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Original Contribution

Minimally-invasive tracheostomy (MIT): A care bundle for safety improvement in high-risk critically ill patients

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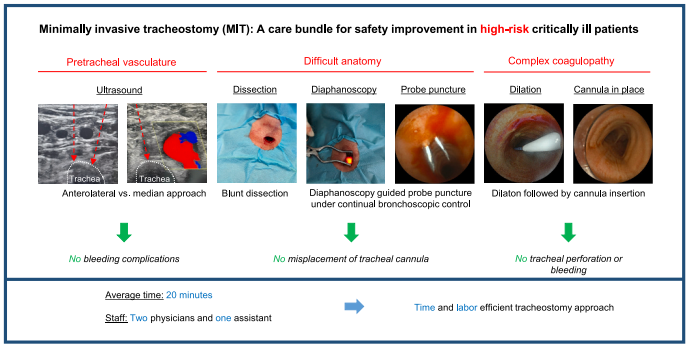
HIGHLIGHTS

- Minimally invasive tracheostomy (MIT) in patients with pretracheal vasculature, atypical anatomy, or coagulation disorders.
- MIT involves a skin incision, tissue dissection, a probe puncture guided by diaphanoscopy, and bronchoscopic surveillance.
- The MIT approach is safe and can be performed without any complications.
- MIT is faster and more efficient with regard to deployment of medical and nursing staff than surgical tracheostomy.

GRAPHICAL ABSTRACT



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ABSTRACT

Background: Detailed reports are scarce on minimally-invasive tracheostomy (MIT) techniques for critically ill patients with challenging anatomy or complex coagulopathies. In such high-risk patients, conventional percutaneous dilatational tracheostomy (PDT) may lead to severe complications.
Methods: Aiming to broaden the scope of MIT for patients previously excluded due to high risks, we developed a new care bundle (MIT technique), specifically designed for intensive care specialists. Our study examined the

Abbreviations: aPTT, Activated Partial Thromboplastin Time; BMI, Body mass index; COVID-19, Coronavirus Disease 19; FiO2, Fraction of inspired oxygen; G, Gauge; hTS, hybrid tracheostomy; ICU, Intensive care unit; INR, International Normalized Ratio; L, Anterolateral; M, Midline; MIT, Minimal Invasive Tracheostomy; PDT, Percutaneous dilatational tracheostomy; PEEP, Positive end-expiratory pressure; PPSB, Prothrombin complex concentrate; SEM, Standard error of the mean; ST, Surgical tracheostomy.

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outcomes of MIT in 32 high-risk patients treated in an ICU of a University Hospital with specific focus on gastrointestinal and liver diseases.
Results: We have modified the conventional PDT technique by incorporating an initial skin incision, blunt dissection, diaphanoscopy-guided probe puncture, and continuous bronchoscopic monitoring. Our care bundle also introduces an anterolateral approach for tracheal entry, a significant advancement for patients with complex neck anatomy or dense vasculature, where an anterolateral trajectory avoids midline blood vessels. This enhanced method has proven to be safer than traditional PDT, with a notable absence of post-procedural hemorrhages, cannula misplacements, or infections.
Conclusion: The use of our refined care bundle enabled swift minimally-invasive tracheostomy in high-risk patients without the occurrence of serious complications.

1. Introduction

Tracheostomy represents a key procedure on intensive care units facilitating prolonged mechanical ventilation in critically ill patients [1]. Aggravated by the COVID-19 pandemic, the demand for intensive care treatment including prolonged mechanical ventilation has been steadily rising over recent years. [2] For decades, surgical tracheostomy (ST) performed by head and neck surgeons, or thoracic surgeons constituted the gold standard for tracheal cannulation on intensive care units [3]. Nevertheless, disadvantages of ST for ICU specialists encompass time and labor intensity, dependence on surgeons or otolaryngologists, and visible unaesthetic scar.

Seeking to develop a faster non-surgical tracheostomy (non-ST) procedure, which could be successfully executed by intensive care specialists, Ciaglia et al. broadly introduced the technique of PDT. Contrary to ST, PDT is based on the percutaneous puncture of the trachea [4]. Over recent years, a multitude of reports on successful PDT in critically ill patients have been published corroborating the feasibility, practicability, and efficiency of this non-surgical intervention in modern day intensive care medicine [5–9]. In addition, PDT usually heals without major scars and does not require a second intervention to close the tracheostoma [10]. Finally, the occurrence of tracheal stenosis, a dreaded long-term complication of tracheostomy, proved to be comparable in ST and PDT [11]. Given the advantages of non-ST, PDT superseded ST as the preferred technique for tracheal cannulation in intensive care medicine [12–14].

However, patients with difficult anatomy (e.g., obesity, thick necks, and reduced neck mobility) or coagulation disorders (e.g., liver cirrhosis and hematological diseases) have widely been excluded from PDT due to concerns for complications, such as tissue damage and bleeding [6,12,15,16]. Thus, for high-risk patients characterized by an elevated risk for bleeding, previous neck surgery, or by an expected difficult percutaneous tracheal puncture, classical ST is still deemed the procedure of choice [6,12,14,15]. With a growing number of obese patients and coagulation disorders frequently occurring during intensive care treatment [17,18], the proportion of high-risk patients ineligible to PDT still remains sizable. Data shows that high-risk patients unsuitable for PDT often experience worse prognosis and clinical outcomes due to delayed ST [19,20]. Therefore, there is a further strong recommendation to adapt PDT for use in these high-risk patients.

In recent years, several reports on a novel tracheostomy procedure, termed hybrid tracheostomy (hTS), merging elements from ST and PDT were published [21–25]. In a seminal study on hTS, Kang et al. presented data showing that hTS proved to be as fast as conventional PDT, and no major bleeding complications occurred despite a sizable portion of the patients taking antiplatelet drugs and anticoagulants [21]. However, a paratracheal placement of the tracheostomy tube was observed in one patient constituting the only serious complication associated with hTS in this report. In sum, Kang et al. concluded that hTS can be safely and swiftly performed in most patients, including those taking anticoagulants, but should be omitted in high-risk patients with difficult anatomy [21]. To date, comprehensive reports on minimally-invasive approaches to tracheostomy of high-risk patients with difficult anatomy or an increased propensity to bleeding are scant. Especially in obese patients with thick necks and reduced neck mobility, tracheostomy is thus far exclusively recommended to be carried out by trained surgeons.

The aim of the study was to provide a care bundle for safety improvement of minimally-invasive tracheostomy in high-risk patients with difficult anatomy and bleeding disorders. For the first time, we describe the joint use of preprocedure ultrasound to select between a median or anterolateral puncture trajectory, an initial skin incision, blunt tissue dissection, a probe puncture supported by diaphanoscopy, and bronchoscopic guidance to reduce tracheostomy-related complications in high-risk critically ill patients. Tracheostomy of high-risk patients was executed by critical care specialists and experienced residents on an intensive care unit and no serious complications occurred. In sum, we present a universal approach to MIT applicable without absolute patient-related contraindications.

