Original Article

Percutaneous tracheostomy in patients on anticoagulants

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ABSTRACT

Aims: To determine if percutaneous tracheostomy is safe in critically ill patients treated with anticoagulant therapies. **Settings and Design:** Single-center retrospective study including all the patients who underwent percutaneous dilatational tracheostomy (PDT) placement over a 1-year period in a 14-bed, cardiothoracic and vascular Intensive Care Unit (ICU). **Materials and Methods:** Patients demographics and characteristics, anticoagulant and antiplatelet therapies, coagulation profile, performed technique and use of bronchoscopic guidance were retrieved. **Results:** Thirty-six patients (2.7% of the overall ICU population) underwent PDT over the study period. Twenty-six (72%) patients were on anticoagulation therapy, 1 patient was on antiplatelet therapy and 2 further patients received prophylactic doses of low molecular weight heparin. Only 4 patients had normal coagulation profile and were not receiving anticoagulant or antiplatelet therapies. Overall, bleeding of any severity complicated 19% of PDT. No procedure-related deaths occurred. **Conclusions:** PDT was proved to be safe even in critically ill-patients treated with anticoagulant therapies. Larger prospective studies are needed to confirm our findings.

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INTRODUCTION

Thrombocytopenia and impaired coagulation are frequently seen in Intensive Care Unit (ICU) patients. Moreover, patients admitted to the ICU often receive anticoagulant therapies that should not be suspended. Few manuscripts[1-12] focused on bleeding associated with a percutaneous dilatational tracheostomy (PDT) in ICU patients, and only five directly evaluated the impact of anticoagulation on bleeding.[7-10,12]

The primary endpoint of this study was the incidence of bleeding PDT related complications in a high-volume ICU with most patients receiving anticoagulant therapy. Secondary endpoints were the incidence of all PDT related complications and in-hospital mortality.

MATERIALS AND METHODS

This study was conducted in a 14-bed, cardiothoracic and vascular ICU of a teaching hospital. The study was approved by the Local Ethical Committee. Charts of all patients undergoing PDT placement over a 1-year period were reviewed, with an in-hospital follow-up.

All PDTs were performed in the ICU. In all cases, the Ciaglia single-step dilator technique (Portex® or Shiley™ cannula) under constant videobronchoscopic endotracheal visualization was applied. Patient demographics, associated

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comorbidities, duration of mechanical ventilation prior to tracheostomy, anticoagulant and antiplatelet therapies, coagulation profile on the day of the procedure (including platelet count and international normalized ratio [INR]), performed technique and use of bronchoscopic guidance, need for procoagulant medications, fresh frozen plasma (FFP) or platelet transfusion before procedure were collected. Bleeding, aborting procedure, accidental extubation, conversion to surgical tracheostomy, paratracheal placement, desaturation, subcutaneous emphysema, development of pneumothorax or death were retrieved. Bivalirudin was the first choice anticoagulant for patients with mechanical devices and in case of heparin-induced thrombocytopenia.

Bleeding episodes were divided into major bleeding (if requiring blood transfusion or surgical intervention) and minor bleeding (if only pressure, dressing or suturing had been required). According to the literature, we hypothesized an overall bleeding rate of 20%.

Statistical analysis

Descriptive statistics was applied to patients' demographics, tracheostomy indications, procedures, types, and management of complications. Continuous variables are expressed as mean and standard deviation. Categorical variables are expressed as counts and percentages.

RESULTS

Over a 1-year period, 36 patients (2.7% of the overall ICU population) underwent PDT in the ICU. No other patients underwent surgical tracheostomies during the study period.

All procedures were performed by a team of four well-experienced anesthesiologists. Ciaglia single-step dilator technique under constant videobronchoscopic endotracheal visualization was used in all cases, with positioning of Portex® cannula in 27 patients and or Shiley™ cannula in 9 patients.

