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Safety of percutaneous dilatational tracheostomy in patients on extracorporeal lung support

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Abstract *Purpose:* To evaluate the safety of percutaneous dilatational tracheostomy (PDT) in critically ill patients on an extracorporeal lung assist device requiring therapeutic anticoagulation. *Methods:* This was a retrospective, observational study on all patients undergoing tracheostomy while on pumpless extracorporeal lung assist or extracorporeal membrane oxygenation in intensive care units of two university hospitals in Germany between 2007 and 2013. *Results:* During the study period PDT was performed on 118 patients. The median platelet count, international normalized ratio, and activated partial thromboplastin time before tracheostomy were 126 × 10^9/L (range 16–617 × 10^9/L), 1.1 (0.9–2.0) and 49 s (28–117 s), respectively. Seventeen patients (14.4 %) received a maximum of three bags of pooled platelets, and eight patients (6.8 %) received a maximum of four units of fresh frozen plasma before the procedure. In all patients the administration of intravenous heparin was briefly paused periprocedurally. No periprocedural clotting complication within the extracorporeal circuit was observed. Two patients (1.7 %) suffered from procedure-related major bleeding, with one patient requiring conversion to a surgical tracheostomy. Two pneumothoraces (1.7 %) were related to the PDT. One patient (0.8 %) had analgosedation-related hypotension with brief and successful cardiopulmonary resuscitation. Minor bleeding from the tracheostomy site occurred in 37 cases (31.4 %). No fatality was attributable to tracheostomy. *Conclusions:* The complication rates of PDT in the patients on extracorporeal lung support were low and comparable to those of other critically ill patients. Based on these results, we conclude that PDT performed by experienced operators with careful optimization of the coagulation state is a relatively safe procedure and not contraindicated for this patient group.

Keywords Percutaneous tracheostomy · Safety · Extracorporeal lung support · Respiratory weaning · ECMO · ECLA

Introduction

Percutaneous dilatational tracheostomy (PDT) in critically ill patients undergoing prolonged mechanical ventilation has gained widespread acceptance in the intensive care unit (ICU) [1, 2]. In fact, PDT has replaced surgical tracheostomy (ST) as the technique of first choice in many ICUs given the ease and speed of the procedure at the bedside and its comparable safety profile in the hands of experienced operators [3]. In the immediate

periprocedural period, haemorrhage is one of the more common complications, especially in patients with compromised coagulatory function [4–7]. Thus, optimizing the patients' coagulatory function prior to PDT is often recommended [5, 6, 8, 9] and has become a common practice [10]. However, in some patients this strategy is limited by a refractory coagulatory state or concomitant anticoagulation with or without antiplatelet treatment. Few observational studies have shown that PDT can be performed relatively safely in these high-risk patient groups [5–9, 11–14].

Major technological improvements in extracorporeal lung assist (ECLA) devices used as rescue therapy [15] and/or for enabling lung protective ventilation [16] has led to promising outcomes in patients with different types of severe respiratory failure and offers attractive additional therapeutic options [17]. These developments have stimulated the use of extracorporeal devices in the clinical setting [18]. Since a prolonged course of weaning is often observed in these patients, a tracheostomy offers the advantage of minimizing sedation requirements, enabling early spontaneous breathing and potentially reducing weaning times [19]. Other potential advantages of a tracheostomy in patients on ECLA, albeit currently without any empirical evidence, are the positive effects on the patient derived from less agitation, less coughing, less pressing against and fighting the ventilator, leading to subsequent avoidance of intermittent intrathoracic pressure peaks and thus facilitating a smooth blood flow through the extracorporeal circuit. The growing numbers of critically ill patients on extracorporeal support will be accompanied by increasing numbers of percutaneous tracheostomy procedures in these patients.

In this clinical setting the mandatory use of therapeutic anticoagulation to prevent clotting of the extracorporeal circuit conflicts with demands for coagulatory function for a safe tracheostomy without bleeding complications.