2. Methods

2.1. Patients

We included 32 critically ill patients from the Intensive Care Unit of a German University Hospital who underwent MIT between March and October 2023. These patients, all requiring prolonged mechanical ventilation, were treated using the MIT care bundle. Prior to implementing this care bundle, the standard tracheostomy procedure in our ICU was either conventional PDT or surgical intervention for those with coagulation disorders or anatomical challenges. This study also analyzes comparative data from 19 patients treated with conventional PDT and 15 patients with ST. We gathered demographic, clinical, laboratory, and procedural data from the medical records. Ethics approval was granted by the University Regensburg Ethics Committee (ethics statement number: 23–3499-104), with the legal guardians of all patients providing written informed consent for the tracheostomy procedure.

2.2. Inclusion and exclusion criteria

In principle, patients requiring mechanical ventilation for longer than 14 days were subjected to tracheostomy. Between March and October 2023, tracheostomy was exclusively performed using the MIT care bundle without predefined inclusion or exclusion criteria. Prior to March 2023, PDT constituted the standard approach to tracheostomy in the majority of patients. Exclusion criteria for PDT signifying the necessity for ST or MIT (after March 2023) were predicated on medical history, physical examination, ultrasound examination, and coagulation status on the day of tracheostomy. Specifically, patients with a history of a previous allogeneic stem cell transplantation, a body mass index (kg/m2) $>$ 30, a short neck with reduced neck mobility, a thick skin, prominent peritracheal blood vessels on ultrasound, goiter or a clinically manifest susceptibility to bleeding were excluded from PDT and subjected to ST or MIT as high-risk patients. Besides, further criteria for considering patients at high-risk for PDT involved a previous history of liver cirrhosis, COVID-19 pneumonia, the use of double antiplatelet therapy, and compromised laboratory parameters, such as a reduced platelet count, a prolonged activated partial thromboplastin time, a compromised INR value or a low hemoglobin level.

2.3. MIT approach for high-risk patients

In our ICU, we implemented a bedside, MIT protocol, negating the need for patient transport. This technique prioritizes proper neck extension, achievable with a simple pillow placement under the shoulders. We describe two approaches: the standard median for routine cases and an alternative anterolateral method to avoid midline vascular structures.

The median approach with puncture of the trachea in midline constituted the standard procedure. Initially, the neck of the patient was extended, sterilized, and draped. Then, the endotracheal tube was retracted to 17–18 cm teeth line under bronchoscopy guidance. Afterwards, a horizontal incision measuring 1–2 cm was made approximately 1.5 cm above the sternal notch. Using fingers and the blunt ends of a pair of scissors, the pretracheal tissue was carefully dissected, and the skin incision margins were retracted by inserting a spreader. Blunt dissection was continued until the anterior tracheal wall was reached, which was either confirmed by direct vision, or in severely obese patients via palpation. Noteworthy, retracting the pretracheal tissue using a spreader stabilizes the incision site significantly and facilitates a clear exposure of the trachea. Under bronchoscopic surveillance and by employing diaphanoscopy for guidance, the trachea was first punctured between two tracheal rings, ideally between the 2nd and 3rd tracheal rings, with a thin 22 G injection cannula. The second tracheal puncture executed with the tracheostomy catheter was placed right next to the probe puncture. Then, a guidewire was inserted, and successive dilations with two dilators incrementing in size were performed. Of note, while the big dilator is still in place, to avoid aerosolization of secretions and protect health-care workers, we paused the ventilator. After quickly removing the dilator and inserting the cannula over the guidewire, mechanical ventilation was restarted via the new tracheal cannula. The anterolateral approach comprising tracheal puncture off the midline was adopted in case of prominent dense blood vessels located in the midline. Similar to the median approach, the anterolateral approach was carried out under permanent bronchoscopic imaging to safeguard correct puncture of the anterolateral tracheal wall followed by guidewire insertion, dilation, and placement of the cannula. Generally, the skin incision was made with a disposable scalpel. For the probe puncture, a 22 G 7 cm long injection needle was utilized. Blunt skin dissection was carried out with a scissor. The skin and pretracheal tissue were retracted using a spreader (3/4 teeth), exposing the trachea. For tracheal access the PDT set Tracoe experc Set vario purchased from Tracoe medical was employed. The Tracoe experc Set vario encompassed a 14 G tracheostomy catheter, a guidewire, a small dilator (14 French), a big dilator (Tracoe experc dilator), and a size 8 tracheal cannula. In case of bleeding from the skin, hemostasis was achieved by applying local pressure. No bipolar coagulation probe was required. Thus, this approach has eliminated the need for electrocautery in achieving hemostasis. Tracheostomies were secured with a circular fixing tape, with cannula changes scheduled after two weeks.

2.4. Imaging techniques used before and after the procedure and continuous bronchoscopic monitoring

Prior to tracheostomy, we conducted a targeted ultrasound assessment, including color flow Doppler, to identify vascular structures or goiters that might influence the choice between a median or anterolateral tracheal entry. Continuous bronchoscopic guidance is a hallmark of our procedure, ensuring precise movement of the endotracheal tube and secure tracheal access. A preemptive bronchoscopic check was performed to remove any significant bronchial blockages, maintaining ventilation stability during the procedure. Post-cannulation, we used bronchoscopy to verify the tracheal cannula's placement and to inspect for potential complications such as bleeding or tissue damage. Only after confirming the absence of complications was the orotracheal tube withdrawn. Immediately following the tracheostomy, we performed a bedside chest X-ray to ascertain the cannula's position and to exclude any adverse events like pneumothorax or pneumomediastinum.

2.5. Anesthesia and ventilation protocols for tracheostomy

Prior to the tracheostomy, all patients received at least six days of intubation and sedation monitored using the Richmond Agitation Sedation Scale. Anesthesia regimens, tailored to each patient, typically included Propofol, Midazolam, Ketamine, and Sufentanyl. A 100 mg dose of Rocuronium was administered five minutes before the tracheostomy to ensure muscle relaxation. We utilized pressure-controlled ventilation during the procedure, with the oxygen fraction increased to 100 % shortly before starting and then returned to baseline levels immediately after completing the tracheostomy. The severity of respiratory insufficiency was assessed using the Horowitz index, defined as the arterial oxygen partial pressure (mmHg) and fraction of inspired oxygen ratio.

2.6. Safety assessment following tracheostomy

Complications related to tracheostomy were defined as bleeding, pneumothorax, pneumomediastinum, perforation of the trachea, misplacement, and failure to change tracheal cannula necessitating intubation. Signs of tracheal perforation like pneumothorax and pneumomediastinum were evaluated on X-ray right after tracheostomy. Misplacement of tracheal cannula was ruled out via bronchoscopy and X-ray right after bronchoscopy. Bleeding from the insertion site of the tracheal cannula was deemed a complication if the occurrence was within two weeks after tracheostomy or if the bleeding required intervention beyond local compression.

