BMC Pulmonary Medicine

RESEARCH

Open Access

Real-time ultrasound-guided laryngeal mask assisted percutaneous dilatational tracheostomy versus bronchoscopy-guided percutaneous dilatational tracheostomy in critically ill patients: a randomized controlled trial

Sameh Taha[1], Jihad Mallat[2,3*], Mohamed Elsaidi[1], Ashraf Al-Agami[1] and Ahmed Taha[2,3*]

Abstract

Background Percutaneous dilatational tracheostomy (PDT) is a common procedure for mechanically ventilated patients in the intensive care unit (ICU). This study compared the real-time ultrasound-guided PDT using a laryngeal mask airway (LMA) with the standard bronchoscopy-guided PDT technique in ICU patients requiring elective tracheostomy.

Methods This randomized controlled study was conducted at Ain Shams University Hospital's Critical Care Department from December 4th, 2021, to December 3rd, 2022. The study population included 60 critically ill patients admitted to the ICU. Thirty patients were randomly assigned to the real-time ultrasound-guided LMA-assisted group, and 30 patients were randomly assigned to the bronchoscopy-guided technique. The primary study outcome was the procedure time, and the secondary outcomes included procedure-related complications rate and cost-effectiveness.

Results The real-time ultrasound-guided LMA-assisted group had significantly shorter procedure time (median 17 [IQR: 15–20] min vs. 35 [IQR: 28–39] min, $p < 0.001$) and lower equipment damage (0% vs. 20%, $p = 0.024$) during the procedure compared to the bronchoscopy-guided group. Additionally, the cost of tracheostomy was significantly lower in the real-time ultrasound-guided LMA-assisted group (median: 300 vs. 800 USD, $p < 0.001$). The real-time ultrasound-guided LMA group had a lower major complications rate than the bronchoscopy-guided group (36.7%) vs. 3.3%, $p = 0.002$).

Conclusions The study demonstrated that real-time ultrasound-guided LMA-assisted PDT had shorter procedure time, reduced equipment damage, lower costs, and was associated with lower complications when compared to the

*Correspondence:
Jihad Mallat
mallatjihad@gmail.com
Ahmed Taha
tahaa2@clevelandclinicabudhabi.ae

Full list of author information is available at the end of the article

bronchoscopy-guided technique. These findings suggest that ultrasound guidance can enhance the efficiency and cost-effectiveness of PDT procedures.

Keywords Ultrasound-guided tracheostomy, Laryngeal mask airway, Percutaneous dilutional tracheostomy, Bronchoscopy-guided tracheostomy, Bleeding, Complications, Critically ill patients, Intensive care unit

Introduction

Intensive Care Unit (ICU) patients frequently need mechanical ventilation for respiratory assistance [1–3]. When prolonged ventilation is expected, a tracheostomy is commonly performed to secure the airway, aid in weaning from the ventilator, reduce dead space, improve patient comfort, facilitate oral care, reduce the need for deep sedation, and enable better communication and mobilization [4–7]. Tracheostomy can be carried out through different methods, including surgical and percutaneous techniques [8]. Percutaneous tracheostomy, a minimally invasive procedure, presents several benefits compared to surgical tracheostomy, including shorter operating time, less blood loss, and a lower risk of wound-related complications [8–10].

Bronchoscopy has conventionally been a guiding method to ensure accurate tracheostomy tube placement and reduce associated complications [11, 12]. Nonetheless, bronchoscopy adds to the procedural complexity, necessitates specialized proficiency, and potentially elevates the risk of infection and other adverse events [13]. Recently, ultrasound-guided percutaneous tracheostomy has emerged as a viable alternative approach, which holds the promise of comparable clinical outcomes while offering enhanced safety and procedural simplicity [14, 15].

Using ultrasound guidance during tracheostomy procedures has become increasingly prevalent across diverse clinical contexts owing to its capacity to provide dynamic imaging of anatomical structures in real-time, potentially minimizing procedural complications [14, 16, 17]. Ultrasound guidance offers enhanced visualization of the trachea, adjacent vasculature, and pertinent anatomical landmarks, facilitating precise needle insertion and identifying potential impediments [18–20]. Furthermore, it prevents the necessity for radiation exposure inherent in fluoroscopy and obviates the expenses linked to bronchoscopy equipment [21].

Several studies have explored the efficacy and safety of ultrasound-guided percutaneous dilatational tracheostomy (PDT) compared to the standard technique using bronchoscopy guidance PDT with controversial results [22–25]. Laryngeal mask airways (LMAs) have been successfully used instead of ETTs during PDT, with better visualization of relevant tracheal structures [26–29]. No studies have explored the efficacy and safety of the ultrasound-guided PDT approach using an LMA compared to the bronchoscopy-guided PDT technique.

Therefore, this study aimed to compare the real-time ultrasound-guided PDT technique using an LMA with the bronchoscopy-guided PDT as the standard technique in patients admitted to the ICU requiring elective tracheostomy.

Methods

Study design

This was an open-label, parallel, randomized controlled study conducted in the Critical Care Department of Ain Shams University Hospital, Egypt, from December 4th, 2021, to December 3rd, 2022. The study was conducted in accordance with the amended Declaration of Helsinki. The local Research Ethics Committee of Ain Shams University Faculty of Medicine (reference number: FMASU MD 164/2021) approved the protocol on December 3rd, 2021. Informed written consent was obtained from the patients or their legal guardians in a private setting, where the study protocol was thoroughly explained to them. The study was retrospectively registered in the ISRCTN registry on 02/07/2024 (registration number ISRCTN14218985). Our study adhered to CONSORT guidelines.

Patients

The eligible population consisted of adult intubated and mechanically ventilated critically ill patients admitted to the ICU with clinical indications for elective percutaneous tracheostomy (e.g., prolonged weaning, decreased consciousness, impaired airway reflexes, excessive secretions), as assessed by the treating team.

Patients were excluded if they had an unsuitable anatomy to undergo a PDT as judged by the patient attending physician (i.e., short neck, tracheal deviation, cervical anatomical anomaly, previous cervical surgery, cervical trauma, cervical tumors, or the inability to perform a neck extension). Furthermore, the study did not include patients who refused to provide informed written consent. Patients with contraindications to the tracheostomy procedure, such as coagulopathy, high requirements for FiO_2 (fraction of inspired oxygen) ≥ 60%, or PEEP (positive end-expiratory pressure) ≥ 12 cmH_2O, were also excluded. Moreover, patients with a history of COVID-19 were not included in the study.

