Original

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Bleeding complications of percutaneous dilatation tracheostomy (PDT) in a group of ICU patients with dual antiplatelet therapy

I Voigt, C Naber

Abstract

***Objective*: Percutaneous dilatational tracheostomy (PDT) is one of the most commonly performed intervention in patients requiring long-term mechanical ventilation in ICUs. The ease of performance and the availability of bronchoscopic control contributed to its safety in the hands of experienced operators and to its widespread acceptance. The bleeding complications of PDT in a group of ICU patients with dual antiplatelet therapy with acetylsalicylic acid (ASS) and clopidogrel were studied.**

***Design*: Retrospective analysis of 56 percutaneous tracheostomies during the study period (July 2008-July 2010) were performed.**

***Patients*: Patients were divided into two groups whereas patients receiving dual platelet inhibition (n=15) were defined as Group 1 and all other patients were classified as Group 2 (n=41).**

***Results*: There was no evidence of major bleeding in the study-group. We found 3 patients in Group 1 and 5 patients in Group 2 who were in need of interventions (prolonged pressure dressing/local endobronchial application of epinephrine) due to prolonged bleeding. The PDT was aborted for one patient in Group 2 because of failed tracheal punction. One patient in Group 2 died during the procedure after perforation of the posterior tracheal wall with consecutive bilateral pneumothoraxes and myocardial depression.**

***Conclusions*: Our data suggest the incidence of bleeding is low in patients with dual platelet inhibition. However, occult bleedings leading to atelectasis due to obstruction of bronchial system, should beware of.**

Key words: Tracheotomy, bleeding complications, dual antiplatelet therapy.

Introduction

Percutaneous dilatational tracheostomy (PDT) is one of the most commonly performed intervention in patients requiring long-term mechanical ventilation in ICUs. Tracheostomy is also one of the oldest known surgical procedure and over the past century PDT has become a safe method of securing an alternative airway. Recent data have suggested that there are even a few advantages compared to a surgical tracheostomy, including the possibility of bed-site intervention, and a lower incidence of postoperative infection and bleeding. (1-4) In recent years PDT has gained popularity to as it reduces pulmonary dead space and seems to make weaning from mechanical ventilation more easy due to reduced need of sedative medication, better patient comfort and a safe access for clearing of pulmonary secretions. Despite the progress in the technical procedure there are a number of contraindications to perform a PDT including thrombocytopenia and coagulation disorders. (5) Both, usually associated with sepsis, liver disease or

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hematologic-oncologic disorders, are well known problems in criticaly ill patients in ICU.

The thrombocyte function is depended on count and is influenced by therapeutic antithrombotic agents.

In patients with myocardial infarction, dual platelet inhibition is standard medication after PCI and stent implantation. Few studies have evaluated the safety of PDT in patients with coagulation disorders and thrombocytopenia, (6-8) but so far there is no data about the influence of dual platelet inhibition with acetylsalicylic acid (ASS) and clopidogrel on bleeding complications after PDT.

The objective of our study was to evaluate the safety, bleeding complication rate of PDT in a group of ICU patients with dual platelet inhibition.

Methods and materials

This retrospective study was conducted in an 11-bed, medical and coronary critical care unit in 600-bed teaching hospital in Essen, Germany.

All patients who underwent PDT between July 2007 and July 2010 were included. Patients' general data were collected from the electronic archived patient file. In our ICU, it is our protocol to routinely document all complications immediately following each procedure. Post interventional complications are also recorded on patients ICU-file.

Patients were divided into two groups whereas patients receiving dual platelet inhibition were defined as group one and all other patients were put into group two. The collection of data included patient age, sex, circumstances of ICU-admission, SAPS II, CRUSADE-Bleeding score (9) and duration of mechanical ventilation prior to the PDT. Coagulation parameters (PTT, INR, platelet count) on the day of procedure until 48h post PDT were determined.

For the purpose of this study, bleeding complications were classified as major (i.e., significant drop of haemoglobin requiring transfusion or surgical intervention) or minor. The application of red cell packages, bleeding complications, airway problems, pneumothorax, tracheal injuries, abortive procedure were noted and patients were followed until death or transport to another facility.

Percutaneous dilatational tracheostomy

All PDT were performed at the bedside in the ICU. All patients received anesthesia using propofol or midazolam and an opioid-agent (fentanyl/remifentanyl). FiO2 was increased to 1.0 and mechanical ventilation was set to a controlled mode of ventilation (SIMV 6-8 ml/kg). At least 4h prior to PDT continuous heparin-therapy was stopped. Routine monitoring was used including invasive BP measurement, oxygen saturation and heart rate. PDT procedure was made by the intensivist consultant in charge. Intubation and resuscitation equipment were available at the bedside. During the study period bronchoskopic guidance was not routinely used, and procedure was done with two different tracheostomy-kits (COOK Medical Inc., Blue Rhino/Blue Rhino Dolphin). Since November 2009 the standard protocol in our ICU includes the Blue Rhino Dolphin kit with bronchoskopic guidance.

