Fiber-optic Bronchoscope-guided vs Mini-surgical Technique of Percutaneous Dilatational Tracheostomy in Intensive Care Units

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ABSTRACT

Background: Percutaneous dilatational tracheostomy (PCDT) using fiber-optic bronchoscope (FOB) is a widely practiced technique, but its availability and cost remain a concern in nations with limited resources. Mini-surgical technique of PCDT incorporating minimal blunt dissection has shown improved results even without the use of FOB. The study is primarily intended to compare these two techniques and establish a safer cost-effective alternative to FOB-guided PCDTs.

Patients and methods: This randomized comparative study [registered (CTRI/2018/04/013191)] was conducted on 120 mechanically ventilated patients. In 60 patients, mini-surgical PCDT (group-M) was performed with 2 cm longitudinal skin incision and blunt dissection till pretracheal fascia without FOB guidance using Portex-Ultraperc™ sets. In remaining 60 patients, PCDT was performed under FOB vision with similar skin incision (without blunt dissection) using Portex-Ultraperc™ sets (group-F). Two techniques were compared with regard to procedural time and percentage of complications occurred during or after the procedure.

Results: Procedure time [group-M: 6.30 ± 1.28 minutes; group-F: 14.43 ± 1.84 minutes ($p < 0.001$)] and mean blood loss [group-M: 5.33 ± 1.69 mL; group-F: 6.87 ± 3.11 mL ($p = 0.001$)] was significantly less in group-M. Higher incidence of desaturation [group-M: 16.7%; group-F: 35% ($p = 0.022$)] was noted in group-F, whereas arrhythmias [group-M: 21.7%; group-F: 6.7% ($p = 0.018$)] were higher in group-M. There was no statistical difference in incidence of pneumothorax and subcutaneous emphysema. There was no incidence of posterior tracheal wall perforation in any of the patients.

Conclusion: Mini-surgical technique is a faster alternative of FOB-guided PCDT with comparable incidence of complications. It can safely be used in intensive care units (ICUs) where FOB is not available.

Clinical trial registration number: CTRI/2018/05/014307

Name of registry: Clinical Trials Registry of India (CTRI), URL—http://ctri.nic.in

Keywords: Arrhythmia, Bleeding, Fiber-optic bronchoscopy, Hypoxia, Intensive care unit, Percutaneous dilatational tracheostomy, Pneumothorax, Subcutaneous emphysema, Tracheostomy.

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HIGHLIGHTS

- Mini-surgical technique of PCDT is a faster technique which involves blunt dissection and does not require use of FOB.
- Guiding modalities like FOB is not mandatory for safer PCDTs and mini-surgical technique can be safely performed in ICUs where FOB is not available.

INTRODUCTION

Tracheostomy is known to mankind since ages. It was first performed by the ancient Egyptians 3500 years ago.[1] Percutaneous dilatational tracheostomy (PCDT) was first mentioned in 1955 and since then various modifications of PCDT have been described.[2] Many meta-analyses have cited various advantages of PCDTs over surgical tracheostomy in intensive care units (ICUs).[3] Various modalities like fiber-optic bronchoscopy (FOB), ultrasonography (USG), and most recently SafeTrach™ and Viva-sight™ have been studied by investigators to guide PCDTs.[4] Use of FOB during PCDT has shown to decrease the incidence of complications but any unanimous verdict regarding its routine use is not present in the literature.[5,6] Moreover, availability, cost, and expertise needed for FOB possess a challenge to its widespread use. Some literature had also shown that FOB-induced hypercarbia and hypoventilation can affect the neurological outcome in some patients.[7,8] Landmark-

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based techniques of PCDT without the use of FOB or USG have also been studied with promising results. Mini-surgical technique of PCDT (MS-PCDT), described by Hashemian et al. incorporating minimal surgical skills, has shown improved results even without use of the FOB.[9] It incorporates blunt dissection, carried out

through pretracheal tissue planes which may result in reduced peri-procedural bleeding and other associated complications, but unfortunately the technique has not been much studied thereafter. Although FOB-guided PCDTs are time-proven, limited literatures are available for their comparison with MS-PCDT. Hence, we decided to compare the safety and efficacy of MS-PCDT to the FOB-guided one and hypothesized that MS-PCDT may be a safer technique for PCDT in ICUs where availability and expertise in FOB are lacking.

