

Article

Outcomes and timing of bedside percutaneous tracheostomy of COVID-19 patients over a year in Intensive Care Unit

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Abstract: (1) Background: Benefits and timing of percutaneous dilatational tracheostomy (PDT) in Intensive Care Unit (ICU) COVID-19 patients are still controversial. PDT is considered a high risk procedure for transmission of SARS CoV-2 to health care workers (HCWs). The present study analyzed optimal timing of PDT, clinical outcomes of patients undergoing PDT and safety of HCWs performing PDT. (2) Methods: 133 COVID-19 patients underwent PDT in our ICU from April 1, 2020 to March 31, 2021, 23 patients were excluded and 110 patients were enrolled. A trained medical team was dedicated to the PDT procedure. Demographic, clinical history and outcome data were collected. Patients who underwent PDT were stratified into two groups: early group, PDT \leq 12 days from orotracheal-intubation (OTI) and late group, $>$ 12 days from OTI; HCW surveillance program was performed. (3) Results: Early group included 57 patients and late group included 53 patients. Early group patients showed shorter ICU length of stay and fewer days of mechanical ventilation than the late group ($p < 0.001$). At day 7 after tracheostomy, early group patients required fewer intravenous anesthetic drugs and experienced an improvement of ventilation parameters, PaO₂/FiO₂-Ratio, PEEP and FiO₂ ($p < 0.001$). No difference in case fatality ratio between the two groups was reported. No SARS-CoV-2 infection was reported in HCWs performing PDT. (4) Conclusions: PDT was safe and effective for COVID-19 patients, since it improved respiratory support parameters, reduced ICU length of stay and duration of mechanical ventilation, and optimized the weaning process. The procedure was safe for all HCWs involved in the dedicated medical team. The development of standardized early PDT protocols should be implemented and PDT procedure could be considered as first line approach in ICU COVID-19 requiring prolonged mechanical ventilation.

Keywords: Intensive care unit; percutaneous tracheostomy; COVID-19; ICU stay; early tracheostomy; late tracheostomy; ICU length of stay; health care workers; mechanical ventilation.

1. Introduction

In December 2019 a novel viral agent named Severe Acute Respiratory Syndrome Coronavirus – 2 (SARS-CoV-2) was identified as the etiologic agent of the CoronaVirus Disease-19 (COVID-19) outbreak occurring in Wuhan, China [1].

SARS-CoV-2 is transmitted from person-to-person via droplets, contact and, also from aerosolized particles [2].

Patients with progressive disease should be monitored closely for worsening respiratory status: they typically require supplemental oxygen to maintain an oxygen saturation (SpO₂) goal $\geq 94\%$ [3].

Orotracheal intubation (OTI) and mechanical ventilation can be used in more severe patients affected by acute respiratory distress syndrome (ARDS) in Intensive Care Unit (ICU) [3].

In ICU, prolonged mechanical ventilation and weaning failure from ventilator support are the most frequent criteria for indications of tracheostomy [4].

Tracheostomy has many beneficial effects such as improving pulmonary mechanics, reducing laryngeal or tracheal nociceptive stimuli, facilitates the weaning process, and shorter requirement of sedatives, neuromuscular blocker agents, analgesic and inotropic therapy. It also reduces the dead space and airway resistance, as well as helping to maintain an easier oral hygiene, promotes oral nutrition and improves communication [5,6].

Decannulation in tracheostomized patient is the final step towards liberation from mechanical ventilation and should be attempted as soon as possible [7].

Tracheostomy procedure is associated with an increased risk of aerosol generation, and it is recommended to be performed in an airborne isolation room, with all involved healthcare workers (HCWs) wearing full adequate personal protective equipment (PPE) [8].

Recommendations on both safety and timing protocols in tracheostomy in COVID-19 patients have been published but there are still controversial issues [9].

The aim of this study is to investigate the following outcomes in COVID-19 ICU patients:

- Benefits of percutaneous dilatational tracheostomy (PDT) on respiratory functions and weaning process
- Timing of tracheostomy and its association with ICU length of stay and mechanical ventilation.
- Risk of SARS-CoV-2 infection in HCWs during PDT procedure.

2. Materials and Methods

2.1. Study Design and Participants

This is a retrospective observational study conducted at the National Institute for Infectious Disease (INMI) “Lazzaro Spallanzani” in Rome, Italy which is an over 200-bed hospital for infectious disease with a 55-bed ICU. We included in this study adult patients with respiratory failure due to COVID-19 hospitalized in our Intensive Care Unit (ICU) from 1st April 2020 to 31st March 2021.