The mean age of patients was 70 ± 11.7 years and 15 patients (42%) were female. Baseline characteristics, primary diagnoses for ICU admission, ICU stay, time on mechanical ventilation before tracheostomy and in-hospital mortality are presented in Table 1. Most patients underwent cardiac surgery (61%) while the others were admitted to the ICU for cardiac arrest (14%), cardiac failure (8%), or respiratory failure (17%).

Twenty-six (72%) patients were on anticoagulation therapy; most of them (number = 22) were on a continuous infusion of bivalirudin and four on a continuous infusion of heparin. One patient was on vino venous Extracorporeal membrane oxygenation (ECMO), one on venoarterial ECMO, one on ventricular assist device (VAD), three with intra-aortic balloon pump (IABP) and 11 on continuous veno-venous hemofiltration. One further patient was on antiplatelet therapy (acetylsalicylic acid 250 mg/die) and two received prophylactic doses of low molecular weight heparin. Only four out of the 36 patients had a normal coagulation profile (INR <1.5; platelet count >100,000/μl) and were not receiving anticoagulant or antiplatelets on the day of the procedure.

In the 4 patients on heparin, the drug was not interrupted for the procedure. In the 22 patients on bivalirudin, the drug was interrupted 6 h before the procedure (15 patients) or 3 h before the procedures (2 patients) while in 5 patients it was not interrupted. Coagulation profile on the day of procedure is presented in Table 1 with blood samples drawn before stopping the anticoagulant infusion.

Table 1: Patients characteristics and coagulation profile

Variable	36 patients
Age, years	70±11.7
Female, *n* (%)	15 (42)
BMI	25±4.1
Reason for ICU admission	
Cardiac surgery, *n* (%)	22 (61)
Acute respiratory failure, *n* (%)	6 (17)
Cardiogenic shock, *n* (%)	3 (8)
Cardiac arrest, *n* (%)	5 (14)
Duration of intubation before tracheostomy, days, median (IQR)	11 (8-17)
ICU stay, days, median (IQR)	38 (29-56)
In hospital death, *n* (%)	21 (58)
Hemoglobin concentration before tracheostomy (g/L)	10.1±1.15
Prothrombin time before tracheostomy (ratio)	1.4±0.21
INR before tracheostomy	1.5±0.31
INR >1.5, *n* (%)	16 (44)
Platelet count before tracheostomy 10^3/μL	128±89.5
Platelet count <100,000/μL, *n* (%)	15 (42)
Platelet count <50,000/μL, *n* (%)	7 (19)
Anticoagulation therapy, *n* (%)	26 (72)
Antiplatelet therapy, *n* (%)	1 (3)

ICU: Intensive Care Unit, BMI: Body mass index, IQR: Interquartile range, INR: International normalized ratio

No patient received pro-coagulation products neither FFP immediately before the procedure, and only 1 patient received Vitamin K (10 mg) the day before the procedure because of INR = 3.5 (before tracheostomy INR = 1.45). Tracheostomy reduces the time of mechanical ventilation and allows to manage patients outside the ICU. It is now part of the routine management of all patients with prolonged mechanical ventilation. When weighting benefits and risks of performing tracheostomy in these patients we decided not to wait for a spontaneous rise of platelet count, not to transfuse platelet concentrates and not to interrupt ongoing anticoagulants in order to minimize the thrombotic complications.

No procedure-related deaths occurred while 4 patients suffered from intra-procedure complications and six had postprocedural complications [Table 2]. One patient had a minor posterior tracheal wall injury not requiring surgery while 3 patients developed minor intraprocedural bleeding managed with peri-stomal compression. After the procedure the following complications were reported: Transient hypoxemia due to abundant blood-streaked tracheal secretions in 1 patient; fever 48 h after procedure in 1 patient; minor, self-limiting bleeding in 1 patient; pneumothorax diagnosed and drained 4 h after PDT in 1 patient. Bleeding from the tracheal stoma requiring blood transfusions (two packed red cells and two units of FFP) was reported in two cases: In one of these, a thrombocytopenic patient (platelet count 26,000/μl), surgical staples application was also required. The same patient also developed a stomal infection without sepsis in the following days.