2.7. Statistical analysis procedures

Data were presented as median (range) or frequency (%). We conducted statistical evaluations using GraphPad Prism, Version 9, and SAS Analytics Software Version 9.4. Statistical significance was determined with the two-tailed Student's *t*-test or Likelihood Ratio Chi-Square Test where appropriate. The significance level was set at $p < 0.05$.

3. Results

3.1. Patient characteristics

As of March 2023, we exclusively employed a minimally invasive technique for the tracheostomy of critically ill patients requiring prolonged mechanical ventilation. In aggregate, 32 adult patients (13 females and 19 males) treated in our medical intensive care unit were subjected to MIT. In patients with coagulopathy, difficult anatomy of the neck or under treatment with dual antiplatelet drugs, actual data recommends a surgical approach [12,14,15]. Patient characteristics of our cohort are depicted in Table 1. Primary reasons for ICU admission comprised pneumonia/sepsis and upper gastrointestinal bleeding with concomitant hemorrhagic shock. Mechanical ventilation was predominantly initiated for respiratory failure and prevention of aspiration due to fulminant upper gastrointestinal bleeding. Comorbidities encompassed liver cirrhosis and acute-on-chronic liver failure, pancreatitis, renal failure, malignant diseases, chronic obstructive pulmonary disease, coronary heart disease, gastrointestinal ischemia, and diabetes mellitus. The median age of patients was 63 years (range 26–84 years). The median weight was 90 kg (range 51–150 kg) and the median body mass index amounted to 28.4 (range 18–46.1 kg/m^2). Prolonged mechanical ventilation was usually necessitated by difficult weaning due to pneumonia, or respiratory muscles weakness.

Delayed tracheostomy in patients requiring prolonged ventilation has been associated with extended ventilator dependence, increased sedation doses, and an overall worse outcome for patients [19,20]. As all

Table 1
Patient characteristics.

Parameter	Patients[a]		
	MIT (*N* = 32)	PDT (*N* = 19)	ST (*N* = 15)
General information			
Age (years)	63 [26; 84]	61 [23; 82]	66 [29; 83]
Female: male (patients)	13: 19	7: 12	6: 9
Weight (kg)	90 [51;150]	85 [53;143]	88 [47;160]
Body mass index (kg/m^2)	28.4 [18; 46.1]	26.3 [17; 44.3]	29.2 [16; 47.3]
Time from intubation until tracheostomy (days)	9 [4; 20]	14 [12; 25]	16 [10; 24]
Diagnosis necessitating intubation			
Respiratory failure	17 (53)	12 (63)	10 (67)
Upper gastrointestinal bleeding	8 (25)	4 (21)	4 (27)
Loss of consciousness (GCS <9)	4 (13)	1 (5)	0 (0)
Resuscitation	3 (9)	2 (11)	1 (6)
Diagnosis necessitating ICU admission			
Pneumonia	14 (44)	12 (63)	9 (60)
Sepsis	6 (19)	2 (11)	1 (6)
Upper GI Bleeding with hemorrhagic shock	9 (28)	3 (15)	4 (20)
Cardiac arrest	3 (9)	2 (11)	1 (6)
Comorbidity			
Liver cirrhosis	16 (50)	13 (68)	8 (53)
Pancreatitis	2 (6)	3 (15)	1 (6)
Coronary heart disease	3 (9)	2 (11)	1 (6)
Diabetes mellitus	4 (13)	2 (11)	1 (6)
Malignancy solid / hematological	2 (6) / 2 (6)	0 (0) / 0 (0)	1 (6) / 2 (13)
Kidney failure	9 (28)	6 (31)	4 (20)
COPD	3 (9)	1 (5)	2 (13)
Gastrointestinal ischemia	2 (6)	1 (5)	1 (6)

[a] Presented as median [range] or number (%).

MIT interventions were carried out bedside by intensive care specialists, the time from intubation to tracheostomy averaged 9 days (4–20 days) in our study. In addition, corresponding baseline characteristics of patients subjected to conventional PDT or ST are documented in Table 1.

3.2. *Establishing MIT in high-risk patients*

So far, in patients considered to be high-risk cases for PDT owing to difficult anatomy or an increased propensity to bleeding, ST has represented the preferred tracheostomy approach. In our study, each patient was initially evaluated for potential risk factors related to complications of tracheostomy (Table 2). All patients considered as high-risk underwent MIT. Sixteen patients were diagnosed with liver cirrhosis, and two patients had a previous history of allogeneic bone marrow transplantation. Furthermore, two patients suffered from COVID-19 pneumonia, which is intrinsically associated with an elevated risk for pneumothorax [26], coagulopathy, and additionally bears the risk of spreading infection during tracheostomy [24]. Physical examination revealed a body mass index of greater than 30 in twelve patients, a short neck in 14 patients, and a reduced neck mobility in 15 patients. Moreover, eight patients presented with an unusually thick skin visible on ultrasound, including one patient with graft versus host disease of the skin and one patient with Pembrolizumab induced skin toxicity. Patients with obesity, a short neck, a reduced neck mobility, or a thick skin are deemed high-risk patients for tracheostomy related complications, and thus are frequently excluded from PDT or MIT procedures in the literature so far [6,12,14,15].

To further assess the risk for bleeding complications, an ultrasound examination supported by color flow of the neck was performed prior to tracheostomy, which revealed the presence of prominent blood vessels

Table 2
Risk factors related to complications of tracheostomy.

Parameter	Patients[a]		
	MIT (N = 32)	PDT (N = 19)	ST (N = 15)
Medical history			
Liver cirrhosis[b]	16 (50)	13 (68)	8 (53)
Allogeneic stem cell transplantation[b]	2 (6)	0 (0)	2 (13)
COVID-19 Pneumonia[c]	2 (6)	1 (5)	7 (46)
Double antiplatelet therapy	1 (3)	0 (0)	0 (0)
Physical examination			
Body mass index (kg/m^2) > 30	12 (38)	4 (21)	8 (53)
Short neck	14 (44)	0 (0)	7 (46)
Reduced neck mobility	15 (47)	0 (0)	6 (40)
Thick skin	8 (25)	0 (0)	2 (13)
Ultrasound examination			
Prominent blood vessels close to trachea	25 (78)	0 (0)	1 (6)
Goiter	4 (13)	0 (0)	1 (6)
Coagulation status on the day of MIT			
Clinically manifest susceptibility to bleeding	23 (72)	9 (47)	10 (66)
Platelet count (G/L)	105 [17; 397]	112 [20; 417]	102 [23; 390]
aPTT (s)	43.2 [23.6; 58.6]	46.1 [25.3; 59]	45.4 [23.8; 56.1]
INR	1.2 [0.94; 2.26]	1.1 [0.98; 1.85]	1.2 [0.97; 2.00]
Hb (g/dL)	7.85 [6.4; 13.6]	8.1 [6.8; 14.2]	8.3 [7.2; 14.7]
Preprocedure administration of TCs[d]	11 (34)	9 (47)	10 (66)
Preprocedure administration of FFP[e]	1 (3)	4 (21)	2 (13)
Preprocedure administration of PPSB	8 (25)	6 (31)	4 (26)
Preprocedure administration of ECs[f]	2 (6)	1 (5)	6 (32)