During this period 2,480 patients with virologically confirmed COVID-19 by nasal pharyngeal swab for reverse transcriptase polymerase chain reaction (rtPCR) assay, were hospitalized to our hospital, of which 451 were admitted in the ICU.

We performed 133 percutaneous dilatation tracheostomies (PDTs) at bedside patient’s ICU room, with Frova Percutwist technique with rotational dilatation of the tracheal stoma through the use of hydrophilic screw (Frova Percutwist® (RDT) (2002) [10], or Ciaglia Blue Rhino by using of a single-beveled curved hydrophylic dilatorb [11], both techniques were acted under video-assisted fibrobronchoscopy.

Inclusion criteria for tracheostomy were acute respiratory failure and the need for prolonged mechanical ventilation.

Exclusion criteria for tracheostomy were infection at the site of tracheostomy, uncontrolled coagulopathy, altered neck anatomy, marked obesity, and multiorgan failure (MOF) [12].

The tracheostomy is performed by a medical team of highly trained HCWs including 16 anesthesiologists and 8 nurses. Each individual PDT procedure was performed by a single team unit including two anesthesiologists and two nurses as it follows: 1) the first anesthesiologist performed the fibrobronchoscopy; 2) the second anesthesiologist performed the tracheostomy; 3) two nurses managed the ventilator, the endotracheal tube, and administered medications for sedation and for curarisation.

The performed PDT procedure can be briefly described in the following phases: the bronchoscope was inserted through the mount catheter without suspending mechanical ventilation in order to avoid hypoxia to the patient, and the Fraction of inspired Oxygen (FiO_2) was set at 100% during the procedure. Once the space between the 1st and 2nd or between the 2nd and 3rd tracheal rings was identified by transillumination under direct vision via video-bronchoscopy, the bronchoscopist operator retracted the endotracheal tube (ETT) up close to the first tracheal ring, maintaining a good view of the tracheal lumen. The second operator in sterile field and with aseptic technique proceeded with the spy-needle insertion in the tracheal space identified, and through the Seldinger wire technique performed the dilation of the stoma and the insertion of the tracheal cannula, without stopping mechanical ventilation. Once inserted, the tracheal cannula was cuffed and connected to the mechanical ventilator while the endotracheal tube was removed, this switch lasted a few seconds to avoid the patient's hypoxia from apnea.

According to international guidelines and institutional policies regarding the HCW protection [2], the team wore during the procedures full personal protection equipment (PPE) that included N95 mask/FFP3 mask, surgical mask, headgear, hood, eye protection, alternatively air purifying respirator (PAPR), long sleeved, water-repellent shirts and double gloves upon entering into an airborne isolation room. The room is a dedicated negative pressure room with at least 6-air changes per hour.

Patient who underwent bedside PDT in ICU were stratified in two groups:

- 1) Early group – included the patients who underwent PDT within the first 12 days of orotracheal intubation (OTI).
- 2) Late group - included patients in which the procedure was performed after 12 days from OTI.

2.2. Data Collection

Data collection included age, gender, BMI (body mass index), SOFA score (sequential organ failure assessment) and APACHE II score (acute physiology and chronic health evaluation) at ICU admission, days of hospitalization pre-ICU admission, previous hospitalization within 6 months, previous surgical procedures in last month, comorbidities: arterial hypertension, other cardiac disease, diabetes, kidney disease (stage 3-5 of CKD), moderate to severe liver disease, chronic obstructive pulmonary disease or bronchial asthma, solid neoplasia or hematological malignancy during the last 5 years, chronic neurological disorders, autoimmune diseases, obesity and other diseases.

During the ICU admission we recorded also the date of endotracheal intubation, tracheostomy, weaning and decannulation, and also ICU outcome (discharge or exitus).

Ventilatory parameters data were recorded at the day of orotracheal intubation (OTI), percutaneous tracheostomy (PDT) and seven days after the PDT, which included respiratory exchange ratio (PaO_2/FiO_2 Ratio), the fraction of inspired oxygen (FiO_2) and positive end-expiratory pressure (PEEP).

Data collection on medications administered by intravenous continuous infusion included (c.i.v.): doses of sedatives, opioids as analgesics, and inotropic agents.

Complications of tracheostomy were assessed during the procedure and throughout the hospital stay.

All tracheostomized patients received pulmonary and physical rehabilitation starting from the beginning of weaning from mechanical ventilation.

