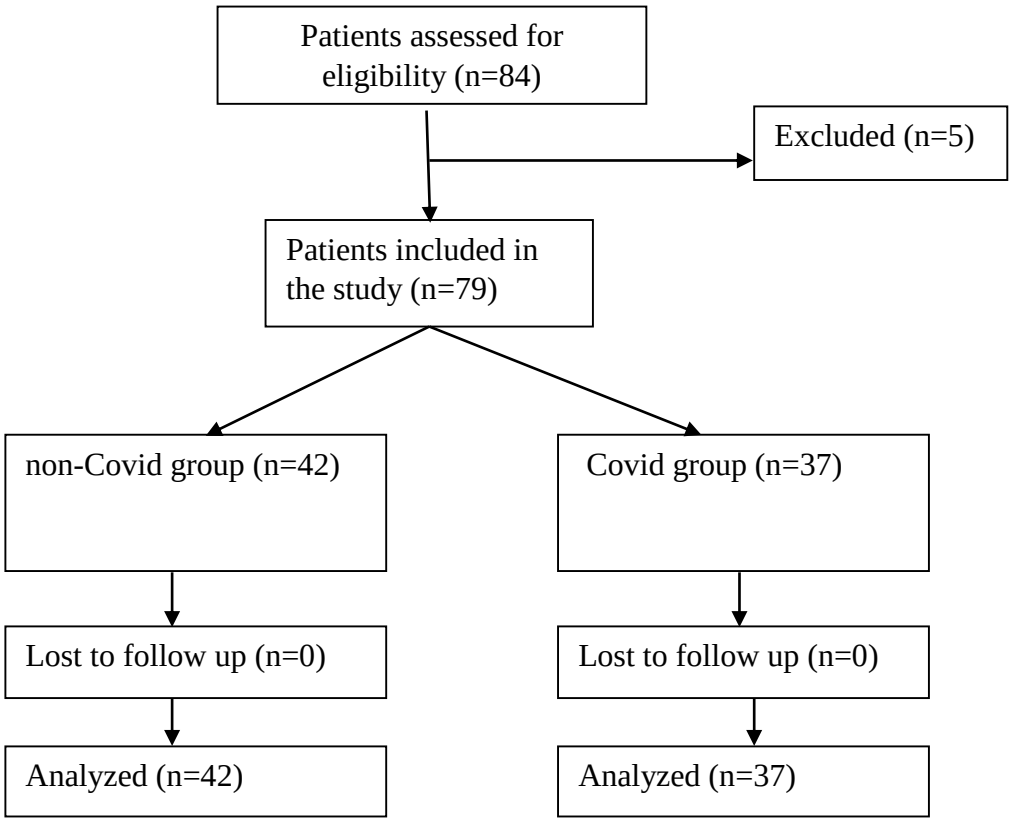


Fig 1. Flow diagram of patient selection and inclusion in the study.

The demographic and clinical characteristics of the two groups are summarized in Table 1. The mean age was significantly lower in the COVID-19 group than in the non-COVID-19 group (66.38 ± 14.36 vs 72.71 ± 10.13 years, respectively; mean difference, −6.336 years; 95% CI, −12.058 to −0.613; *P*=0.030). The mean Glasgow Coma Scale (GCS) score was 6.16 ± 1.44 in the COVID-19 group and 6.33 ± 2.29 in the non-COVID-19 group, with no significant between-group difference (mean difference, −0.171; 95% CI, −1.043 to 0.701; *P*=0.697). Male patients accounted for 24 of 37 patients (64.9%) in the COVID-19 group and 22 of 42 patients (52.4%) in the non-COVID-19 group; the difference was not statistically significant (*P*=0.262). The mean APACHE II score was 27.54 ± 3.29 in the COVID-19 group and 27.40 ± 2.95 in the non-COVID-19 group (mean difference, 0.136; 95% CI, −1.261 to 1.533; *P*=0.847). Predicted mortality based on APACHE II was also similar between groups (55.06 ±

13.07% vs 57.01 ± 11.07%, respectively; mean difference, −2.062; 95% CI, −7.535 to 3.411; *P*=0.445).

