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ORIGINAL ARTICLE

Comparative Study between Ultrasound-guided Percutaneous Dilatational Tracheostomy Versus Bronchoscopy-guided Percutaneous Dilatational Tracheostomy in Mechanically Ventilated Critically Ill Patients

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ABSTRACT

Background: Percutaneous dilatational tracheostomy (PDT) is widely practiced among critically ill patients in intensive care units (ICUs)owing to its safety.Medical professionals increasingly use fiberoptic bronchoscopy or ultrasound for PDT guidance instead of blind procedures. The objective of our study was to compare the safety and efficacy of ultrasound-guided PDT to bronchoscopy-guided PDT in critically ill ventilated patients.

Methods: 40 adult patients were prospectively randomized into two groups: Group I (n=20) guided by bronchoscopy and Group II (n=20) guided by ultrasound.

Results: Group II had a significantly shorter procedural duration ($P < 0.001$). No significant differences emerged in intubation reasons, ventilation duration before tracheostomy, or tracheostomy motives. Procedural challenges, complications, and outcomes were comparable between both groups. Moreover pre- and post-procedure P/F ratios, ICU or hospital stay length, and mortality rates showed no notable differences.

Conclusions: Ultrasound or bronchoscopy guided PDT in critically ill patients showed comparable results in terms of complications and outcomes. However, a significant difference was noted in procedural duration.

Keywords: Percutaneous dilatational tracheostomy; Intensive care units; Bronchoscopy-guided group; Ultrasound-guided group.

INTRODUCTION

Percutaneous dilatational tracheostomies (PDT) are increasingly used for prolonged mechanically ventilated patients, commonly employing Ciaglia dilators and guide-wire forceps [1]. Benefits of surgical and PDT include better communication, clearer airways, reduced sedation, faster weaning, improved comfort and airway protection[2]. While complications are rare, serious instances, including fatalities, have been reported [3]. Many healthcare organizations now use bronchoscopic guidance for accurate tube placement [4]. Furthermore, ultrasound is increasingly utilized during PDT to trace cervical vasculature [5], locate optimal tracheal punctures, guide precise needle insertion, and determine the appropriate tube size [6].

This research **aimed to** evaluate safety and effectiveness of ultrasound-guided PDT in mechanically ventilated

critically ill patients versus PDT guided bybronchoscopy in a prospective manner.

METHODS

This randomized trial was conducted in critical care unit of Menoufia University Hospital and highlighted the necessity of obtaining consent from patients or their families.The research was **registered with the local ethics committee of Menoufia University, Faculty of Medicine (**IRB approval numberand date 9-2016 ANET**);**study reporting complies with consort criteria.

40 patients over the age of 18needing prolonged mechanical ventilation randomly assigned to two groups: group I (n=20) underwent bronchoscopic guided PDT, while group II (n=20) underwent ultrasound guided PDT.

Exclusion criteria included issues with blood clotting(platelet count below 50,000/mm3, INR exceeding 2.0, or aPTT over 1.5 times the standard value), FiO_2 above 0.50, elevated PEEP above 10 cm H_2O, use of vasoactive agents, active bleeding, skin infections near the tracheostomy site, certain cervical anatomical abnormalities(such as a short neck, tracheal deviation, history of cervical surgeries, trauma, tumors, or inability to extend the neck e.g. fracture cervical vertebrae), and prior history of tracheostomy.

All individuals enrolled in this research underwent the subsequent steps:

The compiled dataset for comparison included a diverse range of patient characteristics from both study cohorts that met the inclusion criteria, encompassing age, sex, hospital admission dates, ICU diagnosis upon admission, intubation and tracheostomy reasons, pre-tracheostomy ventilation duration, guidance method (ultrasound or bronchoscopy), procedure duration, skin puncture attempts, post-procedure X-rays, ABG before and after PDT, anatomical complexities, subjective procedure difficulty rating[7], procedure-related challenges, clinical outcomes, ICU and hospital discharge timelines as well as ICU and hospital mortality. Moreover, pre-procedural ultrasound examination of distance between skin and second tracheal ring, tracheal transversal diameter at the second tracheal ring, vasculature between skin and second tracheal ring, and whether there was a change in the planned puncture site after scanning in groupII.