All involved HCWs periodically undergo internal training courses to ensure effective infection prevention and control (IPC) measures, identifying logistical and technical challenges in intensive care unit, considering the possibility of airborne transmission especially through aerosol-generating procedures such as airway suctioning, nebulizer treatment, non-invasive ventilation (NIV), bronchoscopy, intubation and tracheotomy.

Active surveillance and early identification of suspected cases of COVID-19 among HCWs has been established.

Serological SARS CoV-2 test and nasopharyngeal swab test for molecular detection of SARS CoV-2 (rtPCR) were performed for surveillance to all HCWs 14 days after performing the PDT, and at least once every three weeks unless they had symptoms or had been in direct contact with confirmed SARS-CoV-2 positive.

2.3. Statistical Analysis

Quantitative variables are expressed as median (interquartile range, IQR), mean (\pm standard deviation, SD) and 95% confidence interval (95% CI). The means of quantitative variables were compared with the Student T-test and as well used in repeated measure ANOVA over timeline. Nominal data are expressed as N (percentages, %).

Adjusted estimates of ICU length of stay and total days on mechanical ventilation have been obtained for both Early and Late PDT groups thanks to multivariable linear regression models carried out by STATA 15 statistical package (Stata Corp LP, College Station, TX – USA).

Statistical confounding factors selection has been performed through backward elimination, removing from the model all non-significant confounders (p -value >0.05).

At the end, two final regression models were presented: the one involving ICU length of stay as dependent variable concerns Early/Late group, neurological disorders, hypertension, and age categories (<60; 60-70; >70 years) as independent variables; on the other hand, the model involving total days on mechanical ventilation as dependent variable concerns of course Early/Late group, hypertension, diabetes as well as age categories (<60; 60-70; >70 years) as independent variables. Eventually, independent T-tests between Early and Late PDT groups, of both ICU length of stay and total days on mechanical ventilation estimates have been performed.

3. Results

3.1. Outcome at 7 days after PDT in COVID-19 ICU patients

During the study period, 2480 COVID-19 patients were hospitalized in our center; 451 of them, (18.2%) were admitted in our ICU, of these, 133 patients (29.5%) underwent bedside PDT.

We excluded from the study 23 patients: 10 patients died within seven days of tracheostomy; 8 patients transferred to other hospitals: four patients transferred to an extracorporeal membrane oxygenation center, three patients to a coronary care unit and one patient to a surgical care unit; five patients are still admitted at the end of the study. Finally, we studied 110 COVID-19 ICU patients (Figure 1).

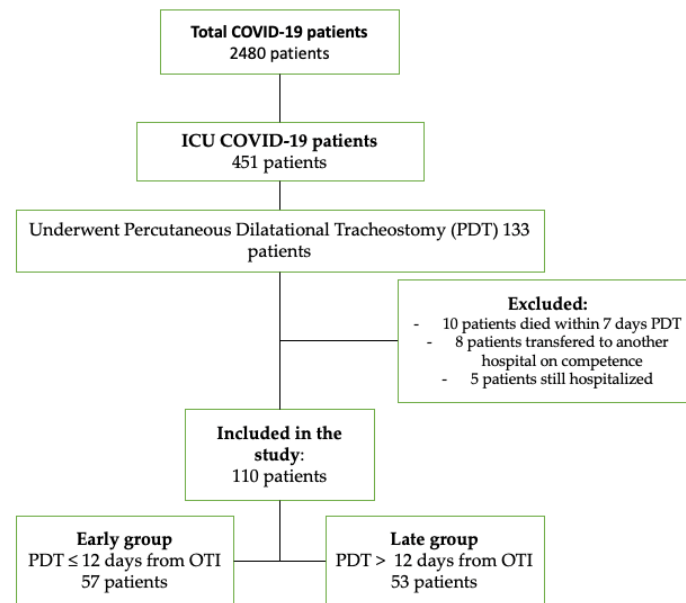


Figure 1. Flowchart of study selection; Abbreviations: ICU, intensive care unit; PDT, percutaneous dilatational tracheostomy.