[a] Presented as median [range] or number (%).
[b] Risk of bleeding complications and suboptimal tissue repair.
[c] Risk of pneumothorax and spreading infection.
[d] Thrombocyte concentrates.
[e] Fresh frozen plasma. [f]Erythrocyte concentrates.

in close proximity to the trachea in the majority of patients (25 out of 32 patients). Four patients showed an enlarged thyroid gland. A clinically manifest susceptibility to bleeding defined by the medical history, the presence of subcutaneous hematomas, or abnormal laboratory parameters was evident in more than half of all patients (23 out of 32). The median platelet count on the day of tracheostomy was 105 G/L (range 17–397), and eleven patients with higher-grade thrombocytopenia below 50 G/L received a thrombocyte infusion before starting tracheostomy. In one patient, MIT was executed during dual antiplatelet therapy. The median values for aPTT and INR on the day of tracheostomy were 43.2 s (range 23.6–58.6 s) and 1.2 (range 0.94–2.26), respectively. Preprocedural improvement of plasmatic coagulation using prothrombin complex concentrate (PPSB) or fresh frozen plasma was carried out in eight patients. The average hemoglobin level prior to tracheostomy was 7.85 g/dL (range 6.4–13.6 g/dL) and preprocedural blood transfusions were only necessary in two patients with hemoglobin levels below 7 g/dL prior to tracheostomy. Regarding the respiratory status prior to tracheostomy (Table 3), the median FiO2 amounted to 0.45 (range 0.3–0.85), the median positive end-expiratory pressure (PEEP) was 8.5 cm H_2O (range 5–13 cm H_2O), and the median driving pressure was 14 cm H_2O (range 7–20 cmH_2O). The median Horowitz index was calculated to be 172.5 (range 74–294) indicating an escalated

Table 3
Ventilator settings prior to tracheostomy.

Parameter	Patients[a]		
	MIT (N = 32)	PDT (N = 19)	ST (N = 15)
FiO2	0.45 [0.3, 0.85]	0.43 [0.3, 0.80]	0.52 [0.3, 0.90]
PEEP (cmH2O)	8,5 [5; 13]	9 [5; 14]	9 [5; 16]
Driving pressure (cmH2O)	14 [7; 20]	12 [6; 18]	15 [9; 24]
Horowitz index[b]	172,5 [74; 294]	180 [90; 280]	163 [72; 297]

[a] Presented as median [range] or number (%).
[b] Horowitz index defined as ratio arterial oxygen partial pressure (mmHg) and fraction of inspired oxygen.

respiratory support for the majority of patients prior to tracheostomy. In addition, risk factors for tracheostomy and ventilator settings prior to tracheostomy for comparative patient cohorts subjected to conventional PDT or ST are documented in Table 2 and Table 3, respectively.

3.3. An optimized approach for MIT of high-risk patients – the median standard approach

All procedures were performed at bedside by intensive care specialists or experienced residents with a background in internal medicine. No trained surgeons were involved in the procedure. As preparation for MIT, focused brief ultrasound examination using color flow was performed to mark a site for skin incision and map a safe trajectory for tracheal access. The intensivist who performed the procedure stood on the right side of the patient, while the bronchoscopist was placed at the patient's head. An intensive care nurse stayed close around the bed. A left-handed intensivist may prefer to be placed on the patients left side. The key steps of MIT are portrayed in Fig. 1A. In patients with dense cervical vasculature, compromised coagulation, goiter or severe obesity, blunt dissection posed a promising avenue to create a safe corridor for tracheal puncture by smoothly displacing blood vessels embedded within the pretracheal tissue. In these high-risk patients, particularly, if no diaphanoscopy could be achieved or the trachea could not be clearly localized by palpation, this initial puncture, so called “probing”, was important to confirm correct tracheal access without damage to blood vessels or surrounding tissues. Importantly, to minimize the risk of lung injury and pneumothorax, the tracheal puncture must be performed perpendicular to the trachea. Thereafter, tracheostomy was carried out with a regular PDT set according to the manufacturer's instruction. Due to the prior tissue dissection, both dilation and placement of the cannula could be performed smoothly, even in patients with obesity. To obviate the risk for tracheal perforation or paratracheal placement of the cannula, and to rule out endotracheal bleeding, bronchoscopic monitoring was used throughout the whole procedure (Fig. 1B). Taken together, to optimize the conventional dilatational tracheostomy approach for high-risk patients, we incorporated blunt tissue dissection to gain positive diaphanoscopy and an initial probe puncture, all performed under continuous bronchoscopic surveillance, resulting in a refined technique for MIT. Of clinical relevance, in most cases a positive diaphanoscopy could be achieved only after blunt dissection, increasing intraprocedural safety. To our knowledge, this is the first study evaluating the usefulness of diaphanoscopy in MIT.

3.4. The anterolateral approach enables MIT despite the presence of dense pretracheal vasculature or atypical anatomy of the neck region

Dense vasculature in the pretracheal tissue poses a crucial risk factor for bleeding complications during tracheostomy [27–30]. Some patients exhibit atypical anatomical variations of the neck vascular structures