Procedure description:

The procedure was conducted using the "single step" Blue Rhino (CBR) method [8], employing the Ciaglia Blue Rhino® G2 Advanced Percutaneous Tracheostomy Introducer Set (C-PTIS-100-HC, BLUERHINO, COOK, USA)®[9]. The set included a puncture needle, a guide wire, a small dilator, and the special Blue Rhino dilator and three curved stylets.

Patients were positioned as in conventional surgical tracheostomy with a pillow supporting their shoulders and their neck slightly extended to facilitate anatomical landmarks identification. All underwent volume-controlled ventilation with 100% oxygen for 10 minutes pre-operatively, during the procedure, and post-operatively before readjusting to the preset FiO2. Pre-procedure, the skin from the chin to below the clavicles was prepped with an iodine-based disinfectant and draped, exposing the larynx to the suprasternal notch.

The suprasternal notch, thyroid and cricoid cartilages, and the first three tracheal rings (or a point between the cricoid cartilage and suprasternal notch if rings were undetectable) were identified to locate the puncture site. Continuous ECG, pulse oximetry, and non-invasive blood pressure monitoring were maintained throughout. The endotracheal tube (ETT) was repositioned above the proposed

tracheostomy site, the cuff slightly deflated, and the tube withdrawn to the cricoid cartilage or just below the vocal cords, as managed by an assistant. The cuff was then re-inflated, and the assistant maintained tube position throughout the procedure.

Patients received fentanyl 100 – 200 mcg, midazolam 0.3 mg/kg and cisatracurium 0.2 mg/kg bolus, immediately before the procedure. 3 to 5 mL of 1% lidocaine with adrenaline (1:200,000) was infiltrated subcutaneously to minimize bleeding. Cricoid cartilage was palpated and a one cm transverse incision was made through the skin and subcutaneous fascia between first and second or second and third tracheal rings or mid-way between cricoid cartilage and sternal notch or 1.5 or 2 fingerbreadths from sternal notch.

Afterward, a 15-gauge needle with a cannula was used to pierce the trachea in a downward-backward direction. Air was drawn into a saline-filled syringe to confirm needle placement. The ETT was rotated 30 degrees; any cannula movement indicated impalement, requiring cannula removal and tracheal repuncture after ETT readjustment. Once the cannula was correctly placed, a "J" tipped guide wire was threaded through the tracheal passage, and the cannula was removed, leaving the guide wire in place.

To initiate stoma formation, a well-lubricated 14 Fr dilator was passed over the guide wire into the trachea and then withdrawn. A guiding catheter (white plastic sheath) was advanced over the guide wire until its safety ridge lay inside the tracheal lumen. Using the guide wire and catheter as references, the CBR (flexible, hollow tube of hard rubber with a hydrophilic coating) was wetted with saline to increase smoothness then advanced to the designated skin mark for tracheal dilation.

Ultimately, a tracheostomy tube with a lubricated introducer was gently placed through the tracheal opening. The introducer, guide wire, and guiding catheter were carefully removed, leaving the tube securely in place. Correct positioning was ascertained with auscultation. Once confirmed, the tracheostomy was secured on the neck, and ventilator parameters were reset.

Bronchoscopy-guided PDT:

Anatomical landmarks identified the tracheostomy puncture site between the second and third tracheal rings. Using a catheter-over-needle device with saline, the trachea was punctured at the selected spot under real-time guidance by **PENTAX EPK-1000 bronchoscope** to adjust the endotracheal tube just below the vocal cords.