To our knowledge, no study has yet been published that evaluates PDT in patients receiving extracorporeal lung support. In order to assess the safety of this procedure in this specific subgroup of critically ill patients we conducted a two-centre retrospective observational study.

Methods

Study design, population and technology

This retrospective observational study was conducted in two university hospitals in Germany (Department of Intensive Care Medicine, University Medical Center Hamburg-Eppendorf and the medical ICU of the Hannover Medical School). The medical records of all patients undergoing a tracheostomy, either percutaneously or surgically, while being on extracorporeal lung assist from 1 January 2007 to 31 March 2013 were analysed with a 3-month follow-up. The extracorporeal devices used included the arterio-venous pumpless extracorporeal lung assist (PECLA) "interventional lung assist" (iLA®; Novalung GmbH, Talheim, Germany), a veno-venous extracorporeal membrane oxygenation (vvECMO) and a veno-arterial ECMO (vaECMO). All extracorporeal circuits used were heparin coated. The principles and details of the three types of extracorporeal pulmonary support have been published elsewhere [17]. Based on the respective intensivist's assessment of the individual benefits and risks of the procedure, most patients on ECLA who were in a prolonged weaning process or were expected to take a prolonged weaning course underwent a tracheostomy procedure. The procedure of first choice was a PDT, and the standard technique applied in both hospitals was the Ciaglia single-step dilator technique [20] under constant videobronchoscopic endotracheal visualization. A brief description of the protocol is given in Attachment 1 of the Electronic Supplementary Material (ESM). The Institutional Review Boards of both participating centres approved anonymized data collection and analyses.

Data collection

Baseline characteristics

The following routine clinical baseline data were collected: age, sex, diagnosis and reason for extracorporeal lung support, simplified acute physiology score II (SAPS-II) and sequential organ failure assessment (SOFA) score on ICU admission, SOFA score on day of tracheostomy, type of extracorporeal lung support, time from commencement of mechanical ventilation to start of extracorporeal lung support, time from start of extracorporeal lung support to tracheostomy, cardiopulmonary state and ventilator settings on the day of tracheostomy, type of tracheostomy and size of inserted tracheal cannula. The following respiratory and haemodynamic parameters prior to tracheostomy were analysed: mean fraction of inspired oxygen (FiO_2) and positive end-expiratory pressure on the ventilator, mean FiO_2, blood flow and sweep gas flow of the extracorporeal device, mean arterial partial pressures of carbon dioxide ($PaCO_2$) and oxygen (PaO_2), arterial oxygen saturation, mean arterial blood pressure and maximum noradrenaline dose. The following haematological and coagulatory parameters were also obtained: mean haemoglobin level, platelet count, international normalized ratio (INR), activated partial thromboplastin time (aPTT), fibrinogen level, white blood cell count, as well as C-reactive protein prior to PDT and amount and type of blood products administered 24 h before and after PDT.

Outcome variables

Complications associated with the tracheostomy procedure were graded as major or minor. Complications were followed up until successful decannulation, death or hospital discharge.

Major complications were defined as procedure-related death, cardiac arrest, acute hypotension requiring new or increased vasopressor support, acute hypoxaemia, loss of airway, tracheal wall injury, false passage cannulation, pneumothorax, tracheostomy cannula obstruction, major bleeding (either stomal, intratracheal or from tracheovascular fistula) causing hypoxaemia and/or requiring emergency transfusion and/or open surgical repair and tracheostomy-related sepsis (stoma infection as the only identifiable source).

Minor complications included localized 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.

Any clotting complications within the extracorporeal circuit were recorded, including any documented evidence of a directly visible new clot formation within the extracorporeal circuit or a sudden malfunction of the device which could be potentially explained by clot formation within 24 h of tracheostomy.

In addition, the length of stay in the ICU and hospital, duration of invasive MV and extracorporeal lung support as well as 28-day and 3-month mortality rates were evaluated. Survival data were obtained from medical records and/or telephone follow-up.