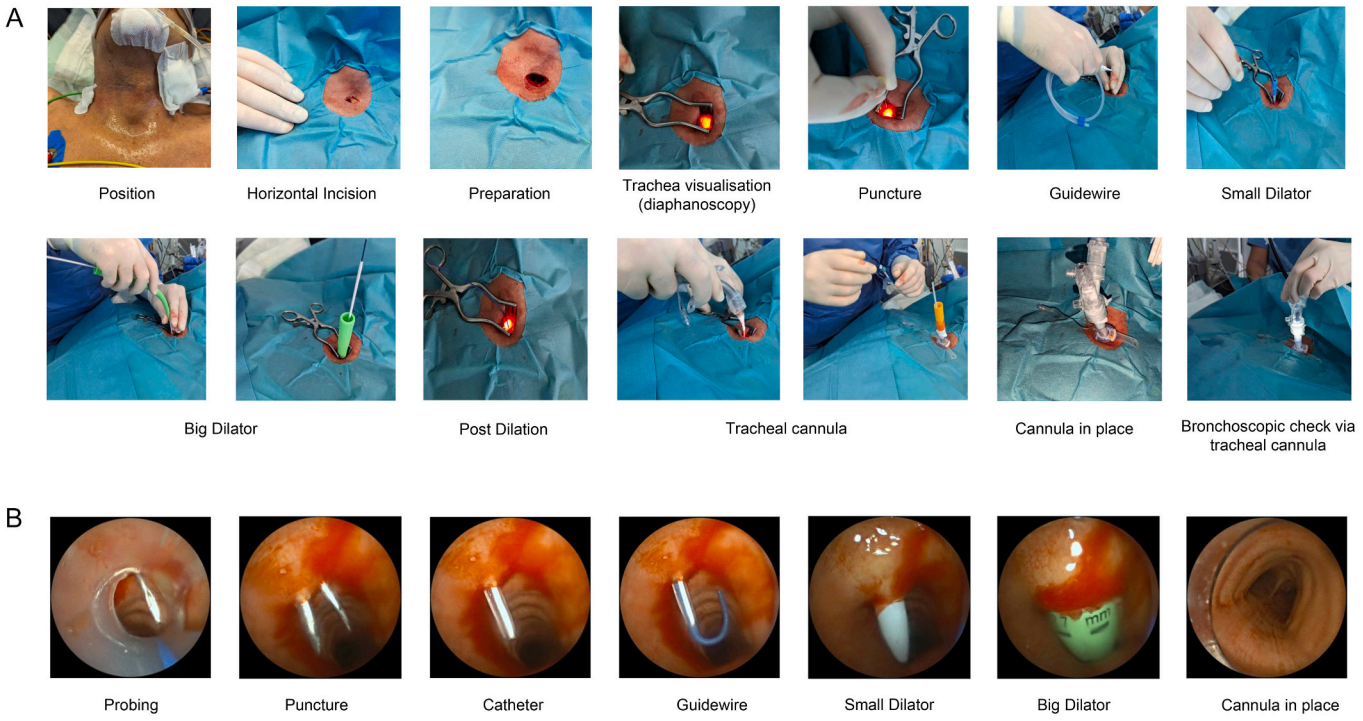

Fig. 1. An optimized approach for the minimally invasive tracheostomy (MIT) of high-risk patients. (A) Initially, the neck of the patient was extended, sterilized, and draped. Afterwards, a horizontal incision measuring 1–2 cm was made approximately 1.5 cm above the sternal notch. Using fingers and the blunt ends of a pair of scissors, the pretracheal tissue was carefully dissected and the skin incision margins were retracted by inserting a spreader. Under bronchoscopic surveillance and by employing diaphanoscopy for guidance, the trachea was first punctured between two tracheal rings with a thin 20 G injection cannula. The second tracheal puncture executed with the tracheostomy catheter was placed right next to the probe puncture. Then, a guidewire was inserted, and successive dilations with two dilators incrementing in size were performed. Finally, the tracheostomy tube was inserted over the guidewire the position of the cannula was checked via bronchoscopy. (B) Bronchoscopic monitoring was used throughout the whole procedure to confirm correct tracheal puncture, guide wire insertion, dilation, and cannula placement.

[31–35]. Particularly, the nearby presence of big aberrant arteries like a high riding innominate artery is considered an absolute contraindication for PDT or MIT [36–38]. Some authors report conversion of PDT to ST due to aberrant high riding innominate artery. At our institution, prominent blood vessels in the pretracheal tissue were traditionally viewed as a contraindication for non-ST due to the heightened risk of bleeding complications. To facilitate MIT in patients with dense pretracheal vasculature, we utilized color Doppler ultrasound prior to the procedure, which guided the selection between a median or anterolateral approach based on the vascular architecture. Generally, the median approach characterized by tracheal puncture in the midline constituted the standard approach to MIT in our study. Even in patients with prominent pretracheal blood vessels visible on ultrasound, the median approach could be frequently adopted (Fig. 2A) by using our optimized approach for MIT. Nevertheless, in some patients, ultrasound imaging revealed dense prominent vasculature located directly in the midline or nearby aberrant big arteries like a high riding innominate artery (Fig. 2B and Fig. 2C). Of note, ultrasound examination of the pretracheal region could detect anterolateral opportunities of tracheal approach with a lower risk of bleeding for MIT. In ten patients, we adopted an alternative approach, termed the anterolateral approach. Here, tracheal puncture followed an anterolateral trajectory to circumvent blood vessels running in the midline (Fig. 2D). In three patients, pretracheal prominent blood vessels were extending from the midline into the subcutaneous fat just below the skin. In order to avoid severing superficial blood vessels, a vertical instead of the standard horizontal skin incision was made in anterolateral orientation to the midline. Protecting and preserving these vessels could reduce eventual wound healing disorders after decannulation. Then, guided by diaphanoscopy, MIT was performed via the anterolateral approach (Fig. 3A). Apart from bypassing vasculature, the anterolateral approach is also suitable for MIT of patients exhibiting a tracheal deviation from midline (Fig. 3B). After successful weaning and subsequent decannulation, the tracheostomy wound healed spontaneously over the course of several months without the occurrence of major scarring (Fig. 3C). In aggregate, the anterolateral approach poses an important technique to enable MIT despite the presence of dense pretracheal vasculature or atypical anatomy.

3.5. MIT is safer than conventional PDT in high-risk patients

No serious complications related to MIT were observed (Table 4). Bleeding from the skin incision site was minimal and could be managed by local compression. Postprocedural relevant hemorrhage or endotracheal bleeding were not observed and significantly reduced compared to PDT ($p < 0.001$ Likelihood Ratio Chi-Sqaure compared to MIT, Table 4). Of note, patients with risk factors for tracheostomy-related complications were a priori excluded from the PDT approach (Table 2). All MIT interventions were successful at the first attempt without the occurrence of tracheal perforation or misplacement of the cannula. The first exchange of the tracheal cannula was routinely performed after two weeks without any problems, which was significantly better than in PDT, where in 5.3 % a failure to change the cannula occured ($p < 0.04$ Likelihood Ration Chi-Square MIT compared to PDT, Table 4). In the comparative cohort comprising nineteen patients subjected to conventional PDT, which constituted the standard of care for tracheostomy at our institution prior to March 2023, significant bleeding incidences necessitating intervention beyond local compression, like subcutaneous injection of epinephrine or placing a stitch, were observed in five patients (26.3 %). Moreover, in one patient (5.3 %) with PDT, the tracheal cannula could not be changed during a routine tracheostomy tube exchange resulting in loss of airway and subsequent emergency intubation (Table 4). Regarding ST, tracheostomy-related severe complications were not observed in our patient cohort. Collectively, MIT could be performed without severe complications and was significantly safer than conventional PDT in high-risk patients.

