ORIGINAL ARTICLE

Percutaneous Tracheostomy in COVID Era: Time to Adapt and Improvise

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Abstract

Background: Percutaneous dilatation tracheostomy (PDT) is required in patients with novel coronavirus disease-2019 (COVID-19) with severe respiratory involvement, but the procedure needs modification to minimize the risk of aerosol exposure to caregivers.

Aim and objective: To share the experience of apnea approach of PDT in COVID patients. Also, to demonstrate the safety of the technique for healthcare workers (HCWs) and patients with respect to hemodynamic and oxygenation parameters. The incidence of adverse events and difficulties during the procedure were also recorded.

Materials and methods: According to this modified approach, percutaneous tracheostomy was performed with apnea technique during open tracheal steps (video attached) and the endotracheal tube was withdrawn to the level of cords under video-laryngoscopic guidance.

Study design: A retrospective data analysis of all the tracheostomy procedures (PDT) performed with the apnea technique during the COVID era (June–September) in non-COVID and COVID patients in intensive care units (ICUs).

Results: During these 4 months, 74 PDT procedures were performed in both COVID and non-COVID patients in the ICUs of our hospital. Out of these, PDT with apnea technique was performed in 45 patients (61%). This technique was successful in 44 patients (97.7%) with mean apnea time of 110 + 8.6 seconds. There was no significant ($p < 0.05$) change in mean arterial pressure and oxygen saturation of 15 COVID patients in pre-PDT and immediate post-PDT period. None of the six team members performing PDT had symptoms or tested positive for COVID-19.

Conclusion: PDT with apnea technique can be performed to minimize the risk of aerosol exposure and does not compromise the quality of care. It is safe both for the patient and HCWs.

Keywords: Aerosol generating medical procedures, Percutaneous dilatational tracheostomy, Tracheostomy.

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Background

In this coronavirus disease-2019 (COVID-19) pandemic, we have witnessed a wide spectrum of patients varying from asymptomatic stage to severe disease.[1,2] Although most patients require supportive care, 20–30% follow a severe course, necessitating hospitalization. Among these about 33% develop acute respiratory distress syndrome (ARDS) with subsequent respiratory failure, necessitating long duration of intensive care and mechanical ventilation (MV).[3,4] Tracheostomy is the standard of care in patients who need prolonged MV due to ARDS or pose the problem of difficult weaning due to post-COVID weakness or lung fibrosis.[5] Though tracheostomy helps in weaning from MV but is an aerosol-generating procedure (AGP) that carries high risk of transmission to healthcare workers (HCWs).[6] There have been recent guidelines that recommend standard open surgical tracheostomy over percutaneous dilatation tracheostomy (PDT) considering the former having less risk of aerosolization, but they are based on weak evidence.[7,8] Both open and percutaneous techniques are AGP and need to be performed cautiously; however, PDT has the benefits of being a bedside procedure with minimum complications in expert hands.

As coronavirus pandemic has changed the ways HCWs approach AGP, we also have incorporated modifications in the standard percutaneous tracheostomy procedure as recommended by experts and performed it under apnea to minimize the risk of exposure HCWs.[9]

Aim and Objective

We aim to describe our experience of performing PDT in apnea and demonstrate its safety for both the patients and HCWs. Any complication, during or after the procedure, requiring the need of conversion to the conventional technique of tracheostomy or rescue ventilation, if required, was also recorded.

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Materials and Methods

Study Design

This was a cross-sectional, retrospective study conducted in tertiary care hospitals and teaching institutions, in mechanically ventilated patients, where percutaneous tracheostomy was indicated. The data were collected from June 1 to September 30, 2020, after approval from the institutional ethical board.

The tracheostomy protocol in the department of critical care was already established and modified to minimize the risk and time

of aerosolization with regards to COVID-19. PDT was performed in non-COVID patients, and finding the technique feasible, it was carried out in COVID patients. Patients were kept fasting for 6 hours prior to the procedure. Anticoagulation with LMWH was continued as per departmental protocol. Informed consent for the procedure was taken from the patient's relatives.