Statistical analyses

Continuous variables are expressed as medians with range. Categorical variables are expressed as counts and percentages. Non-parametric analyses were performed to compare risk factors and outcome variables between the three subgroups of types of extracorporeal support (vvECMO, vaECMO and PECLA). Depending on the number of groups compared and the data type the χ^2 test, Fisher's exact test, Mann–Whitney U test or Kruskal–Wallis one-way analysis of variance were applied. A two-sided p value of <0.05 was considered to be significant and p values are given. The software used for analyses was SPSS ver. 20.0 (SPSS Inc., Chicago, IL).

Results

Baseline clinical characteristics

Demographics

Between 1 January 2007 and 31 March 2013 a total of 128 patients underwent a tracheostomy while on extracorporeal lung support at the two university hospitals. Of these, ten patients underwent a ST. Reasons for the surgical preference for ST and clinical characteristics of these patients are presented in ESM Table 1. The remaining 118 patients underwent PDT and were further analysed. The median age in this group was 46 (range 18–81) years and 49 patients were female (41.5 %).

Diagnoses and treatments

A total of 87 patients (73.7 %) were on ECMO, of which 68 patients (57.6 %) were on vvECMO and 19 (16.1 %) were on vaECMO. The remaining 31 patients (26.3 %) were on PECLA. The main indication for extracorporeal lung support was severe acute respiratory distress syndrome (ARDS), which was present in 100 patients (84.8 %). Of the 68 patients on vvECMO, 67 had severe ARDS and one had severe hypercapnic failure. vaECMO was commenced for (1) right ventricular failure subsequent to ARDS ($n = 8$) or pulmonary embolism ($n = 2$) or (2) biventricular failure as a result of septic cardiomyopathy ($n = 2$) or primary cardiac failure ($n = 7$). Of the 31 patients treated with PECLA, 23 had ARDS and eight had severe hypercapnic ventilatory failure. Table 1 provides a detailed description of all primary diagnoses, co-morbidities and severity of illness scores. Details of ventilatory and extracorporeal times and settings as well as respiratory and haemodynamic parameters are presented in ESM Table 2.

Coagulation characteristics

As per local ECMO protocol in both hospitals the target values for aPTT, INR, platelet count and fibrinogen were 50–60 s, <1.5, >60 $\times$ 10^9/L and >1.5 g/L, respectively. The measured median values for aPTT, INR, platelet count and fibrinogen concentration before tracheostomy were 49 s (range 28–117), 1.1 (0.9–2.0), 126 $\times$ 10^9/L (16–617) and 4.0 g/L (1.0–9.0), respectively. All blood samples were drawn before stopping heparin administration and before any blood or coagulation products were given. A total of 48 patients (40.7 %) received transfusions of red blood cells up to a maximum of six units within 24 h before PDT. Seventeen patients (14.4 %) received a maximum of up to three bags of donor pooled

Table 1 Baseline clinical characteristics of patients with percutaneous dilatational tracheostomy on an extracorporeal lung assist device