3.6. MIT: a quicker and more efficient alternative to surgical methods

In our study, the average duration for MIT amounted to 20 min for

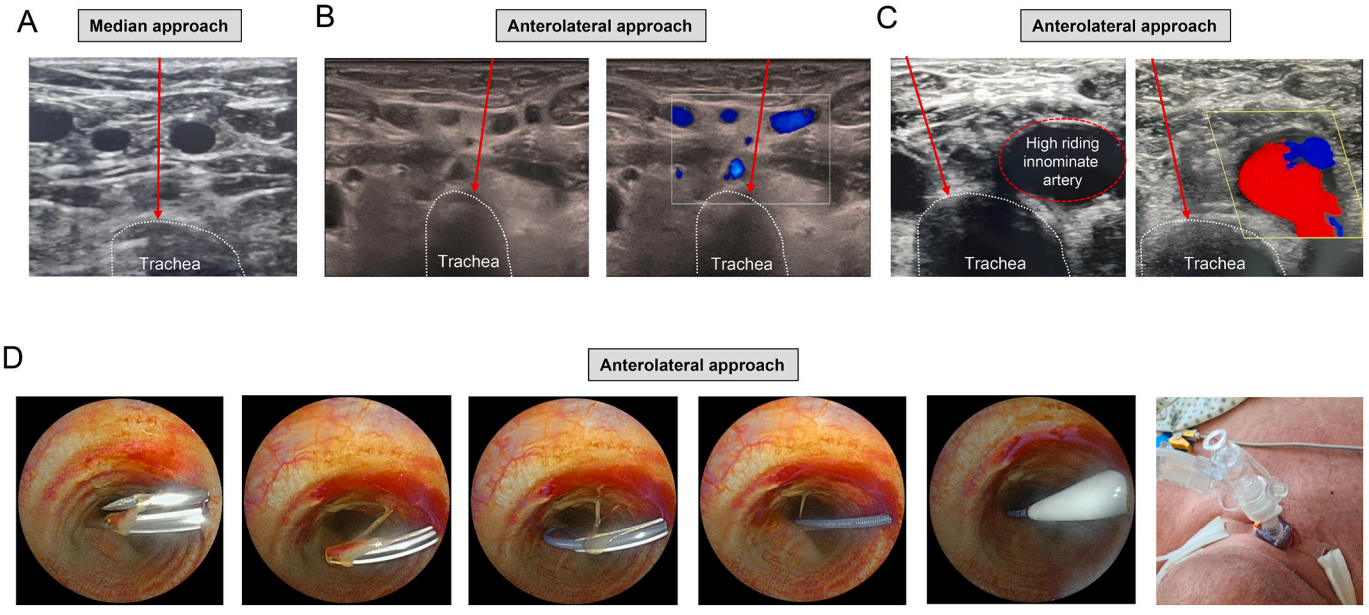

Fig. 2. The anterolateral approach enables MIT despite the presence of dense pretracheal vasculature. (A) Ultrasound imaging showing prominent blood vessels located in the pretracheal tissue. The dotted line in white encircles the trachea. The red line portrays the puncture trajectory for the median approach to MIT. (B) Ultrasound imaging with (left panel) or without (right panel) color flow showing prominent blood vessels located in the pretracheal tissue. The dotted line in white encircles the trachea. The yellow line portrays the puncture trajectory for the anterolateral approach to MIT. (C) Ultrasound imaging with (left panel) or without (right panel) color flow illustrating a high riding innominate artery (red dotted line) adjacent to the trachea. The dotted line in white encircles the trachea. The red line portrays the puncture trajectory for the anterolateral approach to MIT. (D) Key steps in the process of MIT using the anterolateral approach involving tracheal puncture, guidewire insertion, dilation, and cannula placement.

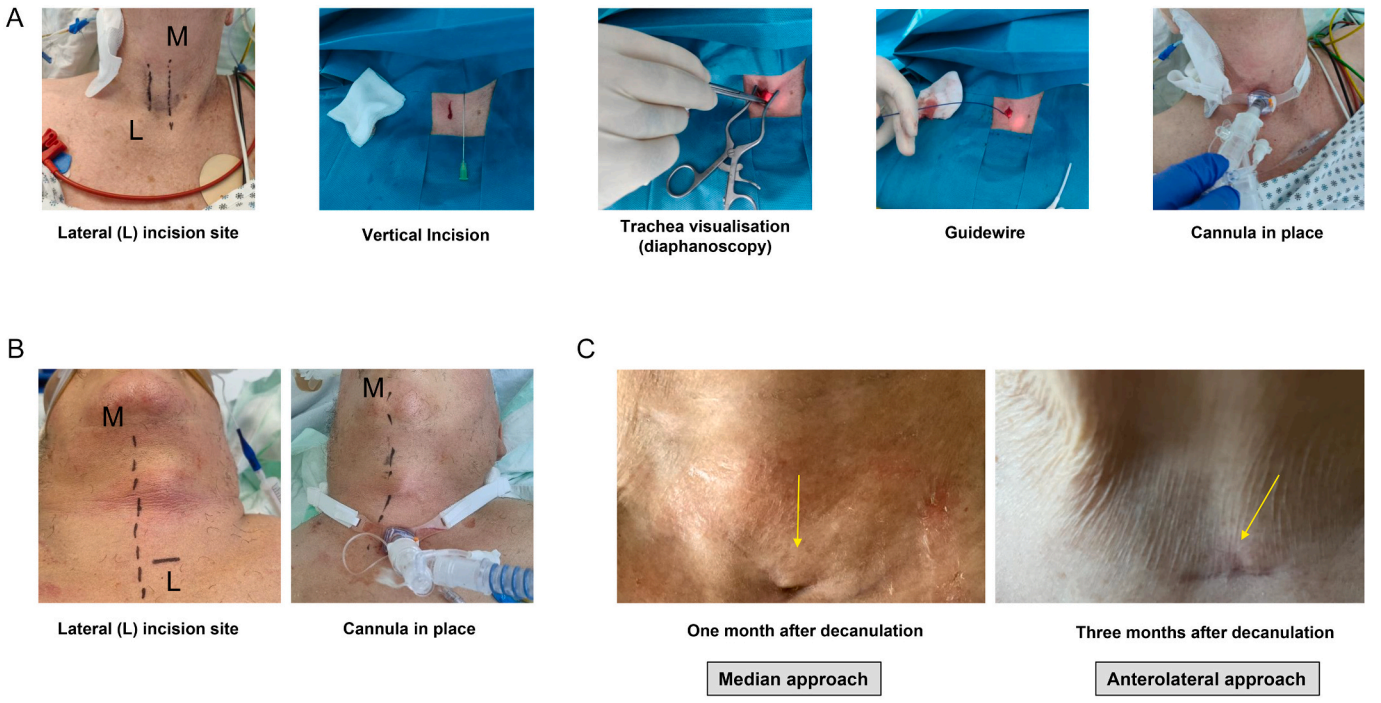

Fig. 3. Versatile applications of the anterolateral approach. (A) In order to avoid severing superficial blood vessels, a vertical instead of the standard horizontal skin incision was made in anterolateral (L) orientation to the midline (M). Guided by diaphanoscopy illuminating the trachea in the midline, MIT was performed via the anterolateral approach. (B) MIT using the anterolateral approach in a patient exhibiting a tracheal deviation from midline (M) indicated by the dotted line. The horizontal incision site located anterolaterally (L) from the midline was marked prior to tracheostomy (left panel). (C) Exemplary images showing wound healing without major scarring (indicated by the yellow arrows) after decannulation in two different patients with previous MIT via the median (left panel) or anterolateral (right panel) approach.

Table 4
Complications associated with tracheostomy.