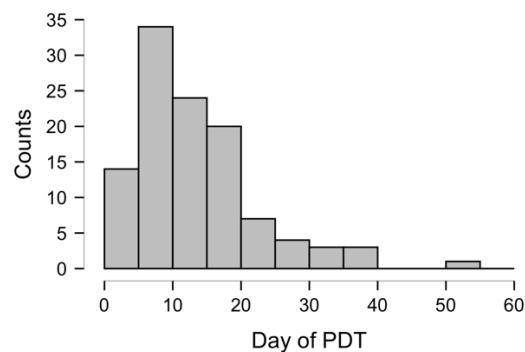


Figure 2. Frequency distribution of tracheostomy (PDT) from orotracheal intubation (OTI).

The median age was 68 years (IQR, 60-74), 64.5% were male, the median body mass index (BMI) was 27.8 (IQR, 25-31). Comorbidities with the highest prevalence were arterial hypertension (69%), obesity (47.3%), diabetes (24.5%) and other heart diseases (21.8%), Table 1.

Table 1. The baseline characteristics of ICU COVID-19 patients underwent PDT.

	Total (n=110)	Early group (n=57)	Late group (n=53)
Age, median (IQR)	68 (60-74)	70 (64-76)	64 (59-72)
Male, n (%)	71 (64.5%)	38 (67%)	33 (62.2%)
Female, n (%)	39 (35.4%)	19 (33%)	20 (37.7%)
BMI, kg/m ² , median (IQR)	27.8 (25-31)	27.7 (25-31)	29 (26-32)
SOFA score, median (IQR)	5 (3-7)	5 (4-7)	6 (3-8)
APACHE II score, median (IQR)	12 (10-17)	12 (10-17)	13 (9-18)
Comorbidities, n (%)			
Arterial hypertension	76 (69.1%)	43 (75.4%)	33 (62.2%)
Other Cardiopathies	24 (21.8%)	15 (26.3%)	9 (16.9%)
Diabetes	27 (24.5%)	15 (26.3%)	12 (22.6%)
Obesity	52 (47.3%)	24 (42.1%)	28 (52.8%)
Kidney disease (stage 3-5 of CKD)	8 (7.2%)	5 (8.7%)	3 (5.7%)

Moderate to severe chronic liver disease	1 (0.9%)	1 (1.7%)	0 (0.0%)
COPD/Bronchial asthma	20 (18.2%)	11 (19.3%)	9 (16.9%)
Previous neoplasia (solid neoplasia or hematological malignancy in the last 5 years)	12 (10.9%)	6 (10.5%)	6 (11.3%)
Previous surgery in last month	4 (3.6%)	2 (3.5%)	2 (3.7%)
Previous hospitalization last six months	8 (7.2%)	3 (5.2%)	5 (9.4%)
Chronic neurological disorders	20 (18.2%)	10 (17.5%)	10 (18.8%)
Autoimmune diseases	15 (13.6%)	6 (10.5%)	9 (16.9%)
Other chronic diseases	32 (29.0%)	23 (40.3%)	9 (16.9%)

Abbreviations: ICU, intensive care unit; BMI, body mass index; SOFA score, sequential organ failure assessment and APACHE II score, acute physiologic and chronic health evaluation at ICU admission; Obesity is defined as BMI > 30 kg/m²; CKD, stages of chronic kidney disease; COPD, chronic obstructive pulmonary disease; IQR, interquartile range.

The time of pre-ICU hospitalization of the cohort had a mean of 6 days (range 4.3-7.5 days, 95% CI), PDT was performed on a median of 12 days, mean 14 days (± 8.9 , SD) from OTI (Figure 2). We stratified patients between early and late tracheostomy, by the median interval time of 12 days between OTI and PDT.