Catheter insertion was carefully monitored with bronchoscopy after confirming air aspiration. A guide wire was gently passed through the catheter to complete the procedure as previously described [8] **(Fig. 1)**, while the bronchoscope ensured accurate puncture site identification, avoiding unintended posterior wall punctures. Verification of tracheostomy tube placement involved passing the bronchoscope through the tube and conducting a chest X-ray an hour later for possible complications.

Pre-procedural ultrasound-guided PDT:

A sterile ultrasound scan with **a Sonoscape C361 portable machine** and a 12 MHz linear probe located the cricoid cartilage, first three tracheal rings, and puncture site via longitudinal sections. This was followed by a color Doppler exam and cross-sectional scans to assess arteries, veins, thyroid gland, trachea, and endotracheal tube **(Fig. 2)**.

At the second tracheal ring level, measurements determined the distance between skin and trachea as well as tracheal diameter. Vessels between skin and tracheal rings were identified and avoided. The endotracheal tube was guided under

ultrasound until the cuff aligned with cricoid cartilage to prevent puncture. The puncture site was marked between the second and third tracheal rings using ultrasound guidance and anatomical landmarks. Subsequently, the procedure was completed as described [8].After inserting the tracheostomy tube, a bronchoscope was used to check for unintentional posterior wall punctures.

Post-operative care of tracheotomy involved:promptly clearing the tracheotomy tube through suctioning immediately following the procedure, a chest X-ray and ABG, maintaining a semi-seated position in bed, suctioning regularly during the initial post-operative days, inhaling humidified oxygen and consistent wound care.

Adverse events were documented for both groups and categorized into periprocedural complications occurring during or immediately after the procedure, and postoperative complications monitored for up to 4 weeks. These complications included:death related to procedure or cardiac arrest, tracheal wall injury, false passage, pneumothorax, pneumomediastinum, tube obstruction, tracheoesophageal fistula, persistent hypotension (SBP < 90 mmHg for > 5 min with intervention), acute persistent hypoxemia (SaO2 < 90% for > 5 min), major bleeding (blood transfusion or hypotension or surgical intervention due to bleeding related to PDT), tracheostomy-related sepsis (stoma infection as the only identifiable source), transient hypotension (SBP < 90 mmHg for < 5 min with intravenous fluids), arrhythmias (40% change in HR relative to baseline, HR >110 bpm, HR <50 bpm, and/or rhythm changes on ECG), hypertension (30% increase in SBP relative to baseline), atelectasis, accidental decannulation, localized subcutaneous emphysema without evidence of pneumothorax or pneumomediastinum, minor bleeding (self-limiting stomal or intratracheal bleeding treated by local compression or topical vasoconstrictors).

Statistical Analysis:

Data were analyzed using IBM SPSS version 20.0 (Armonk, NY: IBM Corp). Qualitative data were described using numbers and percentages. The Shapiro-Wilk test verified normality. Quantitative data were described using range (min and max), mean, standard deviation, median, and interquartile range (IQR). Significance was judged at the 5% level.

The used tests were:-

1 - Chi-square test

For categorical variables, to compare between different groups

2 - Fisher's Exact or Monte Carlo correction

Correction for chi-square when more than 20% of the cells have expected countless than 5

3 - Student t-test

For normally distributed quantitative variables, to compare between both groups

4 - Mann Whitney test

For abnormally distributed quantitative variables, to compare between both groups

5 - Paired t-test

For normally distributed quantitative variables, to compare between two periods

RESULTS

Forty eligible patients out of sixty, aged 18 and older with various medical conditions were randomly assigned to two groups: 20 for bronchoscopic-guided PDT and 20 for ultrasound-guided PDT **(Fig.3)**.

Traumatic brain injury was the primary admission reason in both groups, followed by cerebrovascular stroke **(Table 1)**. A comparable number of patients in groups I and II were intubated for respiratory failure or inability to protect their airway, with no statistically significant

difference between the groups (P = 1.000).Duration of intubation before tracheotomy was consistent across both groups.