Confirmation of an accurate tracheostomy position was done by auscultation, exhaled tidal volume and capnography. After the procedure, a chest x-ray was done to rule out pneumothorax.

Statistical analysis

Statistical analysis was done using SPSS-Software (V14.0). Data was presented as means and standard deviations.

Test of significance was performed by using student t test. Normality of distribution was tested using Kolmogrov-Smirnov Normality test. A $p<0.05$ was considered significant.

Results

During the study period, 56 PDT were performed. Of these 15 (26.7%) patients (Group 1) received a dual platelet inhibition (ASS+clopidogrel). 41 patients without dual platelet inhibition were screened for Group 2. The mean and standard deviation age of patients was 70.8±7.9 and 65.61±13.2. There was no significant difference between these two groups concerning SAPS II and CRUSADE-Score or duration of mechanical ventilation prior the procedure (**Table 1**).

Laboratory values as known bleeding factors showed no

statistical significant difference (**Table 2**). Only platelet count in the dual platelet therapy group slightly missed the significant niveau.

Despite the platelet dysfunction and often elevated INR and PTT in our patients, the actual number of bleeding complications related to PDT was minimal (**Table 3**). We found 3 patients in Group 1 and 5 patients in Group 2 who were in need of interventions (prolonged pressure dressing/ local endobronchial application of epinephrine) due to prolonged bleeding. The PDT was aborted for one patient in Group 2 because of failed tracheal punction. One patient in Group 2 died during the procedure after perforation of the posterior tracheal wall with consecutive bilateral pneumothoraxes and myocardial depression. Overall hospital mortality was 60% in dual antiplatelet inhibition group and 46.3 % in the control group, respectively. Outcome data are shown in **Table 3**.

Decrease of haemoglobin values 48h post-PDT (**Table 2**) and application of red packed cells (**Table 4**) were not different between both groups. The indication for transfusion was in most cases aimed to optimize the oxygen transportation during weaning period.

Beyond the above-noted bleeding episodes, few other complications were noted. Interestingly 2 patients in the dual platelet inhibition group showed atelectasis caused by a large thrombotic mass in the right main bronchus (**Figure 1**).

Discussion

Our results demonstrate a low complication rate for PDT in patients with thrombocyte dysfunction receiving dual platelet inhibition therapy due to acute myocardial infarction. To our knowledge, this is the first study with a special focus on these patients.

There are only a few studies with similar small subgroups of patients with thrombocytopenia or coagulopathy requiring tracheostomy.

With an experience of 1000 patients, who underwent PDT, Sharma et al (6) described an incidence of deranged coagulation profile in 32.5% (thrombocyt<100,000/µl, INR>1.5, PTT>60 s). Patients received platelets or fresh frozen plasma if necessary. They found no difference in major and minor bleedings comparing patients with deranged coagulation profile and the control.

Beiderlinden et al (7,10) studied the complication of PDT in 55 thrombocytopenic patients (platelet count less than $60x10^9$ cells/L) in two studies. The authors did not provide the incidence of bleeding, transfusion requirements or general complications in this subgroup.

Kluge and colleagues (11) retrospectively analysed their experience of PDT in medical patients with severe thrombocytopenia. The indication for medical ventilation in the majority of these patients was acute respiratory insufficiency after bone marrow transplantation or haematological malignancies. Only two (5%) out of 42 patients (mean platelet count $26x10^9$ cells/L) suffered from significant post-PDT bleeding requiring surgical intervention. Minor bleeding was seen in three cases (7%). The median transfusion of platelets before the procedure was 6±2.5 units and was mentioned as a condition for a low complication rate.

Blankenship et al (5) were able to compare nine patients with high risk of bleeding due to coagulopathy (INR>1.5, platelets count <20.000/mm3 or systemic heparin infusion) with a control group. The high-risk group had a mean estimated blood loss of 7.8 ml vs. 5 ml (p=0.22) in the control group. No major bleeding or conversion to a surgical tracheostomy was observed. Amount of units of FFP, red-packed cells and thrombocytes transfusions were lacking in this study.

Auzinger et al (12) presented data from 25 patients with severe liver disease and refractory coagulopathy defined as platelet count less than or equal to $50x10^9$ cells/L or their international normalized ratio (INR) was greater than 1.5 on the day of PDT and for 72h afterward. Clinically relevant bleeding complications were low, so they concluded that this subgroup of patients is not a contraindication for PDT. Provided adequate clotting support was given and in the hands of experienced operators, PDT could be safely performed.

In all of these publications the authors were not specially focusing on patients with platelet dysfunction receiving dual platelet inhibition therapy.