MATERIALS AND METHODS

After the institutional ethical approval and registration with the Clinical Trial Registry of India (CTRI/2018/04/013191), this randomized comparative study was conducted in an ICU of a tertiary care hospital in North India. Mechanically ventilated adult patients who were more than 18 years of age and intubated for more than 7 days were included in the study. Patients with a history of cervical spine injury, distorted neck anatomy, infection at the tracheostomy site, morbidly obesity (body mass index more than 40), platelet count less than 50000/mL, coagulopathy, requirement of positive end-expiratory pressure (PEEP) of more than 10 mm Hg and fraction of inspired oxygen (FiO_2) requirement more than 80% were excluded from the study. The aim of the study was to compare the MS-PCDT with FOB-guided PCDT with regard to procedural time and incidence of complications (bleeding, desaturation, cardiac arrhythmia, pneumothorax, subcutaneous emphysema, and posterior tracheal wall perforation) observed during and after the procedure. Considering the incidence of complications as primary objective from previous studies, to achieve 90% power of study and to limit the a-error to 5%, total sample size was calculated to be 120.[9] Patients were randomized using computer-generated random number tables into two groups, and allocations were concealed in a sealed opaque envelope which were opened before the procedure. In group-M, patients had undergone MS-PCDT while in group-F, FOB-guided PCDTs were performed. According to the guidelines by the American College of Chest Physicians in 2003, all the persons who did PCDTs in the study, had experience of doing 20 supervised PCDT procedures prior to the study.[10] The procedure, necessity, and complications associated were explained to the family members and written informed consent was obtained prior to each PCDTs. During the procedures, electrocardiogram (ECG), noninvasive blood pressure (NIBP), end-tidal carbon dioxide ($EtCO_2$), and peripheral oxygen saturation (SpO_2) were monitored in all the patients. All the patients were administered with fentanyl 2 µg/kg, midazolam 30 µg/kg, and vecuronium 0.1 mg/kg intravenously, before the procedure. Fraction of inspired oxygen was made 100% just before the procedure in all patients. After cleaning, draping, and optimal neck extension, important landmarks like the thyroid notch, cricoid cartilage, and first three tracheal rings were marked. Appropriately sized Portex-Ultraperc™ PCDT kit (by Smiths Medical) was checked before the procedure. In group-M, a midline 2 cm longitudinal skin incision, 1 cm below the cricoid cartilage was made. Then using two curved (4 inch sized) hemostats, blunt dissection was carried out longitudinally as well as transversely down till pretracheal fascia followed by oropharyngeal suctioning (Fig. 1). Then direct laryngoscopy was performed, and endotracheal tube (ETT) was withdrawn till its tip reached the level of the vocal cords. After this, the trachea was stabilized and 14-gauge cannula attached with a 10 mL syringe loaded with 3 mL saline was inserted between the

second and third tracheal cartilage from midline in a posterior and caudal direction, at 45° angle to skin into the tracheal lumen. After confirmation of tracheal entry by free aspiration of air bubbles, the cannula was advanced into the trachea. The J-tipped metallic guide wire was then threaded inside the trachea followed by dilation of the initial access site. The subsequent PCDT procedure was completed by dilatation of stoma using single tapered dilator and successful tracheostomy tube (TT) placement. Once the TT was placed, cuff was inflated, and the placement was confirmed by first square-shaped capnograph along with bilateral chest auscultation. While in group-F, same 2 cm midline longitudinal skin incision was made over second and third tracheal rings. Then, FOB was inserted through a swivel connector attached to ETT and ETT was withdrawn till the tip reached the level of the vocal cords under FOB vision. ETT was fixed at that level, keeping the FOB in place for visualization of further steps (Fig. 2). Under FOB vision, further steps were completed in same order as performed in group-M but without any dissection of subcutaneous tissue. Procedural time was defined as the time taken from skin incision to
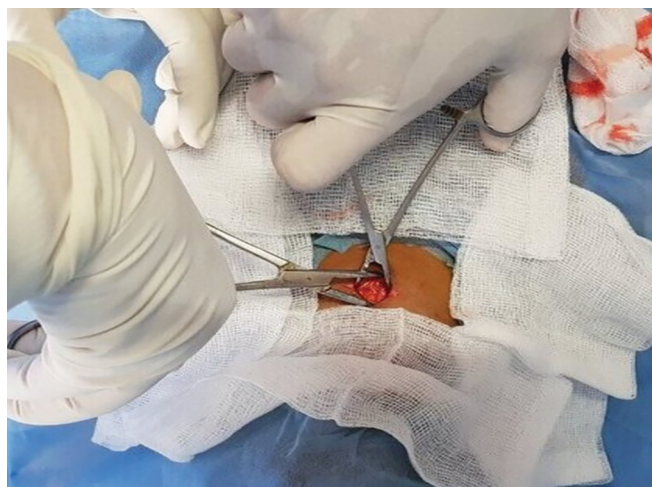