As detailed in **(Table 1)**, 2 patients (10%) in group I and 3 patients (15.0%) in group II needed tracheotomy due to failed weaning, while inability to protect the airway accounted for 18 patients (90%) and 17 patients (85.0%), with no significant difference (P = 1.000). Pre and post P/F ratios in **(Table 1)** showed no significant differences between groups (P = 0.379 and 0.626).

Despite various challenges, there was no significant difference in attempts or adjustments between groups. Adjustments to the puncture site were made for 3 patients (15%) under ultrasound guidance, with none requiring surgery; all PDTs were successfully completed**(Table 2)**.

Notably, group II demonstrated a significantly shorter duration (P < 0.001), with mean times of 21.40 ± 3.15 for group I and 13.85 ± 2.08 for group II **(Fig.4)**.

There was no significant difference in complications between both groups. Moreover, ICU and hospital lengths of stay showed no statistically significant differences; 45% of patients in group II died post-ICU transition to intermediate care compared to 55% in group I, with no fatalities directly linked to the procedure. Following rehabilitation, an equal number of patients from each group were discharged home, while ICU mortality rates were 30% in group II and 20% in group I**(Table 3)**.

Table 1: General patient's characteristics in studied groups

	Bronchoscopic group (n=20)		**Ultrasound group (n=20)**		**Test of sig.**	**p**
	No.	**%**	**No.**	**%**		
Gender						
Male	11	55.0	13	65.0	χ^2= 0.417	0.519
Female	9	45.0	7	35.0		
Age (years)						
Min. – Max.	19.0 – 65.0		21.0 – 69.0		t=0.293	0.771
Mean ± SD.	44.80 ± 14.05		46.10 ± 13.98			
Median (IQR)	43.0 (34.0 – 57.0)		47.0 (35.0 – 57.0)			
ICU main diagnosis Acute exacerbating chronic obstructive pulmonary disease	3	15.0	3	15.0	χ^2= 3.551	0.962
Cerebrovascular stroke	5	25.0	7	35.0		
Guillain barre syndrome	1	5.0	1	5.0		
Myasthenia gravis	1	5.0	0	0.0		
Postoperative brain surgery	0	0.0	1	5.0		

	Bronchoscopic group (n=20)		Ultrasound group (n=20)		Test of sig.	p
	No.	%	No.	%		
Transverse myelitis	1	5.0	0	0.0		
Traumatic brain injury	9	45.0	8	40.0		
Reason for endotracheal intubation						
Respiratory failure	4	20.0	5	25.0	χ^2=0.143	^{FE}p=1.000
Inability to protect airway	16	80.0	15	75.0		
Reason for PDT						
Failure to wean	2	10.0	3	15.0	χ^2=0.229	^{FE}p=1.000
Inability to protect airway	18	90.0	17	85.0		
Duration of MV before PDT(days)						
Min. – Max.	5.0 – 17.0		3.0 – 21.0		U=195.0	0.904
Mean ± SD.	12.65 ± 2.60		12.55 ± 3.73			
Median (IQR)	12.0 (12.0 – 14.0)		13.50 (12.0 – 14.0)			
P/F ratio before PDT						
Min. – Max.	275.0 – 460.0		265.0 – 490.0		0.893	0.379
Mean ± SD.	362.20 ± 60.33		371.50 ± 59.45			
Median (IQR)	355.0 (307.50 – 415.0)		370.0 (335.0 – 400.0)			
P/F ratio at the end of PDT						
Min. – Max.	255.0 – 365.0		230.0 – 450.0		0.491	0.626
Mean ± SD.	302.75 ± 33.03		316.50 ± 60.40			
Median (IQR)	300.0 (275.0 – 325.0)		305.0 (267.50 – 370.0)			

X2: Chi- Square test, t: Unpaired Student t test, U: Mann-Whitney U test. PaO2 denotes arterial oxygen pressure; FIO2, fraction of inspired oxygen; COPD, chronic obstructive pulmonary disease.