Complication	Patients[a]		
	MIT (N = 32)	PDT (N = 19)	ST (N = 15)
Bleeding[b]	0	5 (26.3)*	0
Pneumothorax	0	0	0
Mediastinal perforation of trachea	0	0	0
Misplacement of TS tube	0	0	0
Failure to change tracheal cannula necessitating intubation	0	1 (5.3) **	0

* $p < 0.001$, ** $p < 0.04$, Likelihood Ratio Chi-Square Test.
[a] Number (%).
[b] Requiring intervention beyond local compression.

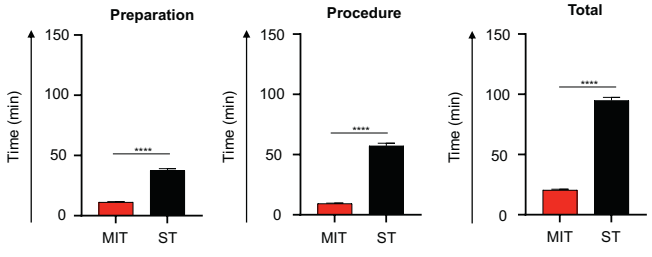

Fig. 4. The multimodal MIT technique is faster than surgical tracheostomy. Average duration of MIT (32 patients) and ST (15 patients) subdivided in total time (sum of time for preparation and time for intervention), time for preparation (measured from start of preparation to skin incision), and time for intervention (measured from skin incision to fixing tracheal cannula). Data represent means ± SEM. *P* values were calculated by two-tailed Student's *t*-test. **** indicates $p < 0.0001$.

the total procedure, with 11 min spent on preparation and 9 min spent on the intervention per se (Fig. 4). These results are comparable to previous reports on the average duration of a conventional PDT. Furthermore, we analyzed the average duration of 15 ST procedures carried out at our institution prior to March 2023. With an average total time of 94 min, the process of surgical tracheostomy was significantly longer than MIT. This difference originated from surgical tracheostomy requiring significantly more time for both preparation (in average 37 min) and intervention (in average 57 min) (Fig. 4). Moreover, we analyzed the staff requirements for MIT, PDT and ST, respectively (Table 5). MIT and PDT are usually carried out by two physicians, of whom one is in charge of the intervention, and the other one is responsible for bronchoscopy, and one intensive care nurse. In contrast, ST at our institution usually involves two surgeons, one surgical assistant, one anesthesiologist assistant, and one anesthetist. Taken together, MIT and PDT require two physicians and one nurse in total, while ST is carried out by a team of three physicians and two nurses. In conclusion, MIT offers a quicker and overall, more efficient procedure compared to its surgical counterpart.

Table 5
Staff requirements for tracheostomy.

Profession		MIT[a] / PDT[b]	ST[c]
Physician	Interventionist/Surgeon	1	2
	Bronchoscopy/Anesthetist	1	1
Total number of physicians required		2	3
Nurse	Surgical assistant	0	2
	Anesthesiologist assistant	1	1
Total number of nurses required		0	3
Total staff required		3	6

[a] Minimally invasive tracheostomy.
[b] Percutaneous dilational tracheostomy.
[c] Surgical tracheostomy.

4. Discussion

In high-risk patients characterized by substantial neck size, peritracheal vasculature, or bleeding disorders, tracheostomy has almost exclusively been recommended to be performed by trained surgeons [5,6,12,15,16]. In order to extend the applicability of non-ST to high-risk patients previously deemed ineligible to non-ST, we developed a universal multimodal MIT approach tailored to critical care specialists. We refined the conventional PDT approach by adding an initial skin incision followed by blunt tissue dissection, a probe puncture guided by diaphanoscopy, and permanent bronchoscopic surveillance. In addition, we developed the novel anterolateral approach to enable MIT in patients with dense pretracheal vasculature or atypical anatomy. In comparison to PDT, our optimized MIT approach was significantly safer and could be performed without severe complications. Finally, we confirmed that MIT is swifter and more efficient than ST.

Over the last decades, conventional PDT has emerged as the standard procedure for tracheostomy in intensive care units [12–14]. Nevertheless, severe complications, including fatalities, related to PDT were observed. In a comprehensive retrospective multi-center study on deaths after PDT, the risk of lethal complications was reported to be 1 out of 600 tracheostomies, with 31.0 % of deaths occurring during the procedure [30]. The majority of PDT-related fatalities were attributed to bleeding originating from vascular injury (27 patients), followed by airway complications (21 patients), tracheal perforation (11 patients), and pneumothorax (4 patients). As crucial risk factors for PDT-related deaths during the procedure, the omission of bronchoscopic guidance, pretracheal vasculature, coagulopathy, and obesity were identified [30]. To avoid complications associated with PDT, the authors advocate the use of stringent bronchoscopic guidance, and recommended that PDT should only be restricted to selected patients without crucial risk factors [30]. Remarkably, not even the use of ultrasound-guided tracheotomy could significantly lower the bleeding risk in PDT [39], thus rendering the presence of prominent pretracheal blood vessels still a significant contraindication to PDT. Whereas PDT was shown to be safe in patients with thrombocytopenia [40,41], complex coagulopathy, such as in patients with liver cirrhosis, has still been regarded as a relative contraindication to PDT owing to the increased risk for severe hemorrhage [5,16,42]. By using our universal multimodal tracheostomy approach, we could obviate previous contraindications to PDT, e.g., pretracheal vasculature or complex coagulopathy in patients with liver diseases. Furthermore, the MIT care bundle enabled safe tracheostomy in high-risk patients with liver cirrhosis and patients with a history of a previous allogeneic stem cell transplantation. Given thrombocytopenia, a compromised plasmatic coagulation, and an impaired tissue repair, both liver cirrhosis and allogeneic bone marrow transplantation predispose for bleeding complications and tissue damage during tracheostomy [16,40,41].

Our MIT approach for high-risk patients merges preprocedure ultrasound, an initial skin incision, blunt tissue dissection to gain diaphanoscopy, a probe puncture supported by diaphanoscopy, and bronchoscopic guidance to enable conventional PDT in high-risk patients without complications. While the combination of these techniques into a multimodal approach for tracheostomy has never been described before, the use of individual elements, such as preprocedure ultrasound [43] or bronchoscopic guidance [44], has been reported in conventional PDT. Nevertheless, for conventional PDT, significant bleeding complications were reported despite the use of ultrasound and bronchoscopic guidance [39,45–47].

The combination of an initial skin incision followed by blunt tissue dissection with conventional PDT once the trachea has been reached is termed hTS, and several studies on the safety of this procedure have been published. Similar to the data in our study, hTS was not associated with significant bleeding complications [21–25]. However, in one study, a paratracheal cannulation was reported as a serious complication of hTS [21]. Hence, the authors recommended hTS as a safe and reasonable tracheostomy approach for the majority of patients, except for subjects with difficult anatomy [21].