Fig. 1: Blunt dissection being carried out during mini-surgical technique of PCDT in group-M
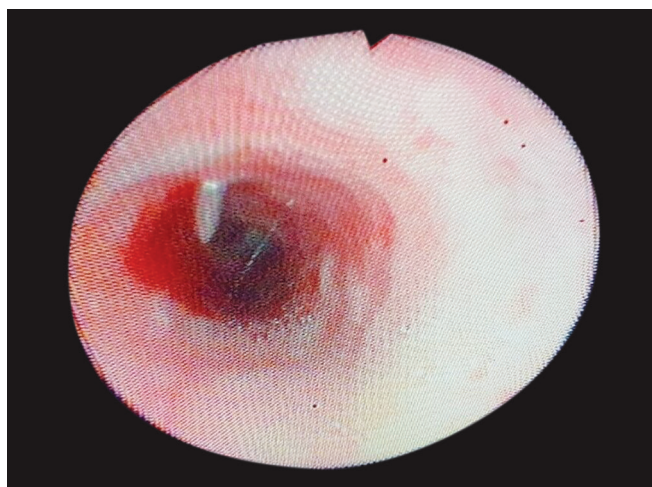

Fig. 2: Needle entry into the trachea under FOB vision during FOB-guided PCDT in group-F

successful placement of TT and achievement of first square-shaped capnograph tracing through TT. In our study, bleeding during PCDT was expressed as the volume of blood soaked by the gauze pieces (bi-layered 2 × 2 inches) provided with the tracheostomy kit. The mean blood soakage for a single gauze piece was taken as 5 mL.

Episodes of desaturation were noted when SpO_2 fell below 90%. During desaturation, the procedure was paused, and the patient was ventilated with 100% oxygen till SpO_2 reached more than or equal to 94% in both the study groups. Patients were carefully monitored for cardiac dysrhythmia and posterior tracheal wall perforation during the procedure. Check bronchoscopy was performed through TT in all the patients to confirm final placement of the TT and all of them underwent postprocedure chest X-ray after 6 hours of TT placement to rule out pneumothorax. Tracheostomy stoma and the surrounding area were examined till 24 hours after the procedure for any swelling or subcutaneous crepitus to note subcutaneous emphysema. Incidence of complications (percentage) was noted as the primary objective and procedural time was compared as the secondary objective in this study.

CONSORT diagram has depicted the division of patients at every stage of study (Fig. 3). The statistical analysis was done using the Statistical Package for the Social Sciences (SPSS version 24.0). Data set was analyzed with Shapiro–Wilk test for assessment of normality. The data set was found to be normally distributed. The quantitative variables like age, procedural time, and bleeding were summarized as mean ± standard deviation and compared using Student's unpaired t-test. The qualitative variables like gender and incidence of complications were summarized as percentages and compared using Chi-square test or Fisher's exact test.

RESULTS

The demographic profile of the patients was statistically comparable in both groups (Table 1). The mean procedure time in group-M was 6.30 ± 1.28 minutes and 14.43 ± 1.84 minutes in group-F (p <0.001). In most of the patients, the trachea was cannulated in the first attempt except two patients (3.33%) in

group-M and one patient (1.6%) in group-F were required two needle interventions and for tracheal cannulation ($p = 0.559$), Mean blood loss was lower in group-M [group-M: 5.33 ± 1.69 mL; group-F: 6.87 ± 3.11 mL ($p = 0.001$)]. Incidence of complications (intra- and postprocedural) was summarized in Table 2. Statistically higher incidence of desaturation was noted in group-F [group-M: 16.7%; group-F: 35% ($p = 0.022$)] whereas arrhythmias were higher in group-M [group-M: 21.7%; group-F: 6.7% ($p = 0.018$)]. There was no statistical difference seen in incidence of pneumothorax and subcutaneous emphysema in between the groups. There was no posterior tracheal wall perforation in any of the patients.