Table 2: Procedure data of both group

	Bronchoscopic group (n=20)		Ultrasound group (n=20)		Test of sig.	p
	No.	%	No.	%		
Anatomical difficulties						
Easy	9	45.0	15	75.0	χ^2= 3.865	^{MC}p= 0.156
Mild	5	25.0	3	15.0		
Moderate	6	30.0	2	10.0		
Number of attempts (trials) at skin puncture						
Min. – Max.	1.0 – 3.0		1.0 – 3.0		t= 0.244	0.809
Mean ± SD.	1.50 ± 0.69		1.45 ± 0.60			
Median (IQR)	1.0 (1.0 – 2.0)		1.0 (1.0 – 2.0)			
Duration of procedure (minutes)						
Min. – Max.	15.0 – 25.0		11.0 – 18.0		t= 8.935*	<0.001*
Mean ± SD.	21.40 ± 3.15		13.85 ± 2.08			
Median (IQR)	21.50 (19.50 – 24.0)		14.0 (12.0 – 15.0)			
Success in tube placement						
Success	20	100.0	20	100.0	-	-
Failure	0	0.0	0	0.0		
Preprocedural ultrasound scanning Skin to tracheal distance (cm)						
Min. – Max.	NA		0.79 – 1.94			
Mean ± SD.			1.11 ± 0.28			
Median (IQR)			1.05 (0.88 – 1.30)			
Tracheal diameter (cm)						
Min. – Max.	NA		1.73 – 2.23			
Mean ± SD.			2.04 ± 0.18			
Median (IQR)			2.06 (1.89 – 2.21)			
Vessels beneath site puncture						
Present	NA		3 (5.0)			
Absent			17 (85.0)			
Puncture site change after ultrasound						
Changed	NA		3 (15.0)			
Not changed			17 (85.0)			

Table 3: Complications and clinical outcomes

	Bronchoscopic group (n=20)		Ultrasound group (n=20)		Test of sig	p
	No.	%	No.	%		
Periprocedural Complications					χ^2	^{FE}p
Minor bleeding	3	15.0	2	10.0	0.229	1.000
Transient hypotension	2	10.0	3	15.0	0.229	1.000
Transient tachycardia and hypertension	2	10.0	1	5.0	0.360	1.000
Transient acute hypoxaemia	2	10.0	1	5.0	0.360	1.000
Orotracheal cuff puncture	2	10.0	3	15.0	0.229	1.000
Postprocedural follow up					χ^2	^{FE}p
Granuloma	1	5.0	0	0.0	1.026	1.000
Dislodgement	2	10.0	1	5.0	0.360	1.000
Major bleeding	1	5.0	1	5.0	0.0	1.000
Minor local stomal infection	2	10.0	2	10.0	0.0	1.000
Minor bleeding	2	10.0	1	5.0	0.360	1.000
Subcutaneous emphysema	0	0.0	1	5.0	1.026	1.000
Tracheostomy tube obstruction	1	5.0	2	10.0	0.360	1.000
Outcome parameters **ICU length of stay in days**						
Min. – Max.	17.0 – 33.0		16.0 – 27.0		t= 1.642	0.109
Mean ± SD.	22.85 ± 4.15		21.0 ± 2.87			
Median (IQR)	22.50 (19.0 – 26.0)		21.0 (19.0 – 23.0)			
Discontinuation of MV						
weaning without decannulation	5	25.0	5	25.0	χ^2= 0.361	^{MC}p= 1.000
Failed weaning	13	65.0	12	60.0		
weaning without decannulation and reventilated again	2	10.0	3	15.0		
Hospital length of stay in days						
Min. – Max.	21.0 – 45.0		23.0 – 51.0		t= 0.474	0.639
Mean ± SD.	34.65 ± 4.99		35.65± 8.01			
Median (IQR)	35.0 (32.50 – 37.50)		35.50 (28.50 – 42.50)			
Mortality						
Survivors	5	25.0	5	25.0	χ^2= 0.600	0.741
Hospital mortality	11	55.0	9	45.0		
ICU Mortality	4	20.0	6	30.0		

X2: Chi- Square test, t: Unpaired Student t test, U: Mann-Whitney U test, FET: Fisher Exact test, MC: Monte Carlo test. Values are expressed as the mean (standard deviation), median [25th-75th percentiles], or number (percentage).