Study outcomes

The primary outcome was the procedure time, defined by the time (in minutes) between the trachea puncture and

the patient's ventilation in real-time US-guided LMA-assisted and bronchoscopy-guided PDT groups. Secondary outcomes were the cost of the procedures (including the perioperative drugs used, the tracheostomy set, and fiberoptic bronchoscope sterilization) and the complications related to the procedures.

Sample size calculation

The PASS 11 software was used for the sample size calculation. Based on a previously published study [14], which showed that the median procedure times were 12 [IQR: 9–14] min in the real-time US-guided PDT group and 18 [IQR: 12-21.5] min in the bronchoscopy-guided PDT group and after adjustment for 10% of dropout rate, a sample size of 60 patients (30 per group) was needed to achieve a power of 80% at an alpha error of 5%.

Randomization and study groups

Patients admitted to the ICU requiring elective PDT were randomized in a 1:1 ratio to real-time ultrasound-guided technique using LMA (US-guided LMA-assisted) or bronchoscopy-guided technique arm in random permuted blocks of 4 to ensure balanced allocation across intervention arms. Randomization sequences within each block were generated using SAS code to conduct blocked randomization, and an independent biostatistician conducted the randomization. Allocation concealment was maintained to minimize selection bias. None of the investigators or ICU staff members were aware of the randomization list before group allocation, as well as block numbers or block sizes at any moment, as the randomization was performed by an automated third party to maintain allocation concealment. Treatment assignments could not be blinded to the ICU staff members.

Study intervention

In both groups, PDT was performed using the Blue Rhino™ Percutaneous Tracheostomy Introducer Set (Cook Critical Care, Bloomington, IN) after deep sedation and analgesia by continuous infusion of propofol and sufentanil intravenous bolus (0.3 gamma/kg). Muscle relaxation was achieved with an intravenous bolus of cisatracurium (0.3 mg/kg). Patients were ventilated under volume-targeted mechanical ventilation with a 100% FiO_2, and ventilatory parameters (tidal volume, respiratory rate, and positive end-expiratory pressure) were kept constant. Continuous hemodynamic monitoring (five-lead electrocardiogram, blood pressure, heart rate, and pulse oxygen saturation) was performed.

Real-time ultrasound-guided LMA-assisted PDT

An LMA Classic™ (LMA Deutschland, Bonn, Germany) or a single-use LMA (Solus, Teleflex Medical, Kernen, Germany) was introduced behind the endotracheal tube (ETT) in situ, which was removed after the LMA was in the correct position. The LMA size selected was 4 for women and 5 for men. The LMA was then securely fixed with tape, and the patient's head was positioned in extension. Inspiratory pressure was adjusted as needed to minimize air leakage.

A single US device (SonoSite M-Turbo; SonoSite Inc, Bothell, Washington) and 6- to 12-MHz probe were used in all patients in the US-guided LMA-assisted group. After skin disinfection, an operator determined the puncture point by palpating standard anatomical landmarks. Before PDT, the operator performed a US examination of the neck region with longitudinal sections to locate the cricoid cartilage, the tracheal rings, and the puncture site (Fig. 1). Then, the operator performed US transversal sections to identify arteries, veins, thyroid, trachea, and endotracheal tube and measure the thickness of the skin to the anterior tracheal wall (Fig. 1). Next, a second operator performed the PDT with US guidance. A puncture needle, attached to a saline-filled syringe, was inserted perpendicularly into the skin and advanced until air was aspirated, confirming that the needle had passed through the anterior tracheal wall. The needle was then angled caudally to prevent retrograde movement of the guide wire. Using a transverse section of the neck, the needle was visualized in an "out-of-plane" view, with its trajectory identified by a clear acoustic shadow ahead of the needle. The guide wire was introduced, the needle was removed, and a small horizontal incision was made at the puncture point. Afterward, the bronchoscope was inserted through the LMA into the trachea, and the tip of the bronchoscope was placed 0 cm to 1 cm below the vocal cords to confirm the correct positioning of the guide wire. The sterility was maintained by covering the USG probe and the Circuit holding arm with a sterile cover. The small dilator was then used to create the initial stoma, followed by the single-stage Griggs forceps dilator over the guide wire. The tracheostomy tube was guided over the guide wire and passed through the stoma. The Real-time US provided the information on the correct positioning of the puncture site. The bronchoscope provided information about the positioning of the guide wire before the trachea's dilatation and then the tracheostomy tube placement. Complications were recorded during and after the procedure.

Bronchoscopy-guided PDT

In a bronchoscopy-guided PDT, the bronchoscopy was performed by trained intensivists. After sedation, as previously described, the bronchoscope was introduced, and the ETT was repositioned under bronchoscopy guidance, with the tip of the tube just below the vocal cords. The thyroid cartilage, the cricoid cartilage, and the first three to five tracheal rings were identified, and the puncture