Among the 7 patients developing peri-procedural bleeding (three during the procedure and four after the procedure), 5 (71%) were on anticoagulation therapy with bivalirudin (three of them had not interrupted it while the remaining two interrupted it 6 h before PDT), one on anticoagulation therapy with heparin (not interrupted) and one was on antiplatelets therapy. Moreover, four of them presented severe thrombocytopenia (platelet count <50,000/μl).

DISCUSSION

The major finding of this study is the low incidence of severe bleeding complications related to PDT despite anticoagulant therapies. Our study is one of the largest ever published on bleeding complications associated with PDT in critically ill-patients receiving anticoagulant or antiplatelet therapies.

Published guidelines from scientific societies suggest strategies to manage anticoagulant and antiplatelet therapies in surgical and nonsurgical procedures, but no guideline focused on PDT.[13,14]

The incidence of major bleeding during PDT is generally considered to be low.[15,16] Classification of bleeding complications during and after PDT varies in the definition and is frequently reported as aggregate complication rate with other, unrelated complications.[17] Fatal bleeding is rare, but case reports of massive hemorrhage from PDT have been published.[18-20]

The development of different circulatory support systems, such as IABP, VAD, ECMO is continuously

Table 2: Percutaneous dilatational tracheostomy-related complications

PDT related complications	*n* (%)	Coagulation profile	Antiplatelet/anticoagulant therapy
Intra-procedural	4 (12)		
Minor bleeding	3 (9)		
	1 (3)	INR: 2.14; PLT: 70,000	None
	1 (3)	INR: 1.33; PLT: 34,000	Bivalirudine (not stopped)
	1 (3)	INR 1.22; PLT: 199,000	Bivalirudine (not stopped)
Minor posterior tracheal wall injury	1 (3)	INR 2.65; PLT: 99,000	None
Postprocedural	6 (18)		
Transient hypoxaemia due to abundant blood-streaked tracheal secretions	1 (3)	INR: 1.7; PLT: 113,000	Heparin (not stopped)
Fever 48 hafter procedure	1 (3)	INR: 1.09; PLT: 200,000	None
Minor bleeding	1 (3)	INR: 1.43; PLT: 70,000	Bivalirudine (stopped 6 h before procedure)
Minor bleeding and pneumothorax	1 (3)	INR: 1.12; PLT: 46,000	Bivalirudine (not stopped)
Major bleeding	1 (3)	INR: 1.4; PLT: 34,000	Bivalirudine (stopped 6 h before procedure)
Major bleeding and stomal infection	1 (3)	INR: 1.39; PLT: 26,000	None

PDT: Percutaneous dilatational tracheostomy, INR: International normalized ratio, PLT: Platelet count

increasing world-wide.[21] All these mechanical equipment require the mandatory use of therapeutic anticoagulation in order to prevent clotting of the extracorporeal circuit. Moreover, patients admitted to the ICU after cardiac surgery procedures, often require anticoagulant or antiplatelet therapies that cannot be suspended. Also, refractory coagulopathy can be often observed in these patients.

Percutaneous dilatational tracheostomy is became the technique of first choice in most ICUs.[22] The safety of PDT technique has been widely demonstrated,[23,24] but published evidence on the safety of this technique in patients with coagulopathy or concomitant anticoagulation or antiplatelet therapies is limited so far.[25-27]

Optimizing patients coagulation function prior to PDT is recommended,[28] but there are no authoritative guidelines suggesting peri-procedural strategies to manage antiplatelet or anticoagulant therapies for bedside PDT. Hence, physicians are often torn between the need to maintain anticoagulation and the risk of peri-procedural bleeding and their decision is likely directed by personal skills, number of procedures performed per year and availability of rescue facilities (e.g., on call thoracic surgeons).

The growing use of new anticoagulants (both direct and indirect inhibitors of coagulation factors) represents a further challenge for physicians. Heparin is no longer the only available drug in ICU patients, and this is a great opportunity for physicians, in particular in patients with heparin-induced thrombocytopenia. On the other hand, while the anticoagulant effect of heparin can be neutralized by protamine, there are no specific reversal agents for any of the newer anticoagulants.