Figure 1: Percutaneous tracheostomy kit – Ciaglia single dilator method

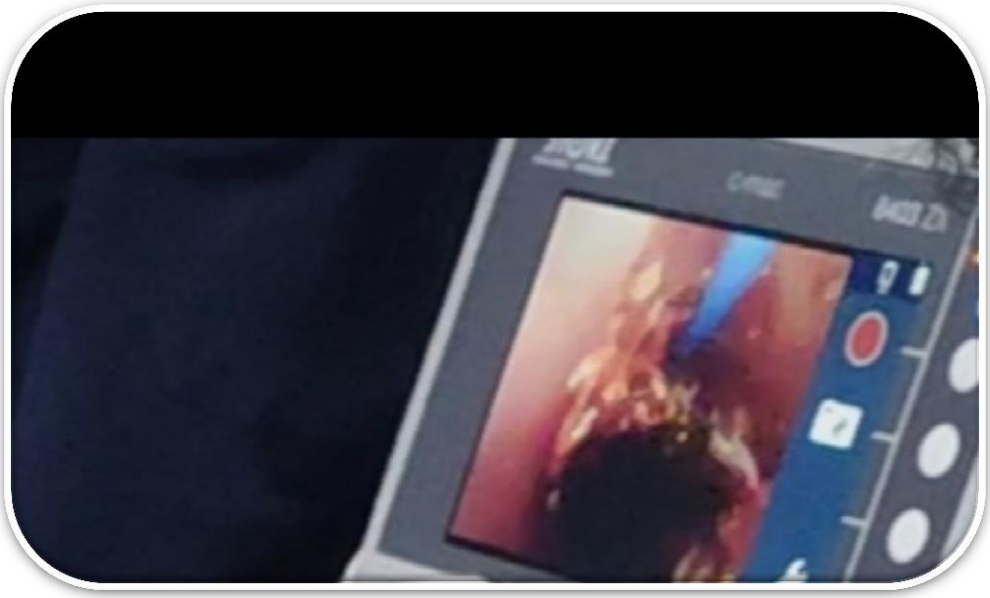

Figure 2: Bronchoscopic view showing the blue rhino in trachea

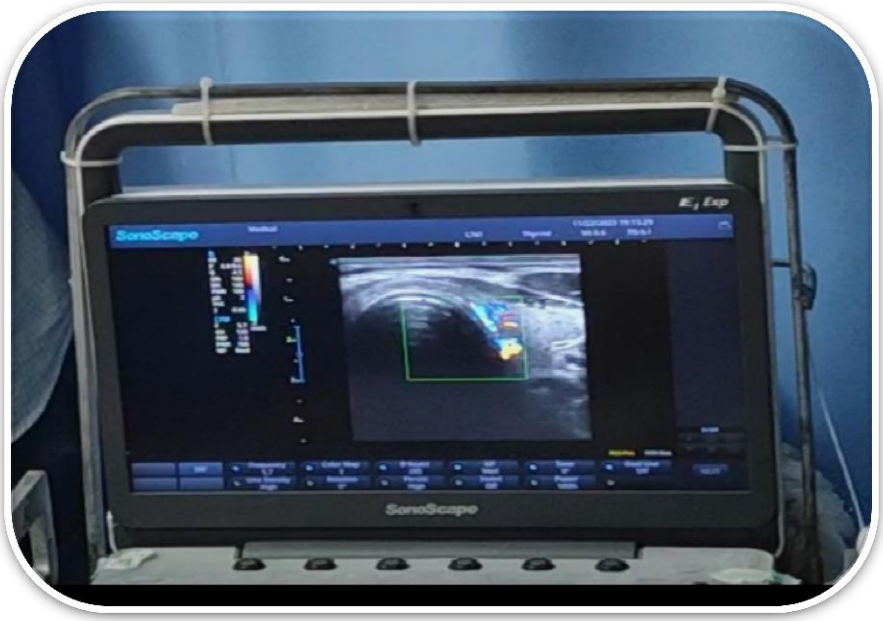

Figure 3: Color Doppler cross section showing the trachea, air-mucosal interface, comet tail artifact, isthmus with nearby vessels, thyroid gland, tracheal ring.

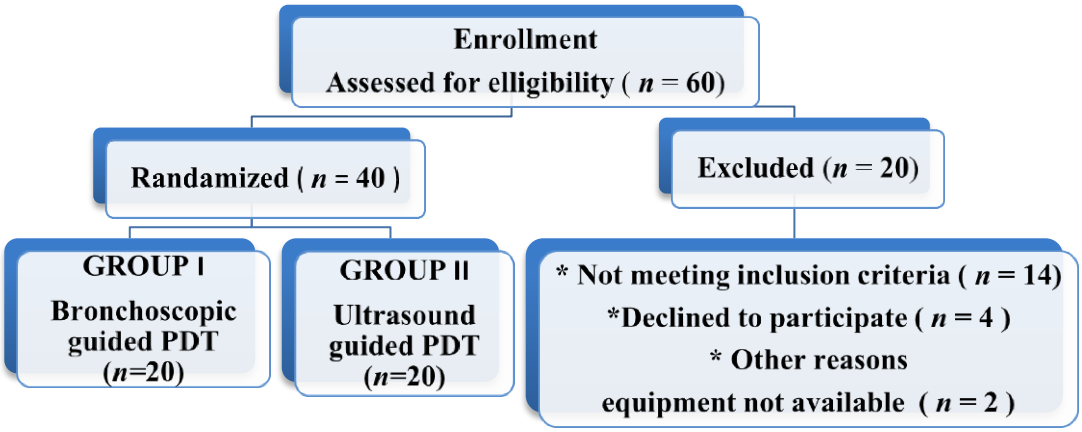

Figure 4: Study flow chart

DISCUSSION

Intensivists predominantly perform tracheostomies on critically ill patients requiring prolonged mechanical ventilation, as weaning off sedation and lowering breathing effort can promote early patient engagement [10,11]. While routine use of fiberoptic bronchoscopy is not recommended, it may be suitable in certain situations to enhance safety [12]. Ultrasound is preferred over bronchoscopy for PDT due to its accessibility and safety benefits, offering precise imaging and landmarks, making it essential in airway management procedures [13–15].

Our study compared the efficacy of ultrasound versus bronchoscopy for PDT. In both cohorts, tracheostomy was mainly

required due to compromised airway protection and unsuccessful weaning in a minority of patients. Gobatto et al. emphasized airway safeguarding as a key reason for tracheostomy [16]. While durations of endotracheal tube use and mechanical ventilation before tracheostomy were consistent across groups, studies noted varying timeframes for PDT post-intubation, ranging from 9 to 17 days [17,18].

Notably, the procedure took less time in group II (13.85 ± 2.08 minutes compared to 21.40 ± 3.15 minutes; $P < 0.001$). While Gobatto et al. observed comparable durations (11 min vs. 13 min;$p = 0.468$), our findings are consistent with Chacko et al., who showed a significant shorter timeframes with ultrasound (10.7 min vs. 13.9 min;$p < 0.0001$) [13,16].