DISCUSSION

Since 2002, single-step dilatation technique for PCDTs became popular and it proved to be better than the other available techniques.[3] FOB and USG have remained the most popular modality to guide PCDT. Researchers in the past have compared various techniques of PCDTs without using any guiding modalities and found comparable success rates with variable incidence of complications.[11,12] Unfortunately, the MS-PCDT technique went into haystack since inception; hence, more safety data need to be generated for this dissection-based method before its widespread application.

In majority of our patients, the PCDTs were performed between 7th and 10th postintubation day. We had maximum number of patients from the age-group of 40–50 years in both the groups. We deliberately did gender matching of the patients to rule out any study bias.

The procedure time was significantly more in FOB-guided technique (p <0.001). It could be attributed to the time required to achieve optimal FOB view and maximize ventilation during the procedure. The time could be an important factor in patients who already had increased airway pressure and inotrope requirement. Blunt dissection helped negotiating variation in vasculature and other important anatomical components in the neck during MS-PCDT technique. In group-F, ETT had to be placed just above vocal cords under FOB vision. The whole manipulation of FOB took some time
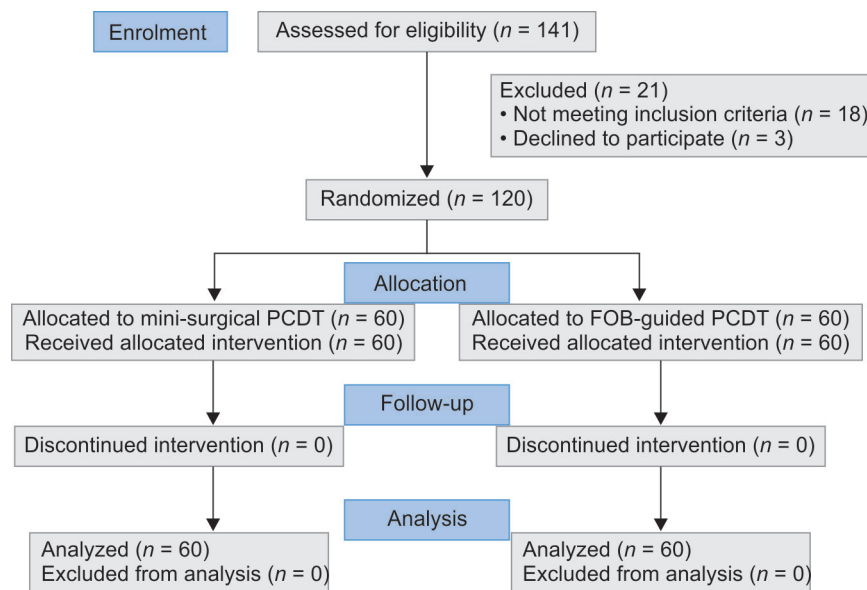

Fig. 3: CONSORT diagram showing the division of patients at each stage of the study

Table 1: Demographic parameters of patients

Variables		Group-M (n = 60)	Group-F (n = 60)	p value
Age (mean ± SD)		43.38 ± 16.32	46.38 ± 14.87	0.403
Male (%)		42 (70)	37 (61.67)	0.337
Female (%)		18 (30)	23 (38.33)	0.397
Diagnosis (number of cases)				
Medicine	COPD	5	7	0.791
	CVA	6	4	0.953
	CAD	3	3	1.000
	Snakebite	0	1	0.493
	DKA	1	0	0.493
Surgery	Peritonitis	10	10	1.000
	Intestinal obstruction	6	4	0.953
	Obstructive jaundice	2	2	1.000
	Blunt trauma abdomen	2	2	1.000
Obstetrics	Ruptured ectopic pregnancy	2	1	0.564
	Eclampsia	2	2	1.000
Neurosurgery	Intracranial hemorrhage	10	9	0.985
	Intracranial tumor	6	8	0.693
	Traumatic brain injury	5	7	0.791