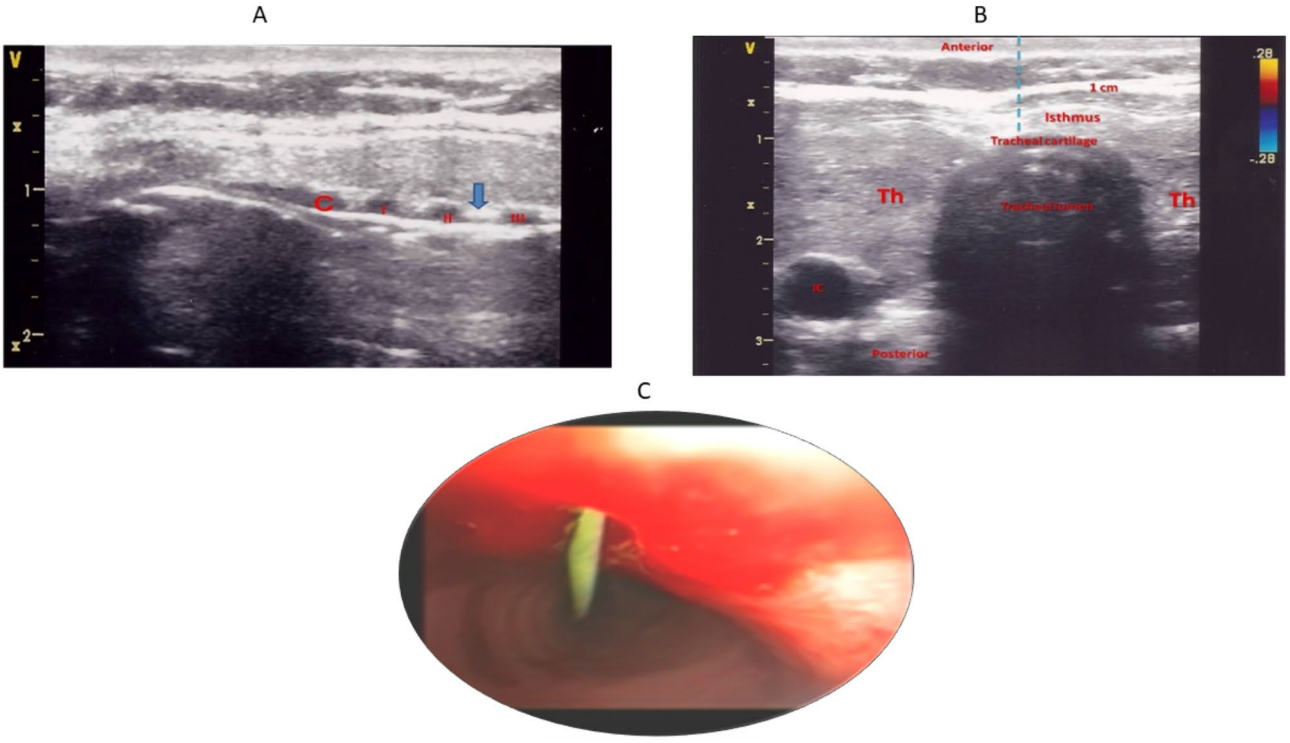

Fig. 1 **A**: Ultrasound longitudinal view of the neck showing the cricoid cartilage and the tracheal rings. **B**: Ultrasound cross-section of the neck showing the thyroid isthmus, tracheal cartilage, and the tracheal lumen. **C**: Bronchoscopy view of the inner lumen of the trachea showing the green guide wire coming from the 12 O'clock position and directed caudally. The arrow points to the best site for needle insertion between the second and third tracheal rings. The dotted line measures the distance from the skin to the tracheal cartilage. C, cricoid cartilage; I, first tracheal ring; II, second tracheal ring; III, third tracheal ring; Th, thyroid gland; IC, internal carotid

site was selected between the second and the third tracheal rings. Then, the trachea was punctured at the chosen site with a catheter-over-the-needle device connected to a 10-mL syringe half-filled with distilled water under real-time bronchoscopy guidance. As soon as air aspiration was observed in the syringe and the catheter was seen in the trachea, the catheter was introduced, and the needle was removed during a continuous observation using bronchoscopy. A flexible guide wire was then gently introduced into the catheter (Fig. 1). After that, the procedure was completed as Griggs had previously described it. Bronchoscopy was maintained during the whole procedure to guide the puncture site, avoid any posterior wall puncture, confirm the correct positioning of the guide wire, and confirm an adequate tracheal dilation.

Complications of tracheostomy

Complications related to the tracheostomy procedure were classified as major or minor. Complications were followed up until death or hospital discharge.

Major complications were defined as procedure-related death, cardiac arrest, hypotension (defined as a systolic blood pressure below 90 mm Hg for more than 5 min or the need for interventions such as fluids or vasopressors to elevate blood pressure), acute hypoxemia (a decrease in peripheral oxygen saturation below 90% for more than 5 min, as measured by a pulse oximeter), loss of airway, tracheal wall injury, false passage cannulation, pneumothorax, tracheostomy cannula obstruction, esophageal injury, tracheoesophageal fistula, accidental decannulation, conversion to surgical tracheostomy, major bleeding, which was defined as continuous hemorrhage from the stoma and/or the trachea with aspiration, despite compression and causing hypoxemia and/or requiring emergency transfusion and/or open surgical repair, and tracheostomy-related sepsis (stoma infection as the only identifiable source).

Minor complications included transient hypotension (defined as systolic blood pressure below 90 mmHg for less than 5 min and no intervention used to increase blood pressure such as fluids or vasopressors); transient acute hypoxemia (defined as oxygen peripheral saturation below 90% for less than 5 min as measured by the pulse oximeter); atelectasis; inadvertent cuff puncture; minor bleeding, either stomal or intratracheal, which was defined as self-limiting bleeding or bleeding successfully treated with local compression, instillation of topical vasoconstrictive agents, and/or electrocauterization. In addition, localized subcutaneous emphysema without

evidence of pneumothorax or pneumomediastinum and local stomal infections not causing sepsis were also classified as minor complications.

Data collection

In both groups, the following data were collected: age, gender, body mass index (BMI), Acute Physiology and Chronic Health Evaluation II (APACHE II) scores, coagulation test (international normalized ratio [INR] and activated partial thromboplastin time [APTT]), comorbidities, oral intubation duration, time allocated for the procedure, bleeding during and after the procedure (minor and major), and complications.

Statistical analysis

The collected data were compiled and analyzed using SPSS (Statistical Package for Social Science) version 26.0 on an IBM-compatible computer. The statistical analysis consisted of two types of approaches. Firstly, descriptive statistics were employed to summarize the data. Qualitative variables were presented as numbers and percentages, while quantitative variables were reported as mean ± standard deviation (SD) or median (interquartile range, [IQR]), depending on the distribution of the data. Secondly, analytic statistics were applied to examine specific relationships and comparisons. The chi-squared test ($\chi 2$) or Fischer exact test was used to assess associations between qualitative variables. Student's t-test was employed when comparing two quantitative variables with a normal distribution. In cases where the data did not follow a normal distribution, the Mann-Whitney U test was used for comparison. Additionally, we used multiple linear regression analysis to adjust for age, patients' severity, duration of intubation, and any other baseline variables that were not well balanced between the two groups ($p < 0.20$). A p-value of less than 0.05 was considered statistically significant.

Results

A total of 65 patients were eligible to be enrolled in the trial. Of these, 5 patients were excluded, and 60 patients underwent the procedure, with 30 patients randomly assigned to the real-time US-guided LMA group and 30 patients to the bronchoscopy-guided group (Fig. 2). Overall, 33 patients (55%) were intubated due to acute respiratory failure, and 27 patients (45%) due to poor neurological status (Table 1). All patients received deep-venous treatment prophylaxis by low-molecular-weight heparin or unfractionated heparin, which was stopped the day before the procedure. APTT and INR were not significantly different between the two groups (Table 1). APTT and INR were in the normal range values.