Tracheostomy Timing and Procedure Characteristics

The mean interval from endotracheal intubation to PDT was 20.22 ± 6.21 days in the COVID-19 group and 17.33 ± 8.11 days in the non-COVID-19 group. This difference did not reach statistical significance (mean difference, 2.883 days; 95% CI, −0.219 to 5.985; *P*=0.068). The mean procedure duration was 3.96 ± 1.25 minutes in patients with COVID-19 and 4.62 ± 2.38 minutes in non-COVID-19 patients. There was no statistically significant difference between groups (mean difference, −0.673 minutes; 95% CI, −1.541 to 0.195; *P*=0.127).

Table 1. Demographic and Clinical Characteristics of Patients Undergoing Percutaneous Dilatational Tracheostomy

Variable	cPDT n=37	ncPDT n=42	Mean Difference 95% CI of the Difference	P-Value
Age (year, mean (SD))	66.38±14.36	72.71±10.13	-6.336 (-12.058- (-0.613))	0.030
GCS(number, mean (SD))	6.16± 1.444	6.33± 2.292	-.171- (-1.043- 0.701)	0.697
Male (number (%))	24 (64.9)	22 (52.4)	-	0.262
APACHE II Score (mean (SD))	27.54±3.29	27.40±2.95	0.136 (-1.261-1.533)	0.847
Predicted Mortality(SD)	55.06±13.07	57.01±11.07	-2.062 (-7.535-3.411)	0.445
Duration of intubation to PDT (day, mean (SD))	20.22±6.21	17.33±8.11	-2.883 (-0.219-5.985)	0.068
Duration of mechanical ventilation (day, mean (SD))	36.05±12.04	30.62±10.55	5.435 (0.285-10.584)	0.039
ICU stay (day, mean (SD))	37.86±11.88	33.29±10.19	4.579 (-0.366-9.525)	0.069
Surgical time (minutes, mean (SD))	3.96±1.25	4.62±2.38	-0.673 (-1.541-0.195)	0.127
Weaning success rate (number (%))	12 (32.4)	24 (57.1)	-	0.028
Actual Mortality (%)	23(62.2)	16(38.1)	-	0.033

ncPDT: non- covid Percutaneous Dilatational Tracheostomy, cPDT: Covid Percutaneous Dilatational Tracheostomy, GCS: Glasgow Coma Scale,SD: Standard Deviation , CI: Confidence Interval

Mechanical Ventilation and ICU Outcomes

The duration of mechanical ventilation was significantly longer in the COVID-19 group than in the non-COVID-19 group (36.05 ± 12.04 vs 30.62 ± 10.55 days; mean difference, 5.435 days; 95% CI, 0.285–10.584; *P*=0.039). The mean ICU length of stay was 37.86 ± 11.88 days in the COVID-19 group and 33.29 ± 10.19 days in the non-COVID-19 group. Although ICU stay was numerically longer in the COVID-19 group, the difference was not statistically significant (mean difference, 4.579 days; 95% CI, −0.366 to 9.525; *P*=0.069). Successful ventilator weaning was achieved in 12 of 37 patients (32.4%) in the COVID-19 group compared with 24 of 42 patients (57.1%) in the non-COVID-19 group. Successful weaning was significantly less frequent among patients with COVID-19 (*P*=0.028). ICU mortality occurred in 23 of 37 patients (62.2%) in the COVID-19 group and in 16 of 42 patients (38.1%) in the non-COVID-19 group. ICU mortality was significantly higher in the COVID-19 group (*P*=0.033).

Procedure-Related Complications

Procedure-related complications occurred in 9 of 37 patients (24.3%) in the COVID-19 group and in 3 of 42 patients (7.1%) in the non-COVID-19 group. The overall complication rate was significantly higher in the COVID-19 group (*P*=0.036). Among patients with COVID-19, hypotension occurred in 3 patients, intraoperative bleeding in 2 patients, and subcutaneous emphysema in 4

patients. No cases of hypoxemia, postoperative bleeding, pneumomediastinum, pneumothorax, or stoma infection were reported in this group. In the non-COVID-19 group, intraoperative bleeding occurred in 2 patients and postoperative bleeding in 1 patient. No cases of hypotension, hypoxemia, pneumomediastinum, pneumothorax, subcutaneous emphysema, or stoma infection were reported. When expressed relative to the total number of patients in each group, hypotension occurred in 8.1% of COVID-19 patients, intraoperative bleeding in 5.4%, and subcutaneous emphysema in 10.8%. In the non-COVID-19 group, intraoperative bleeding occurred in 4.8% and postoperative bleeding in 2.4% of patients (Table 2 and Figure 2)