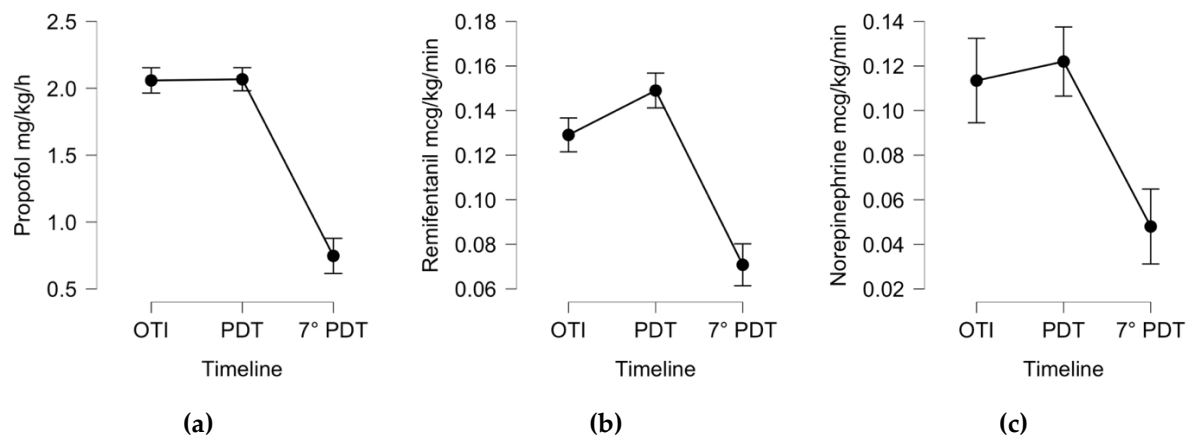


Figure 3. Descriptive plots, means and 95% confidence interval of 110 ICU COVID-19 patients performed PDT using repeated measures ANOVA for the following variables: Propofol (a), Remifentanyl (b), and Norepinephrine (c) administered by intravenous continuous infusion during the ICU stay. **Legend:** OTI, the day of orotracheal intubation; PDT, the day of percutaneous tracheostomy; 7° PDT, day 7 from tracheostomy.

A significant temporal association between PDT insertion and use of sedative, analgesic and inotropic drugs is reported: propofol, remifentanyl and norepinephrine were all significantly reduced at day 7 from PDT ($p < 0.001$ for all parameters, see Table 2 and Figure 3).

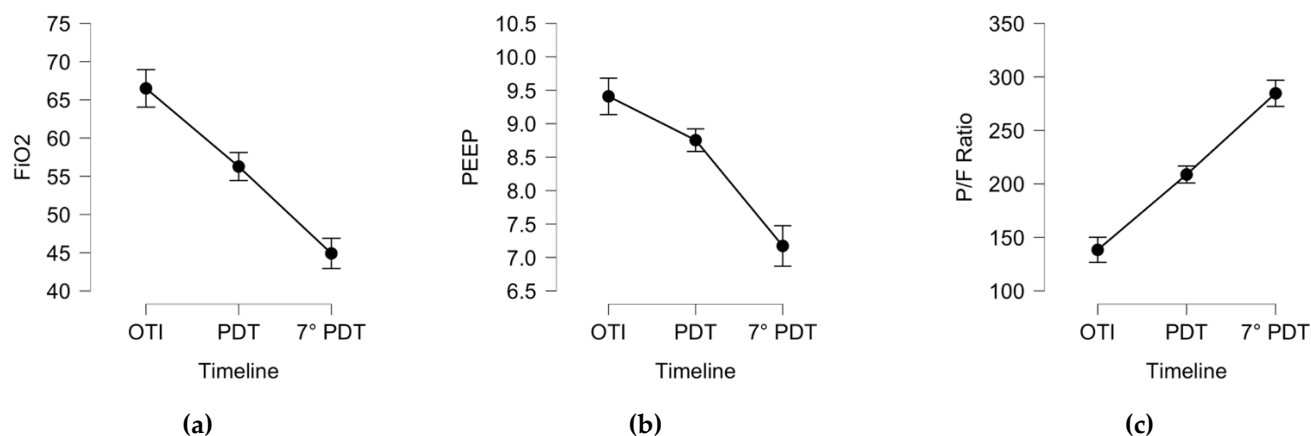


Figure 4. Descriptive plots, means and 95% confidence interval of 110 ICU COVID-19 patients performed PDT using measures ANOVA for the ventilatory variables: FiO₂ (%), Fraction of inspired Oxygen (a); PEEP (cmH₂O), Positive End-Expiratory Pressure (b); P/F Ratio (mmHg), respiratory exchange ratio (c). **Legend:** OTI, the day of orotracheal intubation; PDT, the day of percutaneous tracheostomy; 7° PDT, day 7 from tracheostomy.

Furthermore, a significant association between PDT insertion and improvement of common ventilation parameters as PaO₂/FiO₂ Ratio, PEEP and FiO₂ at day 7 from PDT is reported ($p < 0.001$ for all parameters, see Table 2 and Figure 4).

Table 2. Characteristics of laboratory, ventilation and infusion therapy parameters.