Patients' demographics and characteristics

Table 1 summarizes the baseline characteristics. All variables are well balanced between the two groups except for hypertension, which was significantly higher in the real-time US-guided LMA-assisted group. The duration

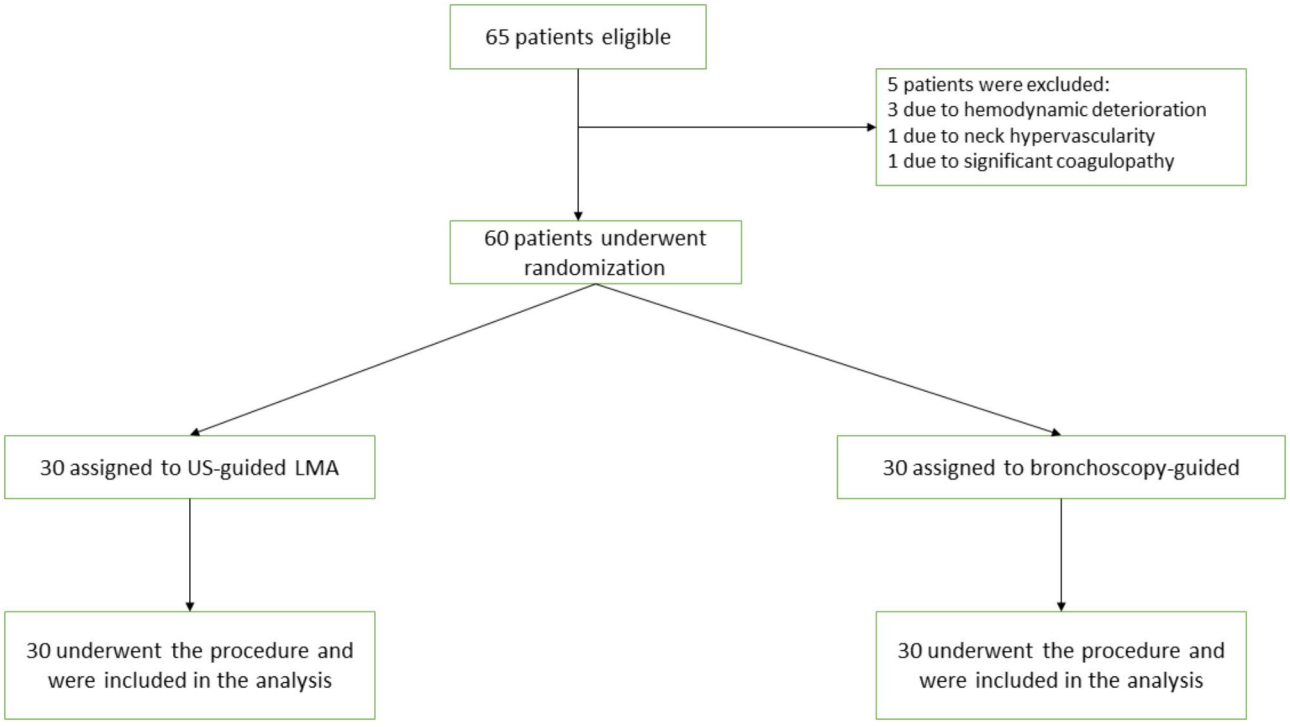

Fig. 2 Study flowchart

Table 1 Sociodemographic and baseline data of the patients (*N* = 60)

Variables	All patients (*n* = 60)	Bronchoscopy-guided (*n* = 30)	Ultrasound-guided LMA-assisted (*n* = 30)	*P*-value
Age, Y	46 [39–61]	50 [42–62]	44 [36–59]	0.21
Sex, male, *n* (%)	47 (78.3)	22 (73.3)	25 (83.3)	0.532
Weight, kg	79.2 [70.0–91.0]	81.2 [71.5–90.2]	75.4 [67.8–91.5]	0.482
BMI, Kg/m^2	28.6 [26.4–32.3]	29.1 [26.9–31.3]	28.1 [24.8–33.5]	0.756
APACHE II score	12 [6–18]	12 [6–18]	12 [6–18]	0.911
Duration of intubation, day	10.7 ± 5.0	9.8 ± 5.3	11.7 ± 4.4	0.123
Comorbidities, *n* (%)				
Diabetes	17 (28.3)	8 (26.7)	9 (30.0)	0.774
Chronic hypertension	20 (33.3)	6 (20.0)	14 (46.7)	**0.028**
Chronic heart disease	7 (11.7)	3 (10.0)	4 (20.0)	1.00
Reasons for intubation, *n* (%)				
Acute respiratory failure	33 (55.0)	17 (56.7)	16 (53.3)	0.795
Poor neurological status	27 (45.0)	13 (43.3)	14 (46.7)	0.795
APTT, sec	35 [30–41]	34.5 [30–42]	35 [29–41]	0.635
INR	1.0 [0.9–1.2]	1.0 [0.9–1.2]	1.0 [1.0-1.2]	0.994

BMI, body mass index; APACHE, acute physiologic assessment, and chronic health evaluation; DM, diabetes mellites; APTT, activated partial thromboplastin time; INR, international normalized ratio; LMA, laryngeal mask airway. Data are expressed as mean ± SD, median [25–75 interquartile], or count (%)

Table 2 Procedure-related characteristics of the studied groups (*N* = 60)

Variables	Bronchoscopy-guided (*n* = 30)	Ultrasound-guided LMA-assisted (*n* = 30)	*P*-value
Tracheal ring position, *n* (%)			0.189
Between 1st and 2nd	7 (24.1)	3 (10.0)	
Between 2nd and 3rd	21 (72.4)	27 (90)	
Between 3rd and 4th	1 (3.4)	0 (0.0)	
Procedure time, min	35 [28–39]	17 [15–20]	**< 0.001**
Equipment damage, *n* (%)	6 (20.0)	0 (0.0)	**0.024**

LMA, laryngeal mask airway. Data are expressed as mean ± SD, median [25–75 interquartile], or count (%)

of intubation was comparable between the real-time US-guided LMA-assisted group (11.7 ± 4.4 days) and the bronchoscopy-guided group (9.8 ± 5.3 days) (Table 1).