Table 2: Incidence of complications other than bleeding

Group	Hypoxemia/desaturation Number of cases (%)	Cardiac arrhythmia Number of cases (%)	Pneumothorax Number of cases (%)	Subcutaneous emphysema Number of cases (%)
M (n = 60)	10 (16.7%)	13 (21.7%)	1 (1.6%)	2 (3.33%)
F (n = 60)	21 (35.0%)	4 (6.7%)	2 (3.33%)	1 (1.6%)
p value	0.022	0.018	0.559	0.559

which impacted the mean procedural time whereas in group-M, the ETT was immediately pulled back till the vocal cords under direct laryngoscopy vision. Rapid procedure minimizes the exposure time to any risk associated with it. Procedure time can further be reduced if a fixed team performs it every time. Hashemian et al. have concluded that MS-PCDT was much faster (2.0 ± 0.7 minutes) than the FOB-guided technique (7.5 ± 3.3 minutes). Their study results were consistent with our findings.[9] Saritas et al. found that mean procedural time was 7.3 minutes (Median 7) in patients who underwent PCDT without FOB whereas it was 13.67 minutes (Median 14) in FOB-guided PCDT group.[13]

According to meta-analysis published by Simon et al., the prime cause of PCDT-related deaths was hemorrhage secondary to the arterial bleed (59.3%).[14] Some unexpected bouts of bleeding can happen at any step of the procedure and it may lead to abandonment of the procedure, but it can be minimized by careful patient selection. Some of the researchers have mentioned that more than 250 mL of bleeding during PCDT should be regarded as severe bleeding.[15] In our study, mean blood loss in group-M was lesser than the FOB-guided group but it was not clinically significant [although statistically significant ($p = 0.001$)]. Maximum bleeding documented in our study was 15 mL in both the study groups. Many a time in group-M, we came across vessels lying adjacent to the field of dissection and those were retracted carefully during the procedure. Even if some bleeding vessel was seen in the procedure field, it was immediately clamped using the hemostat. In case of diffuse oozing of blood from

the procedure, field gauze compression was done to achieve tamponade effect. All these had led to decreased amount of bleeding in MS-PCDT. On the contrary, increased bleeding was noticed during the dilation of the tracheal puncture tract in some patients during FOB-guided PCDT. It was most probably due to avulsion of adjacent blood vessels during introduction of the dilator. None of our patients had undergone surgical exploration, suture ligation, or received blood transfusion due to bleeding. Hameed et al. mentioned that the overall incidence of clinically relevant bleeding was 4.05% with FOB-guided PCDT and concluded that FOB does not offer any help in reducing bleeding during PCDT.[16] Hashemian et al. have also mentioned that there was no significant difference in mild and moderate bleeding between dissection-based and FOB-guided PCDTs.[9] On the contrary, Saritas et al., Agarwal and Sing, and Hassanin et al. in their respective studies found that there was more bleeding with non-FOB guided PCDT, but the techniques followed in all these studies is not per se mini-surgical one.[13,17,18]

The possible steps where desaturation usually happened while performing PCDT were at the time of pulling the ETT till vocal cords, dilating the puncture tract, and putting the TT through the stoma. In addition, FOB occupies most of the space within the ETT, hampering the effective ventilation. So, FOB size should be chosen carefully for patients undergoing FOB-guided PCDT as smaller ETT or larger FOB both can hamper effective ventilation. Aforementioned reasons and higher procedural time have led to almost double incidence of desaturation in

FOB-guided cases in our study. One patient in group-M and two in group-F had accidental extubation during the procedure. In these cases, the ETT was immediately advanced into the trachea without any difficulty to ventilate the patients. Most of the researchers have also mentioned that there is increased incidence of desaturation in FOB-guided PCDT but none of them had mentioned any hypoxemia-related mortality in their study. Findings of our study suggest that extreme caution should be paid to decrease the procedural time and FOB with smaller external diameter should be used to guide the procedure. Agarwal and Sing had to abandon 2 PCDTs in the FOB-guided group due to refractory hypoxemia.[17] Putensen et al. have also agreed to the consensus that the incidence of desaturation in FOB-guided PCDT was more.[3,13,18]

In our study, 13 patients in group-M and 4 patients in group-F had arrhythmias. Most of them were either premature contractions (atrial or ventricular) or paroxysms of supraventricular tachycardia (SVT). Rarely, in few patients very short duration of ventricular tachycardia (VT), was noticed which subsided spontaneously. None of our patients had ventricular fibrillation (VF), pulseless electrical activity (PEA), or asystole in spite of the fact that our study population included critically ill patients with coronary artery disease (CAD) and heart failure. Most of the arrhythmias occurring during our study did not need any active management and resolved spontaneously. Increased incidence of arrhythmias in group-M can be attributed to autonomic fluctuations which might have happened during airway manipulation and dissection over anterior tracheal wall with ETT *in situ*. However, we could not find any literature stating the reason of arrhythmias occurred during PCDT in noncardiac patients. Simon et al. have mentioned three procedure-related deaths due to cardiac arrest and also emphasized that Grigg's forceps dilatational technique of PCDT had caused maximum intraprocedural arrhythmias.[14] However, Hashemian and Digaleh who invented the mini-surgical technique of PCDT did not include the "incidence of arrhythmia" as a study parameter in their research.[9]