Variable[a]	vvECMO (n = 68)	vaECMO (n = 19)	PECLA (n = 31)	All (n = 118)	p value
Age, sex and type of extracorporeal device					
Age (years)	46 (18–72)	47 (23–72)	51 (23–81)	46 (18–81)	0.09
Female sex (% within subgroup)	30 (44.1)	6 (31.5)	13 (41.9)	49 (41.5)	0.66
Type of ECLA (% of all)	68 (57.6)	19 (16.1)	31 (26.3)	118 (100)	–
Reason for extracorporeal support (% within subgroup)					
ARDS	67 (98.5)	–	23 (74.2)	90 (76.3)	<0.001
ARDS with septic cardiomyopathy	–	2 (10.5)	–	2 (1.7)	
ARDS with RV failure	–	8 (42.1)	–	8 (6.8)	
Hypercapnic respiratory failure	1 (1.5)	–	8 (25.8)	9 (7.6)	
RV failure due to PE	–	2 (10.5)	–	2 (1.7)	
Primary cardiac failure	–	7 (36.8)	–	7 (5.9)	
Primary diagnosis (% within device subgroup)					
Pneumonia	61 (89.7)	6 (31.6)	25 (80.7)	92 (77.9)	<0.001
Acute exacerbation of COPD	–	–	3 (9.7)	3 (2.5)	
Acute exacerbation of ILD	–	–	1 (3.2)	1 (0.9)	
Alveolar haemorrhage	3 (4.4)	3 (15.8)	1 (3.2)	7 (5.9)	
Bronchiolitis obliterans	1 (1.5)	1 (5.3)	1 (3.2)	3 (2.5)	
Toxic inhalational trauma	1 (1.5)	–	–	1 (0.9)	
Bleomycin-induced pneumonitis	1 (1.5)	–	–	1 (0.9)	
Haemophagocytosis syndrome	1 (1.5)	–	–	1 (0.9)	
Pulmonary embolism	–	2 (10.5)	–	2 (1.7)	
Acute coronary syndrome	–	4 (21.0)	–	4 (3.4)	
Heart failure post cardiac surgery	–	3 (15.8)	–	3 (2.5)	
Severity of illness scores					
SAPS-II score on ICU admission	47 (21–88)	42 (22–59)	46 (23–69)	47 (21–88)	0.91
SOFA score on ICU admission	11 (4–19)	9 (4–15)	11 (4–17)	11 (4–19)	0.05
SOFA score on day of tracheostomy	11 (4–18)	9 (5–15)	10 (6–16)	10 (4–16)	0.17

ECLA Extracorporeal lung assist, *vvECMO* veno-venous extracorporeal membrane oxygenation, *vaECMO* venoarterial ECMO, *PECLA* pumpless extracorporeal lung assist, *ARDS* acute respiratory distress syndrome, *RV* right ventricular, *PE* pulmonary embolism, *COPD* chronic obstructive pulmonary disease, *ILD* interstitial lung disease, *SAPS* simplified acute physiology score, *SOFA* sequential organ failure assessment, *ICU* intensive care unit

[a] Data are presented as the median with the range in parenthesis, or as a number with the percentage in parenthesis

platelets, and eight patients (6.8 %) received a maximum of up to 4 units of fresh frozen plasma (FFP) before the procedure. In all of these patients pooled platelets and/or FFP were administered immediately before the procedure without further coagulation tests. Transfusion requirements in the 24 h following PDT were similar to those during the previous 24 h. Further details on the haematological and coagulatory parameters before and after PDT are presented in Table 2. In both hospitals the local protocol recommended stopping the administration of intravenous unfractionated heparin 1 h before the planned tracheostomy. Heparin was recommenced immediately after completion of the procedure at the previous rate and adjusted to subsequent coagulation test results.

Complications

No procedure-related deaths occurred, and no periprocedural clotting complications within the extracorporeal circuit and/or malfunction problems of the extracorporeal device were observed.

Five patients (4.2 %) suffered a major complication. Of these, two (1.7 %) suffered from procedure-related major bleeding: one patient on vaECMO developed intraprocedural bleeding from a large pretracheal vein and required emergency conversion to a surgical tracheostomy; the second patient, on vvECMO, developed intratracheal bleeding which caused transient hypoxaemia, but the bleeding stopped spontaneously without any sequelae. Two cases of periprocedural pneumothoraces (1.7 %) were successfully treated with chest drains, and one patient (0.8 %) suffered from analgosedation-related hypotension with brief and successful cardiopulmonary resuscitation and without neurological sequelae.

All other bleeding complications were minor (n = 37 patients, 31.4 %) and were either self-limiting (78.4 %), responded to peristomal compression (10.8 %), or could be stopped with instillation of topical vasoconstrictive agents (8.1 %) or by electrocauterization (2.7 %). The minor stomal bleeding in 32 of these 37 patients (86.5 %) occurred within 7 days of tracheostomy; in the remaining five patients (13.5 %) it occurred at some point after 7 days post-tracheostomy.