Table 2. Procedure-Related Complications of Percutaneous Dilatational Tracheostomy in COVID-19 and Non-COVID-19 Patients

Variable	cPDT (n=37) Number (%)	ncPDT (n=42) Number (%)	P-Value
Hypotension	3(33.33)	0(0)	
Hypoxemia	0(0)	0(0)	
Intraoperative bleeding	2(22.22)	2(66.66)	
Postoperative bleeding	0(0)	1(33.33)	
Pneumomediastinum	0(0)	0(0)	0.036*
Pneumothorax	0(0)	0(0)	
Subcutaneus emphysema	4(44.44)	0(0)	
Stoma infection	0(0)	0(0)	
Total rate of complications	9(100.0)	3(100.0)	

ncPDT:Non- covid Percutaneous Dilatational Tracheostomy, cPDT: Covid Percutaneous Dilatational Tracheostomy

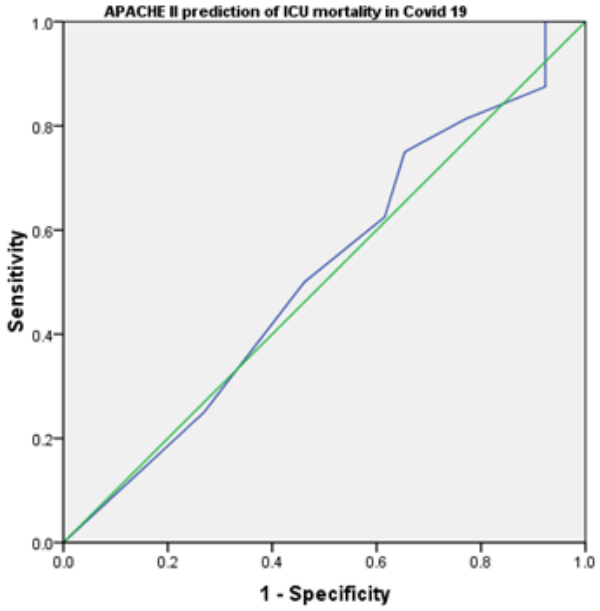


Fig. 2. The ROC curve diagram showing the relationship between specificity and sensitivity of APACHE II and ICU mortality, the area under the curve, the predictor of APACHE II and ICU mortality was 0.516 (95% Confidence Interval = 0.335-0.696) in Covid patients

Predictive Performance of APACHE II for ICU Mortality

Receiver operating characteristic (ROC) curve analysis was performed separately in the COVID-19 and non-COVID-19 groups to evaluate the discriminative ability of the APACHE II score for ICU mortality. In the COVID-19 group, the area under the ROC curve was

0.516 (95% CI, 0.335–0.696), indicating poor discrimination of APACHE II for ICU mortality in this subgroup. In the non-COVID-19 group, the AUC was 0.626 (95% CI, 0.438–0.819). Although numerically higher than that observed in the COVID-19 group, the confidence interval included 0.50, indicating limited discriminative performance for mortality prediction in this subgroup (Figure 3).