Total (N=110), mean ± SD	Day of OTI in ICU	Day of PDT	Day 7 after PDT	p-value ^a
<i>Sedative, analgesic, and inotropic therapy by intravenous continuous infusion</i>				
Propofol, mg/kg/h	2.0 (±0.39)	2.01 (±0.53)	0.7 (±0.87)	$p < 0.001$
Remifentanyl, mcg/kg/min	0.13 (±0.03)	0.15 (±0.05)	0.07 (±0.07)	$p < 0.001$
Norepinephrine, mcg/kg/min	0.11 (±0.12)	0.12 (±0.13)	0.05 (±0.09)	$p < 0.001$
<i>Ventilatory parameters and respiratory exchange ratio</i>				
P/F Ratio, mmHg	138 (±43)	208 (±64)	243 (±95)	$p < 0.001$
FiO ₂ , %	66.5 (±15)	56 (±14)	45 (±14)	$p < 0.001$
PEEP, cmH ₂ O	9.4 (±1.9)	8.7 (±1.5)	7.1 (±1.6)	$p < 0.001$

Table I. Abbreviations: ICU, intensive care unit; PDT, percutaneous dilatational tracheostomy; FiO₂, Fraction of inspired Oxygen; PEEP, Positive End-Expiration Pressure; P/F Ratio, respiratory exchange ratio; ^a Paired Samples T-Test of parameters of ICU COVID-19 patients between the day of the PDT and seven days after PDT.

Table 3 summarizes the clinical progress of COVID-19 patients during ICU stay. The mean time on mechanical ventilation was 36 days (33-39 days, 95% CI). The mean length of stay in ICU was 45 days (41-49 days, 95% CI). The mean time on tracheostomy from its insertion to decannulation was 28.8 days (25-22 days, 95% CI).

The mean time of spontaneous breathing from starting weaning to decannulation was 6.6 days (range 5.6-7.6 days, 95% CI).

Table 3. The clinical characteristics during ICU stay.

	Total (n=110) mean \pm SD	Early group (n=57), mean \pm SD	Late group (n=53), mean \pm SD	p-value ^a	p-value ^b adjusted
Pre-ICU hospitalization, days	5.9 (\pm 8.2)	5.7 (\pm 6.7)	6.1 (\pm 9.7)	0.777	
Day of PDT, days from OTI to PDT	14.0 (\pm 8.9)	7.7 (\pm 2.6)	20.7 (\pm 8.3)	<0.001	
Mechanical ventilation, days	36.0 (\pm 15.5)				
Mean		31.5 (\pm 13.6)	40.7 (\pm 16.2)	0.002	
Adjusted mean ^b		31.6 (\pm 3.9) ^b	40.8 (\pm 4.2) ^b		<0.001
Spontaneous breathing from weaning to decannulation, days	6.6 (\pm 5.4)	5.7 (\pm 4.8)	7.4 (\pm 6.0)	0.1	
Days on tracheostomy, from PDT to decannulation	28.8 (\pm 16.2)	29.6 (\pm 15.3)	27.5 (\pm 16.3)	0.618	
ICU length of stay, days	44.6 (\pm 18.1)				
Mean		39.4 (\pm 15.7)	51.1 (\pm 18.9)	0.002	
Adjusted mean ^b		39.5 (\pm 5.6) ^b	50.2 (\pm 5.7) ^b		<0.001
Outcome					
ICU discharged, patients (%)	78 (71.0%)	38 (66.6%)	40 (75.4%)		
ICU mortality, patients (%)	32 (29.0%)	19 (33.3%)	13 (24.5%)	0.45	

Abbreviations: ICU, intensive care unit; OTI, orotracheal intubation; PDT, percutaneous dilatational tracheostomy; ^a Independent samples T-test comparing the means between early and late group; ^b Adjusted for confounding factors between the two groups using multivariate linear regression models.

The case fatality rate (CFR) during ICU stay was 29% (32 patients) due to: severe respiratory failure (8 patients, 25%), septic shock (12 patients, 37%) [13], multiple organ failure (MOF) (9 patients, 28%), pulmonary embolism (2 patients, 6%) and cerebral venous thrombosis (1 patient, 3%).

1.2. PDT complications

The PDT procedure lasted from 10 to 20 minutes. No early complication during the insertion of the tracheostomy was observed. Peri-procedural and post-procedural complications were assessed during ICU stay and until hospital discharge. At day 7 from PDT, subcutaneous emphysema limited to the neck was present in 3 patients (2%), and spontaneously resolved minor bleeding at the stoma site was present in 23 patients (20%). All patients underwent motor and respiratory physiotherapy during their stay in the ICU after weaning and continued even after discharge.

At day 60 from PDT, three patients were still under tracheostomy but in spontaneous breathing and followed by an accomplishment decannulation.