Stomal infections without causing sepsis were observed in 22 patients (18.6 %). A detailed list of complications according to each type of extracorporeal device is shown in Table 3.

Table 2 Haematological and coagulatory parameters before and after percutaneous dilatational tracheostomy

Variable[a]	vvECMO ($n = 68$)	vaECMO ($n = 19$)	PECLA ($n = 31$)	All ($n = 118$)	p value
Parameters prior to PDT					
Haemoglobin (g/dL)	11.0 (7.8–14.4)	10.1 (8.8–13.3)	8.9 (7.8–12.9)	10.0 (7.8–14.4)	0.02
Platelets ($\times 10^9$/L)	137 (26–617)	93 (16–239)	153 (16–474)	126 (16–617)	0.08
INR (ratio)	1.2 (0.9–2.0)	1.2 (1.0–2.0)	1.1 (0.9–1.8)	1.1 (0.9–2.0)	0.68
aPTT (s)	48 (30–103)	52 (34–92)	44 (28–117)	49 (28–117)	0.15
Fibrinogen (g/L)	4.0 (2.2–9.0)	3.8 (1.0–7.4)	5.1 (3.7–7.0)	4.0 (1.0–9.0)	0.08
White cell count ($\times 10^9$/L)	13.0 (3.3–56.9)	12.7 (5.3–26.1)	12.5 (4.3–55.8)	13.0 (3.3–56.9)	0.79
C-reactive protein (mg/L)	154 (7–430)	140 (38–299)	53 (12–275)	129 (7–430)	<0.001
Patients receiving RBC 24 h prior to PDT	31 (45.5)[d]	9 (47.4)	8 (25.8)	48 (40.7)	0.14
Patients receiving Plt 24 h prior to PDT	8 (11.8)[d]	5 (26.3)	4 (12.9)	17 (14.4)	0.53
Patients receiving FFP 24 h prior to PDT	7 (10.3)[d]	1 (5.3)	–	8 (6.8)	0.13
Clotting factors[b] given 24 h prior to PDT	–	–	–	–	–
Single/double anti-platelet therapy[c]	7 (10.3)[d]/–	–/8 (50.0)	3 (9.7)/–	10 (8.5)/8 (6.8)	<0.001
Parameters within 24 h post-PDT					
Haemoglobin (g/dL)	10.1 (7.9–14.4)	10.4 (8.3–12.9)	9.5 (6.8–13.2)	10.1 (6.8–14.4)	0.87
Patients receiving RBC 24 h post-PDT	30 (44.1)[d]	9 (47.3)	9 (29.0)	48 (40.7)	0.28
Patients receiving Plt. 24 h post-PDT	11 (16.1)[d]	6 (31.5)	4 (12.9)	21 (17.7)	0.22
Patients receiving FFP 24 h post-PDT	9 (13.2)[d]	3 (15.8)	–	12 (10.1)	0.06
Clotting factors[b] given 24 h post-PDT	–	–	–	–	–

PDT Percutaneous dilatational tracheostomy, *RBC* packed red blood cells, *24 h* 24 hour, *Plt.* bag of pooled platelets, *FFP* fresh frozen plasma

[a] Data are presented as the median with the range in parenthesis, or as a number with the percentage in parenthesis

[b] Clotting factor concentrates (e.g. prothrombin complex concentrate, fibrinogen, factor 7)

[c] Aspirin as single antiplatelet medication and Aspirin plus clopidogrel as double antiplatelet treatment

[d] Value in parenthesis is the percentage within the subgroup

Clinical course and further outcomes

The 28-day and 3-month mortality rates were 53.4 and 55.9 %, respectively. Total durations of MV, extracorporeal lung support, and ICU/hospital length of stay are presented in ESM Table 3.