Patient Selection

A multidisciplinary team, including the primary physician, intensivists, and the family, was involved in establishing the need and timing of tracheostomy based on vitals, oxygenation, and ventilation parameters. As many asymptomatic and presymptomatic cases of COVID-19 infection are admitted to the hospital with other illnesses, it was prudent to enhance safety for HCW during AGP, irrespective of the fact that the patient is in COVID or non-COVID intensive care unit (ICU). Also, it is difficult to categorize patients as non-COVID based only on reverse transcription polymerase chain reaction (RT-PCR) due to the possibility of some false negative reports (2–30%).[10] Hence, considering the above facts, we performed PDT utilizing the apnea approach in both COVID and non-COVID patients.

The selection of patients requiring PDT was as per standard guidelines, i.e., those who were on MV for at least more than 5 days with anticipation of prolonged ventilation based on their clinical condition. Patients with uncorrected coagulopathy, BMI >40 kg/m^2, cervical spine injury, unfavorable anatomy, increased intracranial pressure, external ventricular drain, and hemodynamic instability were excluded from this protocol.

Team

Minimum number of HCW were allowed inside the room or bedside, with personal protective equipment (PPE) including gown, gloves, head cover, properly fitted N95 mask, closed eye protection, and face shield. Team members were designated roles prior to the procedure. PDT was performed by an experienced and expert intensivist (operator 1) who had experience of performing >100 PDTs, with a second intensivist/anesthetist (operator 2) at the head end of the patient. Another intensivist/anesthetist (assistant 2) was always near to assist the procedure if need be (Fig. 1). Additionally, a trained nurse (assistant 1) was assigned the duty of administering drugs, operating the ventilator and other devices (ultrasound and bronchoscope, if used). Monitoring of heart rate, blood pressure, and oxygen saturation was done throughout the procedure by the operator at the head end of the patient.

Procedure (Video)

The routine procedure of PDT was modified and performed in two stages to minimize apnea time and decrease the risk of aerosolization (Fig. 2). The patient was sedated, paralyzed, and placed on the control mode of ventilation with 100% FiO_2 for 10 minutes prior to the procedure. Then video laryngoscopy was done by operator 2 to visualize the glottis and endotracheal tube (ETT) was freed from the ties. A clean plastic sheet was placed to cover the patient's face and head to contain spillage from the oral cavity. Operator 1 established the site of the incision by manual palpation of the tracheal anatomy and prepared a sterile neck field for the procedure. The PDT tracheostomy kit was prepared by operator 1 or assistant 1, which included the tracheostomy tube with a syringe attached to the pilot balloon ready for inflation. In the first stage, local anesthesia was infiltrated at the incision

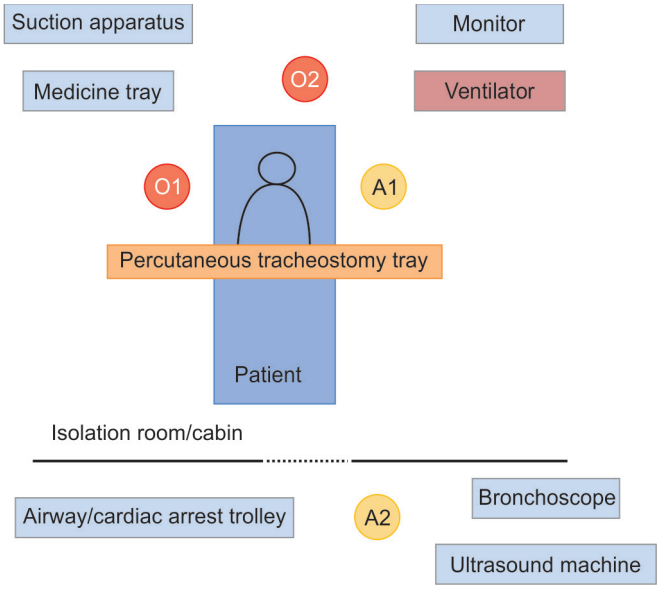

Fig. 1: Arrangement of team members for PDT. Operator 1 performs PDT; operator 2 is at head end of the patient; assistant 1 is assigned the duty of administering drugs, operating the ventilator, and monitoring the patient. They are inside the isolation room and assistant 2 is always near to assist the procedure with bronchoscope and ultrasound, if needed

