Original Article

Development of an institutional protocol for percutaneous dilatational tracheostomy in critically ill COVID-19 patients: Initial experience

Haritha Damarla, Neha Pangasa, Divya Hirolli, Parthadeep Jha, Heena Garg, Tazeen Khan, Lipika Soni, Souvik Maitra, Rahul K. Anand, Bikash R. Ray, Dalim K. Baidya

Department of Anesthesiology, Pain Medicine and Critical Care, All India Institute of Medical Sciences, New Delhi, India

Abstract

Background and Aims: Percutaneous dilatational tracheostomy (PDT) may improve the outcome in critically ill COVID-19 patients on mechanical ventilation. However, the timing of performing tracheostomy may be controversial, and it is an aerosol-generating procedure with a potential risk of viral exposure to healthcare workers.

Material and Methods: An operational protocol for performing PDT was made and subsequently followed in a designated COVID-19 ICU. Critically ill adult patients on mechanical ventilators who underwent PDT were included in this retrospective cohort study. Case files were retrospectively reviewed and patient characteristics, clinical outcome, and procedure-related details were noted.

Results: Forty-one patients were included in the analysis. The median age was 49 (39–67) years, and 41.5% of patients were females. The median duration of mechanical ventilation before tracheostomy was 10 (8–16) days, and the median (IQR) PaO_2/FiO_2 ratio on the day of PDT was 155 (125–180) mm Hg. Further, 48.8% of patients had transient desaturation to SpO2 <90%, and 41.5% survived to ICU discharge. None of the health care providers involved in PDT developed any symptoms of COVID 19.

Conclusion: This descriptive study demonstrates the feasibility, implementation, and apparent safety of the PDT protocol developed at our institution.

Keywords: Coronavirus disease 2019, mechanical ventilation, percutaneous dilatational tracheostomy

Introduction

Patients with severe coronavirus disease-2019 (COVID-19) often require mechanical ventilation in the intensive care unit (ICU). Prolonged ventilation and difficulty in weaning warrants tracheostomy in these patients. However, tracheostomy is an aerosol-generating procedure (AGP) with a potential risk of viral exposure to healthcare workers during the procedure and post-tracheostomy care.[1] There is significant controversy regarding the timing, location, and techniques of tracheostomy in COVID-19 patients. Many societies recommend delayed and surgical tracheostomy to minimize aerosol generation.[2,3] There is a paucity of evidence in the literature to clarify whether the indication and the type of tracheostomy (surgical versus percutaneous) in COVID-19 should be different from other critically ill patients.[4] The guidelines and protocols for the timing of tracheostomy vary across nations. European guidelines propose early tracheostomy,[5] whereas the British,

Address for correspondence: Dr. Dalim K. Baidya, Room No. 5011, 5th Floor, Teaching Block, All India Institute of Medical Sciences, New Delhi - 110 029, India.
E-mail: dalimkumar.ab8@gmail.com

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North American, Singaporean, and South-African guidelines propose waiting for at least 14 days of ventilation or a COVID-19 negative test before tracheostomy.[6] However, all the recommendations are based on expert opinions and probable hypotheses, without any evidence.

However, in modern critical care practice, the benefits of percutaneous dilatational tracheostomy (PDT) cannot be overlooked.[7] Early tracheotomy, defined as a procedure performed within 14 days from translaryngeal intubation, is associated with a significantly higher rate of tracheotomy but a larger number of ventilator-free days, shorter ICU stays, shorter duration of sedation, and lower long term mortality rates than late tracheotomy.[8] In particular, PDT appears to be more cost-effective as it releases operating room resources and provides greater feasibility in terms of bedside capability than surgical tracheostomy.[9] Whereas certain institutes or units prefer to perform surgical tracheostomy in COVID-19 patients, the investigators of the current protocol believe that with certain modifications in the standard technique, PDT can be safely performed. Current investigators made an operational protocol and performed PDTs regularly in a designated COVID-19 ICU during the pandemic.

Although a series of safe and successful PDT in COVID-19 patients have been published recently,[10,11] the clinical outcomes of COVID-19 patients who underwent PDT have not been widely reported in the literature. Therefore, we retrospectively reviewed the case records of the patients who underwent PDT in our ICU. The objectives were to identify the patient characteristics, clinical outcome, timing of PDT, and procedure-related details.

Material and Methods

It was a retrospective cohort study.

All adult patients who underwent PDT in a designated COVID-19 ICU were included in the analysis. Any patient with inadequate documentation of data in case files was excluded.

An operational protocol or standard operating procedure (SOP) for performing PDT was made by the current investigators (DKB, RKA, BRR, and SM) on May 1, 2020. The details of the protocol are presented in Table 1. Subsequently, this protocol was followed in our clinical unit during the pandemic, and all the PDTs were performed by any of these four investigators. Minimal involvement of personnel was ensured during the procedure [Figure 1]. Informed consent was obtained from all the patients or their legally acceptable representatives (LAR) before the procedure and possible publication of data without any disclosure of patient identity.