Discussion

Of the 118 cases of PDT performed on patients while on extracorporeal lung support that were included in our study, the overall rate of PDT-related clinically relevant complications was 4.2 % and the rate of clinically relevant bleeding complications 1.7 %. The noticeable predominance of PDT as the technique of choice for tracheostomy in our patient group corresponds with general contemporary tracheostomy practices in intensive care medicine [1, 2]. In several systematic reviews PDT has been shown to be associated with equal or even lower rates of stomal bleeding complications in comparison with ST [21, 22].

Extracorporeal lung support is associated with severe complications. Bleeding is one of the most common complications in a clinical setting where controlled therapeutic anticoagulation is mandatory to prevent circuit thrombosis and where the ECLA device induces additional coagulation dysfunction [23, 24]. To date, no study has been published on the safety of PDT in patients on ECLA. Gregoric et al. [25] studied 31 patients undergoing PDT while on a ventricular assist device and reported two cases of minor stomal bleeding and one case of peristomal cellulitis. However, these authors do not provide any information on the management of periprocedural anticoagulation.

The rates of major complications for both pneumothoraces and relevant bleeding complications in our study are comparable to rates published in studies on PDT in different critically ill populations [9, 22, 26]. In their prospective observational study, Dempsey et al. [4] observed severe early complications in 3 % of 576 consecutive patients undergoing PDT in a mixed ICU. These severe complications included major stomal bleeding (1 % of cases) and para-tracheal misplacement of the tracheostomy tube with surgical emphysema or tension pneumothorax (0.7 % of cases). Minor bleeding was observed in 4.3 % of cases. The higher rate of minor stomal bleeding of 31 % in our cohort seems plausible due to the patients' mandatory and ongoing therapeutic anticoagulation, but these events did not have a relevant clinical impact. Our results are in line with those of Beiderlinden et al. [8] on patients undergoing PDT in which the subgroup of patients with platelet and coagulatory dysfunction did not have a higher rate of acute bleeding complications (i.e. within 24 h post-tracheostomy) but did have a significantly higher risk of chronic stomal bleeding

Table 3 Percutaneous dilatational tracheostomy-related complications

Variables associated with PDT-related complications[a]	vvECMO ($n = 68$)	vaECMO ($n = 19$)	PECLA ($n = 31$)	All ($n = 118$)	p value
Major PDT-related complications	3 (4.4)	1 (5.3)	1 (3.2)	5 (4.2)	1.0
PDT-related death	–	–	–	–	–
Acute hypotension	–	1 (5.3)	–	1 (0.8)	0.16
Major bleeding	1 (1.5)	1 (5.3)	–	2 (1.7)	0.36
Loss of airway during PDT	–	–	–	–	–
Pneumothorax	1 (1.5)	–	1 (3.2)	2 (1.7)	0.67
Tracheal wall injury	–	–	–	–	–
Sepsis due to stomal infection	–	–	–	–	–
Dislocation of TC post PDT	–	–	–	–	–
Minor PDT-related complications	42 (61.7)	12 (63.2)	14 (45.2)	68 (57.6)	0.04
Minor bleeding	25 (36.8)	7 (36.8)	5 (16.1)	37 (31.4)	0.02
Localized stomal infection	13 (19.1)	3 (15.8)	6 (19.4)	22 (18.6)	0.23
Swallowing dysfunction	4 (5.9)	2 (10.5)	3 (9.7)	9 (7.6)	0.14
ECLA circuit clotting post-PDT	–	–	–	–	–

TC Tracheal cannula

[a] Data are presented as the number with the percentage within each subgroup given in parenthesis

problems occurring beyond the 24-h post tracheostomy period.

Barton et al. [12] reported on non-ECLA patients on therapeutic anticoagulation with a mean heparin holding time of 6.3 h (range 0–13 h) prior to PDT and a rate of PDT-related minor bleeding complications of 1.7 %. Deppe et al. [11] described 48 cardiothoracic patients after valve replacement with an aPTT of >50 s without intravenous heparin discontinuation and without any PDT-related major bleeding complications. Little is known about the safety of PDT in patients on single or double antiplatelet inhibition. Cabrini et al. [13] reported two patients on aspirin and clopidogrel who successfully underwent PDT. Deppe et al. [11] found a PDT-related rate of minor bleeding of 7.4 % in cardiothoracic patients on platelet inhibition. In our study no patient on either single ($n = 10$) or double ($n = 8$) antiplatelet therapy suffered a major bleeding complication.