Procedure-related characteristics of the studied group

The procedure-related characteristics are summarized in Table 2. Tracheostomy sites were similar between the 2 groups. The real-time US-guided LMA-assisted group had significantly shorter procedure time (17 [IQR: 15–20] min) compared to the bronchoscopy-guided group (35 [IQR: 28–39] min). Equipment damage during the procedure was significantly higher in the bronchoscopy-guided group (20%) compared to the real-time US-guided LMA-assisted group (0%) (Table 2).

The tracheostomy costs were significantly lower in the real-time US-guided LMA-assisted group (300 [IQR: 300–450] USD) compared to the bronchoscopy-guided group (800 [IQR: 800–1000] USD) ($p < 0.001$).

Complication-related data of the studied groups

The total number of complications related to the procedure was significantly higher in the bronchoscopy-guided group than in the real-time US-guided LMA-assisted group [19 (63.3%) vs. 4 (13.3%), $p < 0.001$]. The overall major complications rate was significantly higher in the bronchoscopy-guided group than in the real-time US-guided LMA-assisted group [11 (36.7%) vs. 1 (3.3%), $p = 0.002$]. Although the rate of bleeding was higher in the bronchoscopy-guided group than in the real-time US-guided LMA-assisted group, it was not statistically significant (26.7% vs. 10%, $p = 0.181$) (Table 3). However, taking separately each one of the major complications (failure, pneumothorax, false passage, and tracheal ring fracture), no significant differences were found between the 2 groups (Table 3).

Multiple linear regression analysis with procedure time as the dependent variable

After adjusting for age, patients' severity, and duration of intubation, the real-time US-guided LMA-assisted group was independently associated with shorter procedure time compared to the bronchoscopy-guided group (Table 4).

Multivariable linear regression analysis with cost as the dependent variable

After adjusting for age, patients' severity, and duration of intubation, the real-time US-guided LMA-assisted group was independently associated with lower costs than the bronchoscopy-guided group (Table 5).

Table 3 Complications-related data of the studied groups (*N* = 60)

Variables	Bronchoscopy-guided (*n* = 30)	Ultrasound-guided LMA-assisted (*n* = 30)	*P*-value
Minor bleeding, *n* (%)	8 (26.7)	3 (10.0)	0.181
Pneumothorax, *n* (%)	2 (6.7)	0 (0.0)	0.492
False passage, *n* (%)	3 (10.0)	0 (0.0)	0.237
Tracheal ring fracture, *n* (%)	5 (16.7)	1 (3.3)	0.195
Failure, *n* (%)	1 (3.3)	0 (0.0)	1.00
Hypotension, *n* (%)	0 (0.0)	0 (0.0)	1.00
Desaturation, *n* (%)	0 (0.0)	0 (0.0)	1.00
Ruptured ETT cuff, *n* (%)	0 (0.0)	0 (0.0)	1.00
Total, *n* (%)	19 (63.3)	4 (13.3)	**0.004**

ETT, endotracheal tube; LMA, laryngeal mask airway. Data are expressed as count (%)

Table 4 Multivariable linear regression analysis with procedure time as the dependent variable

Variables	Standardized coefficient (ß)	95% confidence interval	*P*-value
Age, y	**0.005**	**-0.108 to 0.119**	0.925
Duration of intubation, day	**-0.068**	**-0.396 to 0.260**	0.678
APACHE score	**-0.182**	**-0.404 to 0.039**	0.105
Hypertension (reference: no)	**-0.075**	**-3.672 to 3.522**	0.967
Groups (reference: Bronchoscopy-guided)	**-16.977**	**-20.363 to -13.592**	**< 0.001**

Table 5 Multivariable linear regression analysis with cost as the dependent variable

Variables	unstandardized coefficient (ß)	95% confidence interval	*P*-value
Age, y	**-1.603**	**-5.643 to 2.437**	0.430
Duration of intubation, day	**-9.637**	**-21.305 to 2.03**	0.104
APACHE score	**1.239**	**-6.647 to 9.126**	0.754
Hypertension (reference: no)	**98.05**	**-29.951 to 226.082**	0.130
Groups (reference: bronchoscopy-guided)	**-1064.174**	**-1184.667 to -943.681**	**< 0.001**

Discussion

Ultrasonography has transformed airway management by offering improved accessibility and portability. It enables visualization of key airway structures, such as the tongue, oropharynx, larynx, and trachea. Integrating ultrasonography for preprocedural assessment and real-time guidance during percutaneous tracheostomy can significantly enhance the procedure's safety and efficacy [30, 31].

The present study investigated the efficacy of two different tracheostomy techniques, the real-time US-guided LMA-assisted and the bronchoscopy-guided techniques, in percutaneous dilatational tracheostomy regarding procedure-related characteristics and related complications. Compared to the bronchoscopy-guided group, the US-guided LMA-assisted group had shorter procedure time, lower costs, and no equipment damage. Complication rates were lower in the real-time US-guided LMA-assisted group than in the bronchoscopy-guided group. The benefits of ultrasound guidance in reducing procedure time and cost were confirmed after adjusting for possible confounders.

The median duration of the procedure was significantly shorter in the real-time US-guided LMA-assisted group than in the bronchoscopy-guided group, even after adjustment for different confounders. Our results are in line with the findings of other studies [14, 24, 25, 32]. In a randomized prospective study that included 74 ICU patients, the median time for tracheostomy was 12 [IQR: 9–14] min in the US-guided PDT group compared to 18 [IQR: 12-21.5] min in the bronchoscopy-guided PDT group ($p = 0.05$) [14]. In a retrospective study that included 61 ICU patients (11 patients in the bronchoscopy-guided group and 49 patients in the US-guided group), Gobatto et al. found that the procedure length was significantly shorter in the US-guided group compared to the bronchoscopy-guided group (median 12 [IQR: 8–15] min vs. 15 [IQR: 15-21.5] min, $p = 0.028$) [24]. However, other studies reported non-significant differences in procedural time between the two groups [22, 33]. Indeed, Gobatto et al. randomly assigned 60 ICU patients to the US-guided group and 58 ICU patients to the bronchoscopy-guided group. The authors found that the median procedure length was similar in both groups, 11 [IQR: 7–19] min vs. 13 [IQR: 8–20] min, respectively, ($P = 0.468$) [22]. In that trial, US-guided PDT was found to be non-inferior to bronchoscopy-guided PDT in ICU mechanically ventilated patients in terms of procedure failure defined as a composite end-point of conversion to a surgical tracheostomy. In a randomized controlled trial that compared the landmark-guided and US-guided PDT,

the mean total procedure time was similar between the two groups (4.86 ± 8.03 min vs. 5.98 ± 10.23 min, respectively, $p = 0.542$) [33]. These differences in the time taken for the procedure by the US vs. bronchoscopy-guided approaches can be due to many factors, specifically the operator's experience, the type of assistance, the patient's anatomy, and the difficulty level.