The rate of bleeding complications of our study (19%) is comparable or even lower than the complication rate of studies performed on similar populations of anticoagulated/antiaggregated patients.[7-10,12] Furthermore, this rate is similar to the rates of complications reported in different populations of general ICU patients.[1-4]

Excluding the case report of Cabrini *et al*.,[12] the only study including a population of patients comparable with the population of patients described in our study is the retrospective study of Braune *et al*.[8] In fact, in the study of Gregoric *et al*.[10] only 29% of patients were mildly coagulopathic (mean INR = 1.34 and mean platelet count = 160,400/μl). Moreover, no details on management of anticoagulant/antiplatelet therapies were provided. On the other hand, Beiderlinden *et al*.[7] reported that among 296 patients receiving continuous heparin infusion, 189 (64%) received only low-dose heparin and actually, they had normal coagulation variables. Among the 190 patients included in the study of Al Dawood *et al*.[9] only 7% received intravenous heparin, and the drug was stopped 6 h before PDT performance.

Therefore, a true comparison can be done only between our study and the study of Braune *et al*.[8] In fact, Braune *et al*.[8] included 118 patients on ECMO and receiving systemic heparinization. Median count was 126,000/μl (interquartile range [IQR] 16.000–617.000) and median INR 1.1 (IQR 0.9–2.00). Heparin infusion was stopped 1 h before PDT performance, and incidences of reported major and minor bleeding were 1.7% and 31.4% respectively.

Of note, both Beiderlinden *et al*.[7] and Braune *et al*.[8] reported that patients with an impaired platelet and coagulatory function did not show a higher rate of bleeding periprocedural complications.

Also to these considerations, different reviews[29,30] showed that PDT is associated with similar rates of bleeding when compared to surgical tracheostomy in a general population. Our findings suggest that PDT can be considered a safe procedure, even in critically ill patients requiring anticoagulant therapies.

We are aware of the fact that optimize the patients in terms of anticoagulant status prior to proceeding with an elective procedure or deferring the procedure until the patient is more stable is an alternative approach especially in low volume center. Nonetheless most of our patients were receiving anticoagulant therapies that should not be suspended because of the risk of potential serious consequences. Moreover, even if timing of tracheostomy (early versus late) is still under debate and there is no clear evidence that early tracheostomy is superior to a delayed intervention, the decision of procrastinating the procedure, given the severe and not soon improvable clinical conditions of the patients, would have overly delayed tracheostomy execution. While we think that percutaneous tracheostomy is advantageous in this clinical situation because is associated with fewer bleeding complications, low-volume centers might consider open tracheostomy for more effective

hemostasis. Moreover, we acknowledge that the use of ultrasound guidance could be useful in order to further reduce possible procedural complications. Nonetheless we didn't have enough experience with the use of this technique and it wasn't part of our daily practice during the study period.

Our study has some limitations. We collected data retrospectively, and our findings should be confirmed in prospective trials. Even if the numerosity of this study is the largest ever reported, it is rather limited and underpowered to detect rare complications as PDT-related deaths.[31] Finally, complications related to anticoagulants suspension were not present in our study; larger prospective trials should assess also the impact (if any) of anticoagulants brief suspension for PDT on the functioning of the treatments or devices requiring anticoagulation (like ECMO, VAD or IABP).

CONCLUSIONS

Among 36 patients undergoing PDT (all but four were on anticoagulants or antiplatelets or with coagulation abnormalities), seven bleeding episodes (3 during the procedure and 4 after the procedure) were observed. No PDT-related death was reported and only 2 out of these 7 patients required transfusion suggesting that bleeding for PDT procedures in these patients is not a big issue in a high-volume center. In patients on anticoagulants (some of them under ECMO therapy) PDT was feasible with acceptable bleeding risk.

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Conflict of interest

There are no conflict of interest.

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