site and subcutaneous tissue but no puncture of the trachea was done at this point of time. Then, pretracheal dissection with widening the track for tracheostomy was done. The ventilator was then placed on standby mode, prior to deflation of the cuff. Preprocedure vitals, oxygen saturation, and the start of apnea time were noted. In the next stage, operator 2 gradually withdrew the ETT to just below the level of vocal cords under direct visualization with the video laryngoscope and then reinflated it. The trachea was then punctured with a 16-G needle. Guide-wire insertion, tracheal dilatation, and tracheostomy tube were inserted in the apnea period. Once the tracheotomy tube was placed and the cuff inflated, oxygenation was re-established with positive end expiratory pressure (PEEP) by switching on the ventilator. Ventilator graphics, capnography, and oxygen saturation were checked for correct placement of the tracheostomy tube. Easy passage of the suction catheter and identification of tracheal secretions also reflects the correct placement of the tracheostomy tube in trachea though it is a crude method. Closed suctioning was attached thereafter.

When the airway was entered during the procedure and guide-wire inserted, surgical gauze was used to cover the area to minimize the spray of aerosols. Finger occlusion of tracheostomy was done in case of difficulty in negotiating the tracheostomy tube and during open tracheal steps.

Bronchoscope and ultrasound were always available just outside the COVID area but were not routinely used in patients who had favorable anatomy and were reserved for troubleshooting only. For patients undergoing the bronchoscopy-assisted approach, the protocol recommended to seal the insertion point of the bronchoscope at the tracheal tube connection with in-line suction sheath and ventilation held when the bronchoscope adaptor was added to the circuit. In case of desaturation either >2% or <90% or prolongation of apnea beyond 5 minutes, the procedure would be interrupted and ventilation restored. Finger/gauge piece occlusion

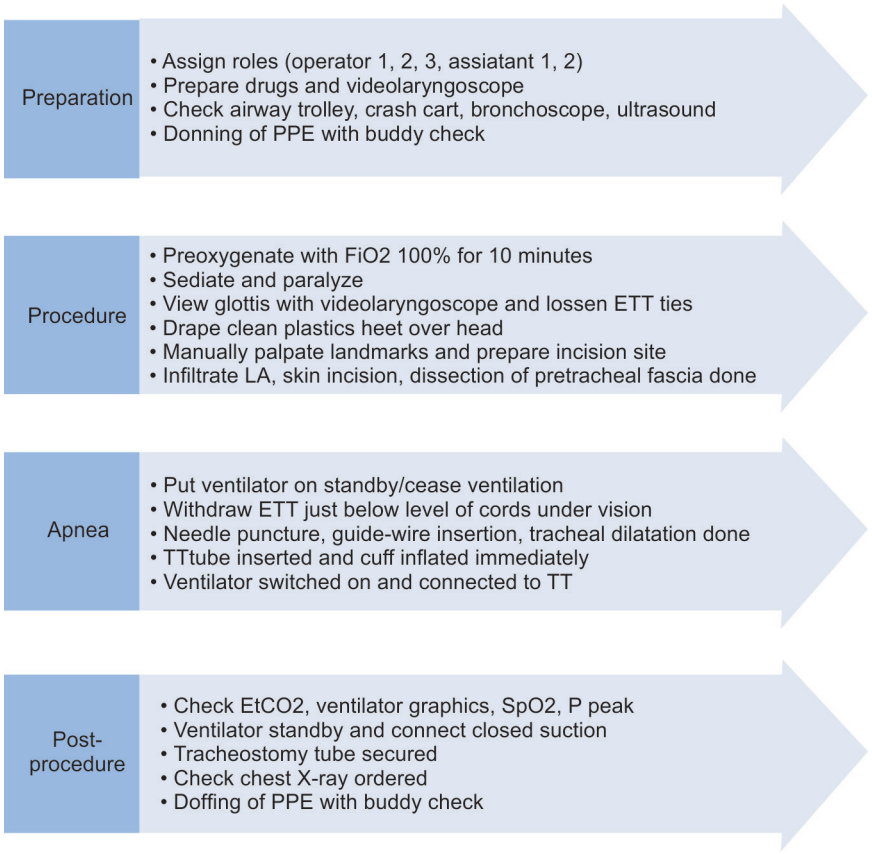

Fig. 2: Critical steps of PDT with apnea technique. PPE, personal protective equipment; FiO_2, fraction of inspired oxygen; ETT, endotracheal tube; LA, local anesthesia, TT, tracheostomy tube; SpO_2, oxygen saturation; $EtCO_2$, end tidal carbon dioxide; P peak, peak airway pressure

of the open tracheal wound will be done and the ETT would be inserted distally beyond the tracheal wound and ventilation re-established after inflation of the cuff. The procedure would be restored in apnea only when saturation was restored above 95% with the same approach or bronchoscopy assisted approach.