Twenty-three patients were discharged to the acute care unit with the tracheostomy cannula still in place, and subsequently all were successfully decannulated. At 90 days from PDT, all survived patients (78 patients, 71%) were decannulated and no complication was observed.

After decannulation, 11 patients (14%) had difficulty in swallowing and underwent logopedic therapy with full recovery at 1 month from decannulation.

1.3. Early versus Late PDT

Fifty-seven patients underwent early PDT within 12 days from orotracheal intubation (OTI), with a mean of 7.7 days (7.0-8.4 days, 95% CI) (Table 3 and Figure 5).

Fifty-three patients underwent late PDT (> 12 days after OTI), with a mean of 21 days (18.5-23 days, 95% CI).

Regarding the ICU length of stay (LOS), the mean ICU LOS of 39.5 days (95%CI, 38-42 days), was significantly lower than the mean LOS in the late group, 50.2 days (95%CI, 48-52 days), ($p < 0.001$).

As expected, similar data were obtained on the time on mechanical ventilation (MV) between the two groups: patients in the early group were exposed to MV for a mean of 31.6 days (95% CI, 30-33 days), significantly lower than the patients in late group, 40.8 days (95% CI, 39-42 days), ($p < 0.001$).

The boxplots of ICU LOS and total days on MV are reported in Figure 5.

There was no statistically significant difference in the mortality between early (19 patients, 33.3%) and late group (13 patients, 24.5%) ($p=0.45$).

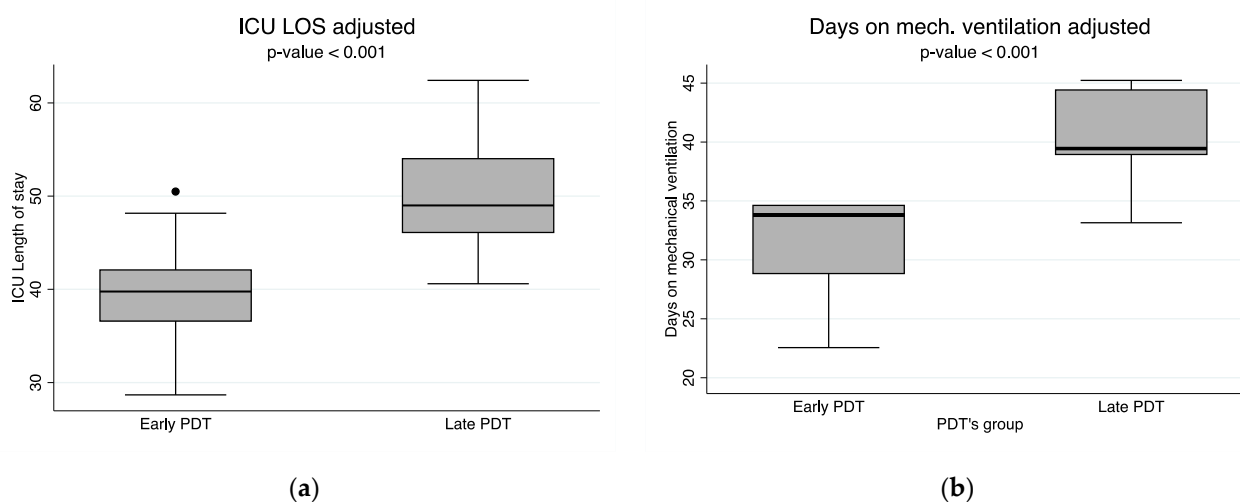


Figure 5. Boxplot of ICU length of stay (a) and days of mechanical ventilation (b) estimates, adjusted for confounding factors between the two groups (Early group and Late group). Legend: PDT: percutaneous dilatational tracheostomy; Early group: the group of patients who submitted to PDT within the first 12 days from orotracheal intubation; Late group: the group of patients who submitted to PDT after 12 days from orotracheal intubation.

3.4 SARS CoV-2 transmission in HCWs who performed PDT

No team member performing PDT procedure developed symptoms related to SARS-CoV-2 infection, as well as all serial serology test to detect IgG and IgM antibodies against SARS-CoV-2 were persistently negative. Additionally, nasopharyngeal swabs for molecular detection of SARS-CoV-2 were always negative at day 14 after the PDT procedure, periodically every three weeks, and in all cases of suspected symptoms or of close contact with SARS-CoV-2 positive cases. In January 2021, all ICU HCWs were vaccinated early during the vaccination campaign promoted by the Italian Ministry of Health.