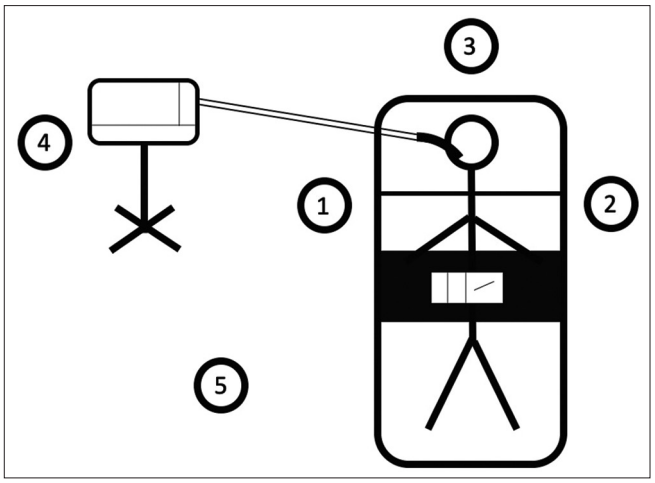

Figure 1: Position of staff during the procedure. 1 = Person doing the procedure, 2 = Assistant, 3 = Bronchoscopist, 4 = Person managing the ventilator, 5 = Nursing staff (if required)

After approval from the Institute Ethics Committee (IEC-235/09.04.2021, RP-16/2021), the ICU charts of all the eligible patients were reviewed and the following data were recorded: a) baseline and demographic characteristics; b) clinical data – severity of COVID-19 pneumonia and intubation and mechanical ventilation parameters; c) outcome – discharge or death and length of ICU stay; d) procedure-related details – attempts, safety precautions, duration, and complications. Duration of tracheostomy was defined as the time from the neck incision to confirmation of tracheostomy tube placement by appearance of first square wave capnography waveform. Desaturation was defined as any reading of oxy-hemoglobin saturation below 90%.

Statistical analysis

All recorded data were tabulated in a Microsoft Excel spreadsheet and analyzed using statistical software Stata 13.0 (StataCorp. 2011. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP). Data are presented as mean ± SD for continuous variables and as absolute numbers or percentages for categorical variables.

Results

In this study, data of n = 41 patients with COVID-19-associated ARDS were included for analysis. At the time of hospital admission, three patients had moderate disease, 20 had severe disease, and 18 patients were critically ill as per WHO case definition.[12] Details of baseline, demographic, and other clinical data are provided in Table 2.

Table 1: Protocol for percutaneous tracheostomy in COVID-19 patients

Preparation	All cases were discussed and considered for tracheostomy after 7 days of mechanical ventilation. Physical or electronic informed consent was obtained from the family or next to kin. Apnea test (Preoxygenation with 100% FiO_2 and PEEP of 5 cm of H_2O in supine position, followed by apnea) was done in all patients planned for PDT. Patients rapidly desaturating during apnea trial were not considered for the procedure. Risk of bleeding assessed and if required corrected, as per coagulation parameters. Thrombo-prophylaxis and enteral feed were withheld prior to the procedure.
Procedure	Involvement of only experienced ICU personnel (4-5 as shown in Figure 1) with appropriate level personal protective equipment (PPE): cap, N95 mask, googles±face shield, gown, double gloves, and shoe cover. Muscle relaxants and opioids were used for paralysis and analgesia. Endotracheal tube suctioning before the procedure with in-line closed suction system and oral suction with use of Yankauer suction. Patient positioning followed by pre-procedural ultrasound scanning of the neck. Patient was ventilated with 100% oxygen before the procedure. All the involved personnel used standard precautions (sterile gown, gloves) for the procedure. Apnea protocol was followed. During the procedure, to minimize aerosol generation, the ventilator was put to standby mode before and during any disconnection or deflation of the ETT cuff. ETT was withdrawn till the cuff was just below the vocal cords with a video-laryngoscope (apnea protocol followed). Cleaning, draping of the neck, followed by incision and blunt dissection. Prior to tracheal puncture, an additional dose of muscle relaxant was used. Flexible bronchoscope inserted through the catheter mount into the ETT just before trachea puncture (apnea protocol followed). Gauge soaked in antiseptic was wrapped around the bronchoscope at the junction with the catheter mount, and the patient's mouth was covered with a soaked gauge to minimize leakage. Tracheostomy was done using the Blue rhino tracheostomy set under bronchoscopic guidance (apnea protocol followed). After insertion of the tracheostomy tube (TT), the cuff was immediately inflated and the ventilator circuit with the in-line suction and viral filter was immediately attached to the TT.
Back-up plan: (desaturation and/or hemodynamic instability during apnea)	Removal of the bronchoscope, repositioning of ETT to mid-trachea or distal to the puncture point, reinflation of the ETT cuff, and resumption of ventilation.
Post-tracheostomy Care	Appropriate-level PPE during post-tracheostomy care Dressing of tracheostomy site with antiseptic soaked gauge Safe suction with a closed-in line suction. Regular checks of cuff pressure. Changing of dressing is avoided unless evidence of local infection Routine changing of TT is avoided