Although three (15%) patients in our study needed puncture site modifications, 18% to 23% of patients in other studies require such changes based on pre-procedural ultrasound assessments, noting vessels overlying the intended site [16,19,20]. All tracheostomies in our trial were successful, aligning with Guinot et al.'s findings of no procedural failures [9].

Although Chacko [13] reported fewer hypoxic events in the ultrasound-only group, oxygenation status did not substantially differ before and after procedures in either group, aligning with Gobatto et al. [20], Helmy et al. [21], and Ravi et al. [22].

Our study found no significant issues or fatalities. Similarly, Chacko et al. and Gobatto et al. [13,16] reported no notable differences in success or complications.

There was no statistical difference in cuff punctures across groups, consistent with Gobatto's findings [16]. However, the bronchoscopy group reported a higher rate of tracheal cuff punctures, according to Ravi [22].

Similar to Gobatto et al., minor bleeding was frequently observed and managed with local compression, showing no significant difference between the groups [16]. Variations in minor bleeding rates were noted across different severity categories [16, 23].

Both groups experienced physiological fluctuations like transient tachycardia and hypertension due to stress and pain, which were effectively treated with sedation and analgesics.

Transient hypotension was also reported with no significant difference, managed with crystalloid replacement. Differences in hypotension rates between guidance methods were not significant per Gobatto et al[20].

There was no significant difference in transient acute hypoxemia between 10% of patients in group I and 5% in group II. Gobatto et al. found that bronchoscopy and ultrasound guidance produced similar short-term reductions in oxygen levels [20]. However, Ravi and Vijay noted a decrease in oxygen levels during bronchoscopy, unlike in those receiving ultrasound guidance [22]. According to Silvester et al., variables like sample sizes, patient characteristics, and equipment differences can affect the likelihood of complications [24].

Regarding post-tracheostomy complications, 5% of patients in both groups experienced major bleeding, with no notable differences between them. These incidents were due to coagulation issues linked to sepsis and granulation tissue formation. They did not require surgical interventions despite the need for blood transfusions. The presence of a granuloma leading to bleeding in group I was highlighted, contrasting the ultrasound group's experience without such problems. Moreover, patients undergoing PDT and traditional surgical tracheostomy

reported granulation and tracheal stenosis instances [25].

10% of cases in both groups had minor local infections near the stoma site; these were not statistically significant and were managed with antibiotics and local care. Various sample sizes and variables, such as multiple punctures, can cause infections [26, 27]. Additionally, three instances of tracheostomy dislodgement were noted, linked to tube material quality, patient movements, and coughing; two patients experienced regrettable consequences. There is still disagreement over whether stay sutures or tube displacement is more effective at stopping bleeding [28].

No incidences of pneumothorax or pneumomediastinum occurred; however, one patient (5%) in group I developed subcutaneous emphysema treated with oxygen therapy within a week, likely due to a misplaced tracheostomy tube and increased coughing.

No significant differences in ICU stay length (p=0.109), hospital stay duration (p=0.639), or hospital mortality rates (p=0.741) between both groups. Studies support efficacy and safety of both approaches by finding no appreciable variations in outcomes [20, 29]. Combining approaches, however, resulted in lengthier procedures without better outcomes [21].

CONCLUSIONS

A notable statistical variance emerged in procedural duration between both groups, with the ultrasound-guided PDT cohort exhibiting significantly shorter procedure time ($P < 0.001$). However, there is little distinction between ultrasound-guided PDT and bronchoscopic-guided PDT in critically ill patients regarding complications and outcomes.

Limitations:

As a single-center study with no agreed definitions of PDT-related issues, limited patient's number, diverse populations and insufficient follow-up time for long-term complications, our findings might differ from others.

Recommendations:

Larger, homogenous trials (age, sex, disease severity) across multicenters examining efficacy of ultrasound-guided PDT in specific ICU subsets like trauma patients, obese patients, and those with relative contraindications may yield critical insights.

Conflicts of Interest: None.

Financial Disclosures: None.

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