Outcomes

The endpoints of the study were to establish patient safety in terms of patient's hemodynamic status and oxygen saturation. Second, outcomes of HCWs in terms of COVID-19 infection were established by RT-PCR testing or symptoms of COVID-19 infection. The incidence of adverse events and difficulties observed by the operator during the procedure were also recorded and analyzed.

Statistical Analysis

The data collection was done for 4 months and compiled. The results were tabulated and analyzed using percentages and proportions with respect to preprocedure and postprocedure hemodynamic stability and oxygenation parameters. A paired Student's *t*-test was used to check the variability of the data. *P*-value of <0.05 was considered significant.

Results

A total of 74 PDT procedures were performed in medical, surgical, and COVID ICUs of our hospital during these 4 months and among them, 45 patients (61%) underwent bedside PDT during apnea. The mean age of these 45 patients was 54.2 ± 8.6 years; 33 patients (73.3%) were males. The mean body mass index of the patients was 32 ± 7.2 kg/m^2. The average ratio of the partial pressure of oxygen to fraction of inspired oxygen (PF ratio) and positive end-expiratory ratio at the time of tracheostomy was 215.86 ± 65 and 6 ± 2.5 mm Hg, respectively, for all patients (Table 1). For COVID patients, average P/F ratio and PEEP at the time of tracheostomy were 157 + 75 and 8 ± 2.4 cm of H_2O, respectively. The mean duration of ventilation before tracheostomy was 10.2 days. The demographic, hemodynamic, and oxygenation characteristics of

Table 1: Clinical characteristics of patients undergoing percutaneous dilatational tracheostomy with apnea technique

Characteristics	*Patients (n = 45)*
Age (years)	54.2 + 8.6
Sex (%)	
Male	33 (73.3)
Female	12 (26.7)
Comorbidities (n, %)	
Cardiac	21 (46.7)
Diabetes mellitus	18 (40)
Chronic liver disease	9 (20)
Chronic kidney disease	12 (26.7)
Stroke	10 (22.3)
Oxygenation values(mean)	
Positive end expiratory pressure (PEEP)	6 ± 2.5
PaO_2/FiO_2 ratio	215.86 + 65
Days on ventilator before tracheostomy	10.2

Table 2: Demographic, hemodynamic, and oxygenation parameters and operative characteristics of 15 COVID-19 patients with percutaneous tracheostomy performed with apnea technique

						Pre-PDT vitals				Post-PDT vitals		
S No.	*Diagnosis*	*Age (years)/ sex*	*Days of MV*	*PaO_2/FiO_2 ratio*	*PEEP*	*MAP*	*SpO_2*	*Duration of PDT (min/sec)*	*Duration of apnea (sec)*	*MAP*	*SpO_2*	*Complications*
1	COVID+, DM, CAD	73/M	11	240	5	72	98	8.15	100	76	98	Nil
2	COVID+, ARDS, HTN	50/M	9	110	8	68	94	10.20	125	72	94	Nil
3	COVID+, ARDS, DM	60/F	8	115	10	70	93	9.45	85	68	92	Nil
4	COVID+, DM	53/M	14	220	6	65	100	11.30	110	68	100	Minor bleeding
5	COVID+, AKI	33/F	10	256	5	76	98	5.45	72	70	98	Nil
6	COVID+, head injury	33/M	7	280	5	80	100	6.30	95	75	100	Nil
7	COVID+, ARDS	35/M	8	100	10	78	93	5.56	86	74	92	Nil
8	COVID+, ARDS	79/M	7	96	10	64	100	7.45	110	68	100	Nil
9	COVID+, ARDS	39/M	10	88	10	73	94	6.30	95	70	93	Nil
10	COVID+, CLD	44/M	9	120	8	66	96	8.20	115	72	96	Nil
11	COVID+, ARDS, DM, HTN	56/M	14	85	12	70	95	9.45	95	68	95	Nil
12	COVID+, ARDS	48/F	11	92	5	82	92	10.30	105	70	92	Nil
13	COVID+, ARDS	63/M	9	107	10	75	97	9.45	95	75	97	Nil
14	COVID+, ARDS, pancreatitis	51/M	12	275	6	68	100	8.10	88	70	100	Nil
15	COVID+, ARDS, AKI	45/F	10	184	10	76	94	6.40	100	72	94	Nil