Few studies have addressed the safety of PDT in specific patient groups at high risk of bleeding due to pre-existing thrombocytopenia and/or coagulopathy of different causes. In their prospective study on the safety of PDT in 25 patients with refractory coagulopathy due to severe liver disease, Auzinger et al. [5] observed major bleeding complications in 4 % of the patients and minor bleeding in 28 % of cases studied. Kluge et al. [7] retrospectively studied 42 critically ill patients with a thrombocytopenia of $<50 \times 10^9$/L, often accompanied by other coagulatory abnormalities, who received platelet transfusions immediately before PDT. The rate of major bleeding complications and minor bleeding events in their study was 5 and 24 %, respectively. In another study undertaken by the same research team on 51 patients with thrombocytopenia and/or impaired coagulatory function post-haematopoietic stem cell transplantation, no major periprocedural bleeding complications were observed, whereas 31 % of patients experienced minor bleeding and 2 % had a pneumothorax [6]. In both of these studies bags of pooled donor platelets were given if the platelet count was $<50 \times 10^9$/L and transfusion was given immediately prior to the procedure without awaiting further coagulation tests. On the basis of this experience, all patients in our study with a platelet count of $<50 \times 10^9$/L were managed the same way, and in all of these patients previous platelet transfusions had demonstrated an appropriate rise in platelet count.

In patients who are dependent on extracorporeal lung support it may arise that therapeutic anticoagulation needs to be reduced intermittently as a result of acute bleeding or interventions carrying significant risks of bleeding. In such cases acute circuit thrombosis becomes a major concern. The risk of circuit thrombosis not only depends on the patient's coagulatory state, but is also inversely correlated with blood flow in the extracorporeal circuit [27]. We did not observe any life-threatening periprocedural complications related to acute circuit thrombosis. Patients on venovenous and veno-arterial ECMO had a median blood flow before tracheostomy of 4.0 L/min, which was sufficiently high to contribute to the prevention of acute circuit thrombosis. Moreover, no relevant acute circuit thrombosis was observed in those 31 patients on arteriovenous PECLA with a median, non-gradable circuit blood flow of only 0.9 L/min despite short-term cessation of intravenous heparin.

There are methodological limitations to our study. Firstly, the interpretation of the results is limited by potential biases introduced by the retrospective study design. Minor, clinically less relevant complications, such as local infections or minor bleeding, may have been missed and underestimated because of incomplete documentation. However, we postulate that all severe and life-threatening complications, because of their clinical impact, were most likely fully documented at the time of occurrence and, therefore, detected by the retrospective

analysis. Secondly, the relatively small number of patients reduces the power of the study to detect rare complications. Finally, although patients were treated as part of routine clinical care, the applicability of the results to other settings must be considered with caution because the results were obtained from centres highly experienced in both extracorporeal lung support and PDT.

Conclusion

In conclusion, the results of our study demonstrate that PDT in patients on extracorporeal lung support is a relatively safe procedure if performed by experienced operators and critical care teams that provide adequate management of coagulation and the extracorporeal circuit. We therefore argue that treatment with extracorporeal lung support requiring therapeutic anticoagulation is not a contraindication for PDT and that its risks and benefits must be weighed against each other on individual bases. Further, larger prospective studies need to confirm these preliminary results on the safety of PDT in patients on extracorporeal lung support.

Conflicts of interest SB and AN have received lecture honoraria from Novalung GmbH, Talheim, Germany. SK is a member of the advisory board of Novalung GmbH and therefore has received advisor honoraria. All other authors declare that they have no conflicts of interest.

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