Even though individual major complications were not significantly different between the two groups (Table 3), we found that the overall number of major complications related to the procedures was significantly higher in the bronchoscopy-guided group than in the real-time US-guided LMA-assisted group (36.7% vs. 3.3%). Our findings are not in alignment with the findings of other studies [14, 16, 22, 32, 33]. The range of major complications was from 0 to 20.8% in the bronchoscopy-guided or landmark-guided PDT compared to a range from 0 to 4% in the US-guided group in those studies. In a meta-analysis that included 588 patients from 4 RCTs, only 10 (1.7%) major complications were reported, and there were no significant differences between patients who were assigned to the US-guided PDT and patients who were assigned to the bronchoscopy-guided PDT or landmark-guided PDT [34]. The pooled minor complications rate was 19.2%, ranging from 9.6 to 37.8%. The minor complication rates were also not different between patients randomized to the US-guided PDT and those randomized to the bronchoscopy-guided PDT or landmark-guided PDT [34]. We do not clearly explain why we observed a high rate of major complications in the bronchoscopy-guided group. All the physicians who performed the PDT (bronchoscopy-guided and US-guided) in this study were well-trained and experienced in PDT procedures. Major complication rates are usually low. In a large retrospective cohort previously published and included 1000 patients who underwent bronchoscopy-guided PDT, the major complication rate was 1.4% [35].

Our institution's standard method for tracheostomy procedures has been bronchoscopy-guided PDT. Bronchoscopy has traditionally been recommended as an adjunctive tool to assist PDT and prevent complications [35–37]. However, no RCTs have been published to date comparing bronchoscopy-guided PDT to landmark-guided PDT. Bronchoscopy guidance during PDT has been routinely used in 69.2–97.7% of cases, according to published surveys [38, 39], and of that remaining, 1% would choose to use a bronchoscopy in the presence of a difficult airway [39]. Nevertheless, other studies have found no difference in the complication rates when a PDT was performed with or without bronchoscopy guidance, suggesting that its use is not routinely required [40, 41].

The advantage of US-guided PDT is its ability to avoid vascular structures anterior to the trachea. The minor bleeding rate was lower in the real-time US-guided LMA-assisted group than in the bronchoscopy-guided group, but the difference was not statistically significant (Table 3). Minor to moderate amounts of bleeding were observed in 33.3% of patients randomly assigned to bronchoscopy-guided PDT compared to no bleeding in patients randomly assigned to US-guided PDT ($p < 0.05$) [14]. In a retrospective study, minor bleeding was observed in 9% of patients who received bronchoscopy-guided PDT compared to 4% in patients who received US-guided PDT, but the difference was not statistically significant ($p = 0.49$) [24]. In an RCT that compared landmark-guided PDT and US-guided PDT, major bleeding was reported in 8% of the patients in the landmark-guided group compared to 0% in the US-guided group ($p = 0.157$), and minor bleeding was reported in 29% of the patients in the landmark-guided group compared to 13% in the US-guided group ($p = 0.177$) [16].

We observed a significantly lower equipment damage rate in the US-guided LMA-assisted group than in the bronchoscopy-guided group (Table 2), which was likely due to the use of laryngeal mask airways in these patients. Laryngeal mask airways have been used successfully instead of ETTs during PDT [26–29]. Those studies showed that using an LMA instead of an ETT during bronchoscopy-controlled PDT significantly improves the visualization of relevant tracheal structures because the tip of the bronchoscope could be positioned at the level of the vocal cords. The improved visibility of tracheal structures should decrease the incidence of complications such as puncture of the bronchoscope [42, 43] and loss of airway by accidental extubation [26, 44, 45] with subsequent hypoxia [45–47], among others.

Our study is the first to include a cost analysis related to the two different approaches to PDT. We found that the real-time US-guided LMA-assisted technique was associated with lower costs than the bronchoscopy-guided approach, even after adjusting for different confounders (Table 5). The cost disparity between bronchoscopy-guided and real-time US-guided LMA-assisted tracheostomy techniques might have arisen from differences in equipment utilization, procedural demands, and associated risks. Indeed, bronchoscopy-guided procedures necessitate using a full bronchoscope tower, including flexible fibro-optic bronchoscopes and advanced video systems, for continuous visualization throughout the procedure. This reliance on high-specification equipment and supplementary accessories significantly elevates costs. In contrast, real-time US-guided LMA-assisted tracheostomy employs a handheld portable bronchoscope, used only intermittently to confirm the placement of the guidewire. This limited and targeted utilization markedly reduces equipment-related expenses. Also, continuous use of the bronchoscope

during bronchoscopy-guided procedures heightens the risk of equipment damage, such as punctures to the fiberoptic system, which can lead to costly repairs or replacements. By comparison, the selective and sparing use of the bronchoscope in real-time US-guided LMA-assisted procedures minimizes this risk, further contributing to cost efficiency. We believe that the equipment damage had a major contribution to the differences in costs between the two groups since equipment damage was observed in 20% of patients in the bronchoscopy-guided group compared to 0% in the US-guided LMA-assisted group ($p = 0.024$, Table 2). This finding should be validated in future larger studies from different countries.

The study's results have important clinical implications. Using ultrasound guidance during tracheostomy procedures along with LMA offers several advantages. It ensures accurate tube placement and reduces complications. Additionally, ultrasound guidance with LMA leads to shorter procedure times, improved efficiency, and reduced equipment damage. The cost analysis highlights the economic benefits of the ultrasound-guided tracheostomy technique. Incorporating ultrasound guidance can enhance patient outcomes, procedural efficiency, and cost-effectiveness.

The study demonstrates several strengths, including prospective randomization, strict maintenance of allocation concealment, and a high percentage of enrollments of eligible patients. The clear and well-defined inclusion and exclusion criteria ensured the study population was appropriate. Using multivariable linear regression analysis allowed for the adjustment of potential confounding factors. The clinical outcomes were clinically relevant, and the data analysis was blinded. Overall, these strengths enhanced the validity and reliability of the study findings. Also, to the best of our knowledge, our study is the first RCT comparing this new technique of PDT (real-time US-guided puncture LMA-assisted technique) to another PDT technique.