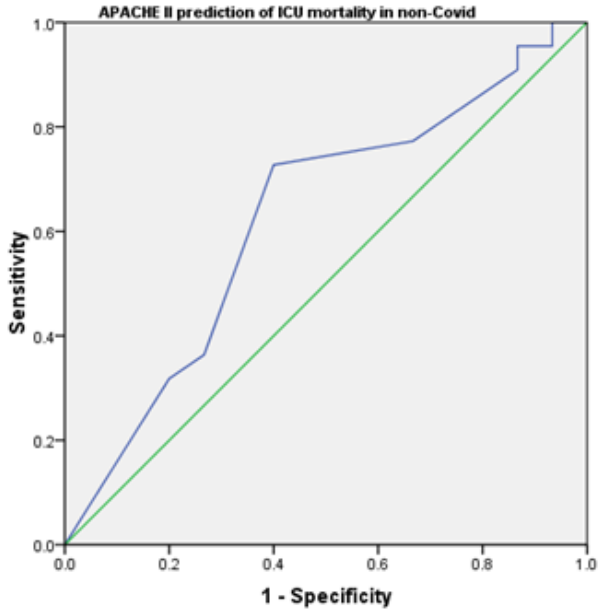


Fig 3. The ROC curve diagram showing the relationship between specificity and sensitivity of APACHE II and ICU mortality, the area under the curve, the predictor of APACHE II and ICU mortality was 0.626 (95% Confidence Interval = 0.438-0.819) in non-Covid patients.

Discussion

The aim of this study was to compare the complications of PDT in COVID and non- COVID patients in the medical ICU. In our study, 37 COVID 19 patients and 42 non- COVID patients underwent PDT.

Complications were 9 (24.3%) in the COVID 19 group and 3 patients (7.1%) in the non - Covid group. There were 3 cases of hypotension in the COVID group, which may be due to a severe response to propofol administration. Hypotension responded to 250 cc bolus of normal saline. The most important complication in the COVID 19 group was subcutaneous emphysema in 4 patients, one after 48 hours and the other three patients after one week, although 3 patients had mild Pneumomediastinum and mild emphysema before tracheostomy. It seems that tracheostomy in patients who already have Pneumomediastinum or emphysema will aggravate emphysema after PDT. Although the mean age of non-COVID patients in this study was higher than that of COVID-19 patients, other indicators of disease severity were greater in the COVID-19 group-while severity based on APACHE scores was comparable; consequently, the increased rate of tracheostomy complications appears to be attributable to the direct effects of the COVID-19 virus on the airway, particularly the trachea.

Marta Mesalles-Ruiz et al. conducted a retrospective, single-center study to compare the outcome of tracheostomy in COVID-19 patients with non-COVID-19 patients. Their study results showed a higher mortality rate in COVID patients (50% vs. 27.3% in non-COVID-19 patients). The tracheostomy procedure did not affect the morbidity and mortality rates (1).

In a study, Boujaoude et al. examined the safety of PDT in 32 Covid patients with acute respiratory failure

under mechanical ventilation. The mean onset of intubation to PDT was 22 days and the mean hospital stay was 40 days, 18 patients (56%) were liberated from the ventilator, 5 patients (16%) remained ventilator dependent, and 9 patients (28%) died (2).

In our study, mortality was similar to that of Marta Mesalles-Ruiz et al.The mean time to start intubation to PDT in the Covid group was 20 day. The mean hospital stay in the ICU was 36 days, which was not significantly different from this study. The success rate of ventilator weaning in our study was 32%, which was much lower than that of Boujaoude et al. It seems that in our ICU, most patients were treated with non-invasive.

In a retrospective, multicenter study, Yun et al. examined the outcome of elective tracheostomy in 80 Covid 19 patients admitted to the ICU. The mean time from endotracheal intubation to tracheostomy was 17.5 days. The most common complication was bleeding in 14 patients (17.5%) and severe bleeding (5%) in 4 cases, 31 patients (38.8%) had successful weaning within 60 days after intubation. 17 patients (21.2%) were discharged from the ICU and 43 patients (53.8%) died. Mortality was 73.7% (22 patients) in the early group and 21 patiens (42%) in the late group. They concluded that tracheostomy in the ICU has few complications and that tracheostomy earlier than 14 days has more complications(6).

The rate of complications and mortality of Yun's study was slightly higher than our study, although the rate of bleeding was higher, but in our study in the Covid group, subcutaneous emphysema was the main complication.

Part of this difference in complication may be due to differences in the experience of the intensivist and genetic differences in patients. However, in our study, no severe bleeding was observed in the two groups.

Although Apache Score seems to be suitable for predicting mortality in ICU patients, but according to the RUC Curve in our study, it is not suitable for predicting mortality in patients after tracheostomy, especially in Covid 19 patients.