MV, mechanical ventilation; PaO_2/FiO_2 ratio, ratio of partial pressure of oxygen to fraction of inspired oxygen; PEEP, positive end expiratory pressure; MAP, mean arterial pressure; SpO_2, oxygen saturation; DM, diabetes mellitus; CAD, coronary artery disease; ARDS, acute respiratory distress syndrome; HTN, hypertension; AKI, acute kidney injury; CLD, chronic liver disease

Table 3: Comparison of baseline values of mean arterial pressure (MAP) and oxygen saturation (SpO_2) of 15 Covid-19 patients with the immediate post-tracheostomy parameters

	Pre-PDT	*Post-PDT*	*Change*	*p value*
MAP	72.2 ± 5.5	71.2 ± 2.6	−1	0.44
SpO_2	96.4 ± 3.04	96 ± 3.04	−0.2	0.08

15 COVID patients in which this procedure was done are described in Table 2.

The mean apnea time of the procedure was 110 ± 8.6 seconds (1.83 minutes) with a range of 85–155 seconds. Minor bleeding during dissection in three patients and more than one attempt in the placement of the tracheostomy tube in two patients were the reasons for apnea time to be prolonged, maximum up to 155 seconds. The apnea technique was successful in 44 patients (97%) as rescue ventilation was started only in one patient (non-COVID) due to a fall in SpO_2 of >2% from baseline, where the ETT was repositioned, the patient was ventilated with finger occlusion at the tracheostomy puncture site. The procedure was resumed again in apnea thereafter when saturation improved to >95%. There was no change in the hemodynamic status and oxygenation in all patients, immediately and six hours post-PDT when compared to that before the tracheostomy. Table 3 shows that change in mean arterial pressure, and oxygen saturation immediately post-PDT in 15 COVID patients was not significant. All patients were followed for 24 hours for acute complications and there was no complication such as pneumothorax, subcutaneous emphysema, bronchospasm, major bleeding, hypotension, or cardiac arrhythmias in any patient.

These 45 PDT with apnea were performed by a team of four experienced intensivists along with two trained nurses. None of them had any COVID-related symptoms, such as fever, cough, sore throat, malaise, body aches, shortness of breath, and loss of sense of taste and smell during the study period. RT-PCR for COVID-19 was done in three of the team members which turned to be negative. During the procedure, the difficulties faced by the operators in decreasing order of frequency include psychological stress of environment and PPE (56%), limited mobility of hands while in doing the procedure (35%), fogging in goggles leading to decreased visibility (22%), difficulty in communication (20%), and excessive perspiration (13%).

Discussion

In these rapidly changing times, the "standard" of care is fast evolving and physicians are adapting to newer methods to manage patients. In this changing clinical scenario, modifications in AGP are of utmost importance to mitigate the risk of transmission to the HCWs but the providers may not be accustomed to these new standards and, hence, confront new challenges each day. Hence, we describe our experience of PDT performed in 45 patients on MV during apnea. To the best of our knowledge, this the first and the largest report from India about safety data on apnea during PDT in patients in the COVID era.

We included both COVID and non-COVID patients in our inclusion criteria for modified PDT as there are asymptomatic and carriers of COVID-19 virus admitted to hospital with other illnesses, so precautions must be taken in all patients. Moreover, the sensitivity in antigen testing and RT-PCR viral testing is also a concern. Also, the anticipated time for viral clearance is not clearly known, and some patients have may have long periods (up to 4 weeks) of viral shedding. Hence, during these times, all patients admitted in the hospital should be handled with safety and infection control precautions as if for potential COVID-19 positive patients.