4. Discussion

The PDT procedure is safe for both health care professionals and COVID-19 patients. The early PDT procedure has a beneficial impact for COVID ICU patients in terms of ICU LOS and time on MV in order to both improve pulmonary performance and reduce weaning process.

During mechanical ventilation with the endotracheal tube (ETT) in ICU, all patients were sedated with drugs in continuous intravenous infusion, by using propofol and remifentanyl, and in case of unstable hemodynamic situation, by using norepinephrine. In 10 cases, continuously infused midazolam was used as an additional sedative agent for less than 48 hours. Likewise, curarisation was used for less than 48 hr. At day 7 after PDT procedure, a significantly decreased doses of continuous intravenous of sedation and inotropic therapy was reported (Figure 1 and Table I).

One additional clinical benefit of PDT compared to ETT is the lack of pharyngeal and laryngeal stimuli due to the ETT, as well as the reduction of the tracheal stimuli. This allows a gradual reduction of continuously infused sedative agent, and of the dosages of the inotropic agent used to counteract arterial hypotension. Furthermore, there is a statistically significant improvement of the ventilation support in terms of PaO₂/FiO₂ Ratio,

FiO₂ and PEEP, all relevant parameters to increase lung performance and to obtain earlier recovery of ICU COVID-19 patients.

In a few studies it has been shown that propofol, remifentanyl, midazolam and curare could be responsible for the patient's immunodepression and at the same time for a prolonged release of cytokines, micro-aspiration, abnormal peristalsis, microcirculatory effects, and predisposition to infections [14,15]. Also, the acceleration of weaning process decreases tracheobronchial colonization by pathogen and the incidence of ventilator-associated pneumoniae (VAP) [16]. After the weaning in ICU, motor and respiratory rehabilitation also through the use of incentive spirometry, had an important impact in accelerating the patient's recovery. Finally, decannulation of ICU COVID-19 patients was performed successfully and without complications after 30 days.

An early tracheostomy accelerates the weaning process, reduces the predisposition to VAP and systemic infections, accelerating the patient's awakening and motility and facilitates nursing care.

The study shows that early group patients (PDT \leq 12 days from OTI) have a shorter ICU LOS and that they are more prone to be ventilator-free. Nevertheless, the early PDT did not significantly change the CFR during ICU stay.

Instruction and education of the health care professionals, with a focus on infection control and prevention measures, particularly on aerosol-generating procedures, are the key bullet points to ensure health care professional safety and to protect patients.

Even though health care professionals who participated PDT and OTI procedures had the highest increased risk of being infected by SARS CoV-2, tracheostomy in COVID-19 ICU patients within a comprehensive and integrated training program appears a safe procedure. All over all study period, no health care professional became positive to both nasopharyngeal swabs for molecular detection and serology tests for IgG and IgM antibodies against SARS-CoV-2, even before COVID-19 vaccination.

5. Conclusions

Clinical and epidemiological data from the current study support that bedside percutaneous tracheostomy is safe for health care professionals and effective in COVID-19 patients.

The tracheostomy was associated with decreased demand of sedation, analgesics, and inotropic therapy. Moreover, percutaneous tracheostomy improved both respiratory function and single respiratory parameters at day 7 from OTI, all surrogate markers used to predict earlier recovery of COVID-19 ICU patients. Early tracheostomy shows a beneficial impact in terms of shortening the duration of the mechanical ventilation and the ICU LOS in COVID-19 patients with severe respiratory failure.

Bedside percutaneous tracheostomy in COVID-19 intubated patients is safe for healthcare professionals performing the procedure, fully trained with dressing courses and infection prevention and control protocols.

Before drawing conclusions, few limits are raised. First, this study is designed using data from a longitudinal cohort of patients admitted in a single health care facility. Second, control for confounders in any observational study may be incomplete despite all efforts. However, the study also has some strength, a large sample size, a focus on a single procedure with different timing, and the full representativeness of real-life management of ICU COVID-19 patients with severe respiratory failure.

In summary, the development of early PDT protocols in COVID-19 ICU is essential to reduce ICU stay and duration of mechanical ventilation. Early PDT should be considered as first line approach in COVID-19 ICU patients with severe respiratory failure. Early PDT is a fast and safe procedure performed at the patient's bedside, to avoid unnecessary transport of the patient to the operating room for open surgical tracheostomy. The decannulation of the patients is successfully performed with no complication. Finally, nursing management of the COVID-19 patients with tracheostomy is fully comfortable.

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