The study has important limitations. First, the study was conducted at a single center, which may restrict the generalizability of the results to other healthcare facilities. Second, the complication rate in the bronchoscopy-guided group was higher than reported in the literature [48], which might be related to our small sample size. Third, the patients were followed only until hospital discharge and were not assessed for late complications such as tracheal stenosis, vocal abnormalities, or scar characteristics. Fourth, blinding was not possible because of the nature of the procedures, and the outcome assessments were not blinded. Fifth, the laryngeal mask airway was used only in the US-guided PDT, and therefore, its effects could not be evaluated independently. Sixth, although all operators were experienced in both techniques, we did not formally quantify or compare their individual experience levels with each method. It is possible that some differences in operator proficiency may have influenced complication rates, particularly in the bronchoscopy-guided group.

Conclusions

The findings of this single-center randomized controlled trial suggest that real-time US-guided LMA-assisted PDT may offer advantages in procedure time, cost, and complication rates compared to the bronchoscopy-guided technique. However, further multi-center randomized controlled trial with larger sample sizes are needed to validate these results and assess the generalizability of this technique.

Abbreviations

ICU	Intensive care unit
US	Ultrasound
PDT	Percutaneous dilatational tracheostomy
LMA	Laryngeal mask airway
ETT	Endotracheal tube
RCT	Randomized controlled trial
FiO_2	Fraction of inspired oxygen
PEEP	Positive end-expiratory pressure
IQR	Interquartile range
BMI	Body mass index
APACHE	Acute Physiology and Chronic Health Evaluation

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12890-025-03645-6.

Supplementary Material 1

Author contributions

All authors have contributed significantly to all parts of this paper, and all authors agree with the content of the manuscript. Authors A.T., S.T., M.E., and A.A., contributed to the design; authors A.T., and S.T., contributed to data collection; authors A.T., S.T., and J.M., contributed to the data analysis; authors A.T., S.T., M.E., A.A., and J.M., contributed to writing, interpreting, and re-viewing the final manuscript. All members of the team contributed to the management or ad-ministration of the trial. All authors have read and agreed to the published version of the manuscript.

Funding

This research project received no funding from any external sources. The authors independently conducted the study and received no financial support or grants from organizations or individuals for this work.

Data availability

The data that support the findings of this study are available from the authors but restrictions apply to the availability of these data, and so are not publicly available. Data are, however, available from the corresponding authors upon reasonable request.

Declarations

Ethics approval and consent to participate

The work was approved by the local Research Ethics Committee of Ain Shams University Faculty of Medicine (reference number: FMASU MD 164/2021) approved the protocol on December 3rd, 2021. The study was retrospectively registered in the ISRCTN registry (registration number ISRCTN14218985) on 02/07/2024.

Informed consent
Informed written consent was obtained from the patients or their legal guardians in a private setting, where the study protocol was thoroughly explained to them.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Author details
[1]Department of Anesthesia, Intensive Care and Pain Management, Faculty of Medicine, Ain Shams University, P.O. Box 11331, Cairo, Egypt
[2]Critical Care Institute, Cleveland Clinic Abu Dhabi, P.O. Box 112412, Abu Dhabi, United Arab Emirates
[3]Cleveland Clinic Lerner College of Medicine, Case Western Reserve University, Cleveland, OH 44106, USA

Received: 5 January 2025 / Accepted: 2 April 2025
Published online: 25 April 2025