Atiporn Kittipattana et al. compared tracheostomy outcomes in COVID-19 patients with non-COVID-19 patients in a retrospective and prospective cohort study. Outcomes included ventilator weaning, length of hospital stay, and mortality.

Their study results showed that the mortality rate in COVID-19 patients was lower than in non-COVID-19 patients (29.3% vs. 40.4%), although the ventilator weaning rate was similar. Although COVID-19 patients had longer hospital stays, there was no significant difference in postoperative complications(12).

Botti et al. compared the complications, risks, and benefits of PDT with surgical tracheostomy in a retrospective study of 47 patients with acute respiratory distress syndrome. The study was conducted at the Referral Center. Seventeen patients underwent PDT and 30 patients underwent open surgical tracheostomy (OST).

Twenty-six patients (55.3%) had postoperative complications (local infection, bleeding, and subcutaneous emphysema), and there was no difference between the two groups in terms of complications. The authors conclude that OST may be preferred if the person performing the tracheostomy is an ENT specialist because people performing PDTs may be exposed to the aerosol produced. The authors of the article recommend performing OST or PDT according to the personal experience of the person performing the procedure(22).

Our study was not similar to the study by Atiporn Kittipattana et al. in terms of mortality, perhaps due to genetic differences and sample size but similar to the study of Botti et al was done in the referral center. The rate of complications in the study of Botti et al. was much higher than in our study and other studies, although it may be due to differences in the estimated amount of bleeding. As in our study in the Covid group, subcutaneous emphysema was part of the complication, but in our study there was no complication of local infection.

In a study, Rovira et al. compared Covid 19 patients who underwent tracheostomy with PDT and open surgery. The study was performed as a retrospective multicenter

observational cohort on 201 patients with Covid 19 pneumonia. 124 patients underwent PDT and 77 patients underwent surgical tracheostomy. The complication rate was 16.9% in the PDT group and 22.1% in the surgical tracheostomy group. There was no difference between the two groups in terms of postoperative mortality (13.7% in the PDT group and 15.6% in the surgical tracheostomy group). The mean Apache score was 14 in the PDT group and 15 in the surgical tracheostomy group. They concluded that the tracheostomy method has no effect on complications and mortality(10).

Çalışkan, Gülbahar et al. conducted a retrospective study comparing tracheostomy messages in COVID-19 patients with non-COVID-19 patients. Outcomes included ventilator weaning, length of ICU and hospital stay, and mortality. Their study results showed that mortality rates were similar in COVID-19 patients and non-COVID-19 patients. Ventilator weaning rates, length of hospital stay, and postoperative complications were not different.(16).

In Rovira et al study the complication rate was similar to our study, but the mortality rate was lower than our study because the Apache Score rate was higher in our study. In Çalışkan, Gülbahar et al. study the mortality rate was the same in COVID-19 patients as in non-COVID-19 patients.

Conclusion

Our study showed that the rate of complications was higher in the Covid group than in the non-Covid group. Complications in the COVID-19 group included hypotension and emphysema. In patients with COVID-19 due to decreased albumin, increased responded to sedative drugs during the procedure, but in the non-COVID-19 group, bleeding was the most common complication and was mild and did not require special action. In the Covid group, one patient had major bleeding 2 h after the procedure that improved with the intervention. In both groups, no bleeding complications required transfusion.

One of the strengths of the study was that one person performed PDT in both groups for a long time (8 years of experience in a medical ICU with 16 beds), so comparing the complications in the two groups seems more logical.

Study Limitations

Limitations of this study include the lack of matching between groups regarding age, gender, and underlying comorbidities; the short patient follow-up period; and the subgroup analysis conducted to examine the association between specific conditions and surgical complications.

Recommendations

Although PDT is safe in patients with COVID-19, we recommend a study aimed at comparing the complications of surgical tracheostomy with PDT.

Declaration

Availability of data and materials

available from the corresponding author on reasonable request and subject to institutional approval.

Conflict of Interest

The authors declare that they have no funding.

Funding

The authors declare no funding.

Authors' contribution

All authors contributed to this project and article equally. All authors approved the final manuscript

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Ethics approval and consent to participate

The study protocol was approved by the Ethics Committee of Babol University of Medical Sciences (approval code: MUBABOL.REC.1394).

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