Table 2: Baseline and demographic data

Parameters	Values
Median (IQR) age	49 (39-67) years
Sex (male/female)	24/17
Weight (Kg)	68 (60-80)
Severity of COVID-19 pneumonia: Critical/Severe/Moderate	18/20/3
Admission to intubation duration [Median (IQR)]	1 (1-4) days
Ventilation days on the day of tracheostomy [Median (IQR)]	10 (8–16) days
Plateau pressure/ PEEP/ Compliance on the day of tracheostomy [Median (IQR)]	26 (24-26) cm H_2O/ 8 (7–10) cm H_2O/ 25 (23-26) mL/cm H_2O
PaO_2/FiO_2 on the day of tracheostomy [Median (IQR)]	155 (125-180) mm Hg

IQR=Interquartile range; PEEP=Positive end expiratory pressure

Before tracheostomy, the anterior neck was scanned in all patients by 2D ultrasound with Doppler to identify any blood vessels overlying the trachea. The procedure was performed under real-time fibreoptic bronchoscopic guidance by Ciaglia Blue Rhino® Advanced Percutaneous Tracheostomy Introducer Sets. The median duration of tracheostomy was 5 (4–7) min, and desaturation below 90% was noticed in 48.8% of patients. Tracheal puncture was performed in the first attempt in 67.5% of patients and in the second attempt in 24.4% of patients. The posterior wall of the trachea and guidewire were visible by fibreoptic bronchoscopy in all patients. False passage of guidewire was noted in one patient, and no other mechanical complications such as posterior wall puncture, pneumothorax, or pneumomediastinum were noted. In this cohort, 41.5% (95% CI: 27.8–56.3) patients survived to ICU discharge. The Median (IQR) duration of ICU stay was 17 (14–21) days, and the median duration from tracheostomy to first spontaneous breathing trial to T piece (SBT) was 4 (3–5) days among survivors.

Discussion

As per World Health Organization (WHO), severe COVID-19 disease is characterized by SpO2 <90% and a

respiratory rate of >30/min, while critically ill patients have added complications such as ARDS, sepsis, septic shock, or thrombosis.[12] In our study, nearly all the patients were severe or critically ill at presentation, and the majority of the patients required intubation within 1 day. Early PDT performed in less than 12 days in COVID-19 has shown to reduce the requirement of PEEP and FiO2, need for sedation causing prompt awakening and improved mobility, ventilator days, and ICU length of stay.[13] This, in turn, may enhance the availability of ICU beds, which becomes crucial in the midst of a pandemic and resource shortage. In our study, PDT was considered in daily clinical rounds from day 7 of mechanical ventilation if the patient continued to require control mode ventilation with PEEP >8 cm H2O and FiO2 >0.5. The median duration of mechanical ventilation on the day of PDT was 10 days, and 41.5% of the patients finally survived to ICU discharge. Another large series of 270 COVID-19 patients suggest similar timing of PDT (mean: 10.6 days).[10] However, most of the patients were still critical on control mode ventilation on the day of PDT (compliance: 26 mL/cm H2O and PaO2/FiO2: 155 mm Hg) and thus required a median of 4 days to undergo first T piece trial after PDT.

Though early PDT has been shown to have beneficial outcomes in the weaning process, it is recognized as an aerosol-generating procedure with the risk of viral infection to health care professionals.[14] Aerosolization of secretions can be minimized by executing the procedure under intentional and controlled apneic conditions with muscle paralysis.[15] Pre-procedure USG scanning of the neck helps in identifying pre-tracheal vessels and has the potential to reduce complications.[16] As per our protocol, we used both apnea and pre-procedure USG scanning for all patients. Apnea during the procedure was carried out by switching the ventilator to standby mode before and during any disconnection or deflation of the endotracheal tube (ETT) cuff. The average duration of PDT was only 5 min. Despite this, nearly half of the patients had SpO2 <90% with the lowest SpO2 record of 85%, which reflects the severity of the disease in our cohort. However, all the desaturation episodes were transient with rapid recovery of oxygenation. Although all the procedures were performed under bronchoscopic guidance, one patient had a false passage. However, it was promptly detected and trans-laryngeal intubation was performed. Subsequently, PDT was done at a later setting.

We did not repeat RT-PCR for the patients before the procedure, and the evidence show that repeat RT-PCR testing and waiting for the patient to turn RT-PCR negative is not necessary.[17] This appears to be a reasonable approach as none of the health care professionals performing the PDT developed symptomatic COVID-19, although asymptomatic spread cannot be ruled out. A new PDT set was used every time and no part was reused. USG probes were covered with disposable drapes and transparent dressing and were disinfected with low-level disinfectants such as soap water after every use, and the bronchoscope was disinfected with glutaraldehyde solution after every use.[18,19]

Retrospective nature was the main limitation of the study. Therefore, details of various parameters such as post-tracheostomy sedation requirement and ventilator weaning could not be documented.

To conclude, this descriptive study demonstrates the feasibility, implementation, and apparent safety of the PDT protocol developed at our institution.

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Conflicts of interest
There are no conflicts of interest.

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