References

1. Wunsch H, et al. The epidemiology of mechanical ventilation use in the united States. Crit Care Med. 2010;38:1947–53.
2. Goligher E, Ferguson ND. Mechanical ventilation: epidemiological insights into current practices. Curr Opin Crit Care. 2009;15:44–51.
3. Metnitz PG, et al. Epidemiology of mechanical ventilation: analysis of the SAPS 3 database. Intensive Care Med. 2009;35:816–25.
4. Hsu CL, et al. Timing of tracheostomy as a determinant of weaning success in critically ill patients: a retrospective study. Crit Care. 2005;9:R46–52.
5. Heffner JE. The role of tracheotomy in weaning. Chest. 2001;120:s477–81.
6. Merola R et al. Tracheostomy practice in the Italian intensive care units: A Point-Prevalence survey. Med (Kaunas). 2025;61.
7. Merola R et al. Timing of tracheostomy in ICU patients: A systematic review and Meta-Analysis of randomized controlled trials. Life (Basel). 2024;14.
8. Brass P, Hellmich M, Ladra A, Ladra J, Wrzosek A. Percutaneous techniques versus surgical techniques for tracheostomy. Cochrane Database Syst Rev. 2016;7:Cd008045.
9. Higgins KM, Punthakee X. Meta-analysis comparison of open versus percutaneous tracheostomy. Laryngoscope. 2007;117:447–54.
10. Delaney A, Bagshaw SM, Nalos M. Percutaneous dilatational tracheostomy versus surgical tracheostomy in critically ill patients: a systematic review and meta-analysis. Crit Care. 2006;10:R55.
11. Rashid AO, Islam S. Percutaneous tracheostomy: a comprehensive review. J Thorac Dis. 2017;9:S1128–38.
12. Soni KD, Kumar A, Aggrawal R, Saxena A. Do we need bronchoscopy during percutaneous tracheostomy? J Anaesthesiol Clin Pharmacol. 2016;32:541–3.
13. Mohan A, et al. Guidelines for diagnostic flexible bronchoscopy in adults: joint Indian chest society/national college of chest physicians (I)/Indian association for bronchology recommendations. Lung India. 2019;36:S37–89.
14. Ravi PR, Vijay MN. Real time ultrasound-guided percutaneous tracheostomy: is it a better option than bronchoscopic guided percutaneous tracheostomy? Med J Armed Forces India. 2015;71:158–64.
15. Kang HT et al. Comparison Between Real-Time Ultrasound-Guided Percutaneous Tracheostomy and Surgical Tracheostomy in Critically Ill Patients. Crit Care Res Pract. 2022;2022:1388225.
16. Rudas M, et al. Traditional landmark versus ultrasound guided tracheal puncture during percutaneous dilatational tracheostomy in adult intensive care patients: a randomised controlled trial. Crit Care. 2014;18:514.
17. Kumar P, et al. Percutaneous tracheostomy under Real-time ultrasound guidance in coagulopathic patients: A Single-center experience. Indian J Crit Care Med. 2020;24:122–7.
18. Gupta PK, Gupta K, Dwivedi AN, Jain M. Potential role of ultrasound in anesthesia and intensive care. Anesth Essays Res. 2011;5:11–9.
19. Kristensen MS, Teoh WH, Graumann O, Laursen CB. Ultrasonography for clinical decision-making and intervention in airway management: from the mouth to the lungs and pleurae. Insights Imaging. 2014;5:253–79.
20. Terkawi AS, Karakitsos D, Elbarbary M, Blaivas M, Durieux ME. Ultrasound for the anesthesiologists: present and future. ScientificWorldJournal. 2013;2013;683685.
21. Vanzant D, Mukhdomi J. Safety of Fluoroscopy in Patient, Operator, and Technician. in *StatPearls* (StatPearls Publishing Copyright © 2024, StatPearls Publishing LLC., Treasure Island (FL)). 2024.
22. Gobatto ALN, et al. Ultrasound-guided percutaneous dilational tracheostomy versus bronchoscopy-guided percutaneous dilational tracheostomy in critically ill patients (TRACHUS): a randomized noninferiority controlled trial. Intensive Care Med. 2016;42:342–51.
23. Alansari M, Alotair H, Al Aseri Z, Elhoseny MA. Use of ultrasound guidance to improve the safety of percutaneous dilatational tracheostomy: a literature review. Crit Care. 2015;19:229.
24. Gobatto AL, et al. Comparison between ultrasound- and bronchoscopy-guided percutaneous dilational tracheostomy in critically ill patients: a retrospective cohort study. J Crit Care. 2015;30:e220213–227.
25. Sarıtaş A, Kurnaz MM. Comparison of Bronchoscopy-Guided and Real-Time Ultrasound-Guided percutaneous dilatational tracheostomy: safety, complications, and effectiveness in critically ill patients. J Intensive Care Med. 2019;34:191–6.
26. Dosemeci L, Yilmaz M, Gürpinar F, Ramazanoglu A. The use of the laryngeal mask airway as an alternative to the endotracheal tube during percutaneous dilatational tracheostomy. Intensive Care Med. 2002;28:63–7.
27. Linstedt U, Möller F, Grote N, Zenz M, Prengel A. Intubating laryngeal mask as a ventilatory device during percutaneous dilatational tracheostomy: a descriptive study. Br J Anaesth. 2007;99:912–5.
28. Pratt T, Bromilow J. Laryngeal mask airway for airway control during percutaneous dilatational tracheostomy. Anaesth Intensive Care. 2011;39:1009–13.
29. Linstedt U, Zenz M, Krull K, Häger D, Prengel AW. Laryngeal mask airway or endotracheal tube for percutaneous dilatational tracheostomy: a comparison of visibility of intratracheal structures. Anesth Analg. 2010;110:1076–82.
30. Singh M, et al. Use of sonography for airway assessment: an observational study. J Ultrasound Med. 2010;29:79–85.
31. Garg R, Gupta A, Ultrasound. A promising tool for contemporary airway management. World J Clin Cases. 2015;3:926–9.
32. Kumar P, et al. Comparison of percutaneous tracheostomy methods in ICU patients: conventional anatomical landmark method versus ultrasonography method - A randomised controlled trial. Indian J Anaesth. 2022;66:S207–12.
33. Dugg K, et al. Comparison of landmark guided and ultrasound guided percutaneous dilatational tracheostomy: efficiency, efficacy and accuracy in critically ill patients. J Anaesthesiol Clin Pharmacol. 2022;38:281–7.
34. Gobatto ALN, Besen B, Cestari M, Pelosi P, Malbouisson LMS. Ultrasound-Guided percutaneous dilational tracheostomy: A systematic review of randomized controlled trials and Meta-Analysis. J Intensive Care Med. 2020;35:445–52.
35. Hinerman R, Alvarez F, Keller CA. Outcome of bedside percutaneous tracheostomy with bronchoscopic guidance. Intensive Care Med. 2000;26:1850–6.
36. Polderman KH, et al. Percutaneous dilatational tracheostomy in the ICU: optimal organization, low complication rates, and description of a new complication. Chest. 2003;123:1595–602.
37. Tomsic JP, Connolly MC, Joe VC, Wong DT. Evaluation of bronchoscopic-assisted percutaneous tracheostomy. Am Surg. 2006;72:970–2.
38. Vargas M, et al. Tracheostomy procedures in the intensive care unit: an international survey. Crit Care. 2015;19:291.
39. Kluge S, et al. Tracheostomy in the intensive care unit: a nationwide survey. Anesth Analg. 2008;107:1639–43.
40. Jackson LS, et al. Percutaneous tracheostomy: to bronch or not to bronch–that is the question. J Trauma. 2011;71:1553–6.
41. Abdulla S, Conrad A, Vielhaber S, Eckhardt R, Abdulla W. Should a percutaneous dilational tracheostomy be guided with a bronchoscope? B-ENT. 2013;9:227–34.
42. Kirkpatrick MB, Smith JR, Hoffman PJ, Middleton RM. 3rd. Bronchoscope damage and repair costs: results of a regional postal survey. Respir Care. 1992;37:1256–9.
43. Shen LY, et al. Percutaneous tracheostomy placement with external laser light transillumination identifies proper tracheal orientation and improves surgeon insertion confidence. Am J Surg. 2007;194:409–12.
44. Cattano D, et al. The use of the laryngeal mask airway during guidewire dilating forceps tracheostomy. Anesth Analg. 2006;103:453–7. table of contents.
45. Freeman BD, Isabella K, Lin N, Buchman TG. A meta-analysis of prospective trials comparing percutaneous and surgical tracheostomy in critically ill patients. Chest. 2000;118:1412–8.

46. Kost KM. Endoscopic percutaneous dilatational tracheotomy: a prospective evaluation of 500 consecutive cases. Laryngoscope. 2005;115:1–30.
47. Walz MK, et al. Percutaneous dilatational tracheostomy–early results and long-term outcome of 326 critically ill patients. Intensive Care Med. 1998;24:685–90.
48. Kornblith LZ, et al. One thousand bedside percutaneous tracheostomies in the surgical intensive care unit: time to change the gold standard. J Am Coll Surg. 2011;212:163–70.

Publisher's note