In another study, the rate of complications associated with hTS was also inferior to conventional PDT, but high-risk patients defined by a BMI >35 kg/m^2, a high PEEP, or a short neck were a priori excluded [25]. In order to facilitate MIT in high-risk patients ineligible to hTS, we included unique technical features, such as an initial probe puncture with a thin 22G needle guided by diaphanoscopy to confirm correct tracheal access. Especially in patients, where diaphanoscopy could not be obtained even after blunt dissection, and the trachea could not be clearly localized by palpation, the probe puncture was essential to establish safe tracheal access without causing tangible damage to surrounding tissue. Moreover, we utilized preprocedure ultrasound to individually decide, whether a median or anterolateral approach for tracheal puncture should be adopted depending on the presence of pretracheal vasculature, a twisted trachea, or goiter. Whilst a anterolateral trajectory for tracheal puncture guided by ultrasound and diaphanoscopy was already reported in two patients, one with goiter and another one with a prominent tracheal deviation [47], the circumvention of dense tracheal vasculature using the anterolateral approach has never been published. As already mentioned, pretracheal vasculature is often seen as a contraindication for PDT [27–30]. Although rare, periprocedural mortality is usually due to vascular hemorrhage. In our study, the anterolateral approach to tracheostomy in cases with dense pretracheal vasculature could be safely performed emphasizing exact knowledge of pretracheal sonoanatomy. Especially for patients exhibiting atypical anatomical variants with the anterior jugular veins or inferior thyroid veins running in the midline [32–35], the anterolateral approach could be critical to prevent laceration of pretracheal vasculature during tracheostomy. Nevertheless, the choice between median or anterolateral approach for tracheal puncture is always guided by ultrasound enabling clear visualization of neck vessels. In aggregate, we present data emphasizing the feasibility of MIT in patients with obesity, difficult anatomy, and an increased propensity to bleeding. According to current literature and guidelines, tracheal cannulation in patients considered at high-risk for tracheostomy related complications is predominantly recommended to be executed surgically [6,7,13,15,16]. Adopting an optimized tracheostomy approach, we could extend the applicability of MIT to patients previously deemed ineligible to non-ST.

In contrast to our MIT approach, which is predominantly intended for critical care specialists, most studies on hTS were exclusively carried out by surgeons and otolaryngologists [21–25]. Collectively, our tracheostomy approach termed MIT constitutes an optimized version of current hTS procedures yielding a MIT approach virtually void of patient-related contraindications. Against the backdrop of currently available tracheostomy approaches for critically ill patients, our multimodal approach to tracheostomy harbors significant advantages (Table 6).

Furthermore, it could be demonstrated that early tracheostomy (<14 days of intubation) in critically ill patients benefits overall outcome by reducing ventilator dependence, sedation doses, ventilator associated pneumonia, and hospital mortality [19,20]. Particularly in high-risk patients with contraindications to PDT or hTS, critical care specialists are heavily dependent on the capacities of surgeons or otolaryngologists to carry out surgical tracheostomies, which in some cases, due to administrative reasons or coordination issues between the teams, can delay the procedure. At our institution, surgical tracheostomies usually take more than one hour and generally involve five persons, three physicians and two assistants. Hence, surgical tracheostomy constitutes a time- and labor-intensive procedure. Contrary to surgical tracheotomy, our approach of MIT, which is universally applicable to patients requiring prolonged mechanical ventilation irrespective of established risk factors, is significantly less time-intensive and requires only two physicians and one intensive care nurse. We hypothesize that the broad application of our MIT approach might contribute to curbing

Table 6
Comparison of tracheostomy approaches for critically ill patients.

Approach	Key features	Key points
ST[a]	• Epithelialized tracheostoma	Disadvantages for ICU application: - time and labor intensive - exclusively performed by surgeons – sometimes surgical intervention to close the tracheostomy required - visible, unaesthetic scar after closure
PDT[b]	• Percutaneous tracheal puncture	**Lethal complications:** - bleeding from vascular injury - tracheal perforation **Contraindications:** - prominent pretracheal vessels - difficult anatomy - complex coagulopathy **Severe complications:** - bleeding from vascular injury - misplacement of cannula
hTS[c]	• Skin incision • Blunt dissection	**Contraindications:** - dense pretracheal vessels - difficult anatomy - complex coagulopathy
MIT[d]	• Ultrasound to determine median/anterolateral approach • Horizontal/vertical skin incision • Bronchoscopic guidance • Blunt dissection to gain positive diaphanoscopy • Probe puncture	**No relevant complications** **Virtually no contraindications** **Suitable for high-risk patients**

[a] Surgical tracheostomy.
[b] Percutaneous dilational tracheostomy.
[c] Hybrid tracheostomy.
[d] Minimally invasive tracheostomy.

hospital mortality of critically ill patients by promoting early tracheostomy.

We are aware of the limitations of this study originating from the small cohort and the retrospective nature of this study. Clearly, the findings presented here on the safety and time efficiency of this tracheostomy approach have to be validated in larger patient cohorts. Furthermore, all procedures included in this study were carried out by staff with extensive expertise in tracheostomy. Hence, the data on safety could differ if MIT is carried out be staff inexperienced in tracheostomy procedures. Finally, we report on data gathered from a single-center influenced by the specific requirements of this medical center, such as required staff for surgical tracheostomy. Multi-center trials are needed to independently validate the claims regarding efficiency and safety at large scale.

5. Conclusion

Taken together, we highlight MIT as a care bundle to reduce tracheostomy-related complications in high-risk patients usually deemed ineligible to non-ST. Combining interventional critical care skills with anatomical, sonographic and bronchoscopic knowledge, MIT in high-risk patients could be performed bedside by intensive care specialists without the occurrence of serious complications paving the way for the further exploration of this approach in prospective trials.

Ethics approval and consent to participate

This retrospective study was approved by the Ethics Committee of the University Regensburg (ethics statement number: 23–3499-104), and written informed consent was obtained from all patients prior to tracheostomy.

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Statement

All authors agree with the present version of the manuscript.

CRediT authorship contribution statement

Dennis Christoph Harrer: Writing – original draft, Methodology, Investigation, Data curation, Conceptualization. **Patricia Mester:** Writing – review & editing, Resources, Data curation, Conceptualization. **Clara-Larissa Lang:** Resources, Data curation. **Tanja Elger:** Methodology, Data curation. **Tobias Seefeldt:** Methodology, Data curation. **Lorenz Wächter:** Methodology, Data curation. **Judith Dönz:** Data curation. **Nina Doblinger:** Data curation. **Muriel Huss:** Data curation. **Georgios Athanasoulas:** Data curation. **Lea U. Krauß:** Data curation. **Johannes Heymer:** Methodology, Investigation, Formal analysis. **Wolfgang Herr:** Validation, Supervision. **Tobias Schilling:** Validation, Supervision, Formal analysis. **Stephan Schmid:** Data curation. **Martina Müller:** Supervision, Project administration. **Vlad Pavel:** Methodology, Investigation, Data curation, Conceptualization.

Declaration of competing interest

Not applicable.

None of the authors report any conflict of interest concerning the manuscript.

Data availability

Original datasets are available from the corresponding author on reasonable request.

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