Almost all the studies regarding PCDT have mentioned pneumothorax as one of the prominent intraprocedural complication and some of them have mentioned its incidence as high as 5.6%.[14] Mechanisms explaining the pathophysiology of this complication can be direct pleural injury, dissecting through a plane within the deep cervical fascia, low dissection leading to mediastinal injury, and rupture of an alveolar bleb. Khandelwal et al. reported that para-tracheal insertion of TT and even posterior tracheal wall injury may lead to pneumothorax due to its close proximity with the parietal pleura.[19] FOB that has been kept within the ETT for prolonged duration leads to compromised ventilation which results in higher peak airway pressures. This may be particularly deleterious to the patients with preexisting lung diseases. In our study, one patient (1.6%) in group-M and two patients (3.3%) in group-F developed pneumothorax but none of them developed signs of desaturation and hypotension. In group-M, injury to adjoining structures including pleura was avoided by blunt dissection, meticulous palpation of anatomical details, and visualized dilatation of the tracheal puncture tract. In a retrospective study, Tobler et al. had reported the incidence of pneumothorax during PCDT was almost 1.6% and they concluded that postprocedural chest X-ray should be made mandatory after PCDT in which there is a strong suspicion of pneumothorax.[20] Even USG is also being used these days to detect early pneumothorax following PCDT, but more trials are needed to reach any consensus.

Incidence of subcutaneous emphysema due to disruption of trachea has been reported to be 1.4–1.8% during PCDTs.[21] Common causes include multiple punctures of the anterior tracheal wall, excessive dilatation of the trachea, para-tracheal insertion, posterior tracheal lacerations and concomitant pleural injury. If it causes significant discomfort to the patient along with hemodynamic alterations and respiratory compromise, it needs to be treated. In our study, two patients in group-M and one patient in group-F had subcutaneous emphysema with spontaneous remission within 24 hours and had no such further episodes during ICU stay. One patient in group-M was obese (BMI 34) and over dilatation of tracheostomy stoma might have led to subcutaneous emphysema. Another patient in group-M had tracheal deviation which was not clinically evident prior to the procedure. It took two needle interventions to cannulate the trachea of the patient and it might have led to subcutaneous emphysema. On routine pneumothorax work-up, we found that only one patient had both pneumothorax and subcutaneous emphysema. Hashemian and Digaleh and Saritas et al. have also found a very low incidence of this complication in their respective studies.[9,13] All the patients were followed up till the time they were in hospital or till they have died. We did not notice any postprocedure clinically significant bleeding or infection in any of the patients.

Scarcity of recommendations on necessity of FOB during PCDTs has led the authors to review more literature and only two such recommendations could be traced.[22,23] French expert panel have recommended routine use of FOB during PCDTs but their opinion was based on two nonrandomized and one randomized trials on just 60 patients, mostly from Western countries.[22] On the contrary, in a recently published multicentric study on 923 patients from India, the researchers have performed FOB in only 28.1% of all PCDTs, although they have mentioned that the use of FOB may reduce hemorrhagic complications during PCDT.[24] The Indian Society of Critical Care Medicine (ISCCM) expert panel has also published a practice recommendation in 2020 which mentions that FOB can be used during PCDT if available but it does not decrease the incidence of complications during PCDTs.[23] So, to be in sync with recent pieces of evidence, we wish to state that the use of FOB may be desirable but it is not mandatory during PCDT. MS-PCDT can be a safe and effective alternative to FOB-guided PCDTs. However, more safety data need to be generated from larger studies to validate our findings.

Conclusion

Mini-surgical PCDT is a relatively faster alternative with similar incidence of complications when compared to FOB-guided PCDTs. We suggest that the mini-surgical PCDT should be tried in ICUs where FOB is not easily available, and it decreases the dependency on imaging devices to safely perform PCDT.

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