Various modifications of PDT have recently been described for tracheostomy in COVID patients, and apnea technique has been regarded as safe in a controlled environment in expert hands. Niroula et al. performed the PDT during apnea while using disposable (single-use) bronchoscope to avoid the need for endoscopy staff and minimize the surfaces requiring disinfection postprocedure.[11] Similar to their technique, we also withheld ventilation for the entire duration when the tracheal lumen was open, from needle puncture of trachea till the cuff of the tracheostomy tube was inflated. But we used videolaryngoscopy to guide the repositioning of the ETT to the level of the cords after the ventilator was on standby mode. This is unusual from the routine procedure where ETT is repositioned prior to skin incision and was modified to minimize the spray of aerosols and apnea time. Also, the patient's face was covered with a plastic sheet below the drapes, and gauze piece was used to cover the tracheal puncture site in between the steps. We also differ in our technique as we performed tracheal dilatation using the Griggs forceps in all our procedures.

In our study, ETT was withdrawn to just below the level of vocal cords whereas Angel et al. have modified the technique by repositioning the ETT into the distal trachea, and bronchoscope was placed adjacent to the tube at the level of vocal cords.[12] Vargas et al. have published their experience of performing PDT with a similar technique in three patients but have replaced the ETT with a small size tube of internal diameter 6 mm.[13] In our opinion performing needle puncture and tracheal dilatation with ETT (even small size) in the tracheal lumen can cause injury to the ETT and leak, thus increase the risk of aerosolization.

Regarding safe apnea time, Benumof et al. stated that following preoxygenation in healthy adults the safe apnea time is up to 8 minutes for endotracheal intubation. They have reported that time to desaturation of SpO_2 <90% after succinylcholine administration was 8 minutes in healthy patients, 5 minutes in moderately ill adults, and 2.7 minutes in obese adults.[14] Thus, we decided apnea time of 5 minutes for intervention but our experience in airway management and tracheostomy allowed us to perform the PDT with the mean apnea time of <3 minutes.

Identification of anatomical landmarks with ultrasonography has been performed by some practitioners during PDT.[15] However, the results of a previous study conducted by our team on comparison of landmark guided PDT and USPDT (ultrasound-guided PDT) performed on 100 patients showed that in 94% of cases the site of puncture was between T2-3 or T3-4 with no deviation from the midline (unpublished data). With this previous experience, we performed PDT with ultrasonography and bronchoscopy at standby for cases with difficult anatomy. Avoiding the routine use of both these devices not only helped to complete the procedure conveniently within the apnea time but also reduced the number of personnel exposed, exposure time, and equipment needed to be disinfected postprocedure.

No major intraprocedural complication occurred in any patient. All patients were receiving anticoagulation for DVT prophylaxis or therapeutic doses for COVID. Minor bleeding within 24 hours of PDT was seen in three patients (0.6%). Two patients were managed by packing around tracheostomy wounds and one required bedside placement of surgical stitch at the PDT site.

In order to actually determine the risk of infection to HCWs during AGP, the presence of viral RNA in air samples needs to be measured.[16,17] This will require the support of microbiologists, environmental scientists, physicians, and hospital administration and may direct future research. In the meantime, we can use modifications to mitigate the risk to HCWs during aerosol generation. During the study period, there was no COVID transmission among all the physicians of the tracheostomy team and all remained negative in terms of symptoms of COVID-19 or RT-PCR. We limited the number of personnel involved in the procedure and all had donned full PPE. The consistent and proper use of PPE by HCWs is a crucial factor in combating against this infectious crisis.[18] The PPE itself may be a scarce resource and if available is itself a Pandora box accompanied by technical limitations. Among all, psychological stress, fogging in goggles, and difficulty in communication were the most common difficulties faced by the operators during the procedure. Training sessions were conducted for proper donning, doffing, and using sign language for communication during the care of COVID patients.

There are a few limitations of this study. The cohort of patients was small as there had to be a judicious patient selection before planning PDT. Second, PDT was performed by most expert personnel, as is the recommendation for orotracheal intubation because it is of utmost importance to take all precautions during AGPs as well as minimize the apnea time.[19]

In conclusion, novel apnea technique for PDT in patients with novel coronavirus is both safe and feasible.

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