Our study included 15 patients and presented so far the

first experience focusing on this subgroup. Although the indication for tracheostomy is still a controversial debate in ICU literature, it can be a valuable tool to avoid oral and laryngeal injuries, improve patient's comfort and aids weaning from mechanical ventilation. If weaning fails it is necessary before initiating a home ventilation therapy. Although 33.3% respectively 26.9% of patients in our study received red packed cells transfusion 72h post-PDT, we noted no life-threatening bleeding complication. The trigger for transfusion was in most cases a lower haemoglobin value (9.2 g/dl vs. 10.9 g/dl, p=0.003) prior the PDT procedure to aid the weaning process. In addition to that patients who received transfusions had a higher CRUSADE-Bleeding-Score (42±17 vs. 58±16, p=0.003) and a higher creatinine value (1.5±1.6 mg/dl vs. 2.5±1.6 mg/dl, p=0.02) (**Table 5**). Although there was no evidence of better outcome in ICU patients after raising the haemoglobin value over 10 g/dl, Walsh et al (13) described a similar phenomenon in a survey about transfusion decisions in British ICUs. Concerning platelets and coagulation factors, no FFP or platelet units had to be transfused in our study.

Bleeding that was noticed during the procedure stopped in most cases immediately after the insertion of the tracheostomy tube by tamponading effectively the dilatation way and was not noted as minor bleeding. Using the Blue Rhino Dolphin kit (Cook medical) for PDT seems to be even more atraumatic in our experience leading to fewer bleeding complications. Cianchi and co-workers (14) compared the new Dolphin system with the single-step dilatational tracheotomy (Ciaglia Blue Rhino) in 70 ICU patients. Although they found no major bleeding, the presence of limited intra-tracheal bleeding at post-PDT bronchoscopic examination was more frequent in the Dolphin group than in the Rhino group (68.6% vs. 34.3% respectively, p=0.008). In our study two patients (both Blue Rhino Dolphin kit) presented atelectasis due to bronchial obstruction of a large thrombotic mass (**Figure1**). For that reason we routinely do a re-bronchoscopy 48-72h after PDT to evacuate coagulated blood.

One limitation of our study was that different protocols for PDT (different kits, with/without bronchoscopic guidance) were used. Another limitation was the retrospective data acquisition and the small sample size.

The overall mortality in both study groups might appear high given the SAPS II Score (predicted mortality 18.1%), however it is comparable to other studies investigating PDT. (15-17)

Conclusion

Based on our experience, PDT has a low complication rate, even in patients with thrombocyte dysfunction receiving dual platelet inhibition after acute myocardial infarction. We conclude that this subgroup of patients is not a contraindication for PDT. However, occult bleedings leading to atelectasis due to obstruction of bronchial system, should beware of. Immediately bronchoscopic evaluation in case of respiratory problems should be standard protocol.

Table 1. Clinical data in patients with and without dual platelet therapy

Characteristics		Dual platelet therapy (n=15)	Control (n=41)	p value
Age (years)		70.8±7.9	65.1±13.2	ns
Gender, M/F		12/3	27/12	ns
Scores				
	CRUSADE	50.3±17.7	45.4±18.3	ns
	SAPS II	36.0±8.4	35.3±9.8	ns
MV day		7.5±3.8	8.6±4.6	ns
Reason for ICU admission				
	CPR	5	10	
	Other	10	31	

Legend: ns=non significant

Table 2. Laboratory values before and 24/48h after percutaneous dilatational tracheotomy (PDT)

		Dual platelet therapy (n=15)	Control (n=41)	p value
Hb (g/dl)				
	PDT	10.5±1.9	10.4±2.0	ns
	24h	10.3±1.8	10.4±2.0	ns
	48h	10.3±1.7	10.2±1.9	ns
Platelet count (100,000/ul)				
	PDT	179±92	237±111	ns (p=0.059)
	24h	187±95	244±111	ns (p=0.079)
	48h	201±110	250±102	ns
aPTT (sec.)				
	PDT	43.8±15.9	47.9±15.8	ns
	24h	41.1±8.4	46.6±12.4	ns
	48h	41.4±12.7	47.4±18.5	ns
INR				
	PDT	1.1±0.2	1.2±0.3	ns
	24h	1.2±0.1	1.2±0.4	ns
	48h	1.2±0.2	1.2±0.4	ns
Creatinine (mg/dl)				
	PDT	1.8±1.5	1.9±1.7	ns
	24h	1.7±1.2	1.7±1.4	ns
	48h	1.6±1.2	1.6±1.3	ns

Legend: ns=non significant

Table 3. Post-PDT complications and outcome parameters in patients with or without dual platelet therapy

	Dual platelet therapy (n=15)	Control (n=41)
Post-PDT complications		
Death	0	1
Aborted procedure	0	1
Major bleeding	0	0
Minor bleding	3	5
Atelectasis by bronchus occlusion	2	0
28d mortality		
Death	8	13
Alive	7	26
Hospital discharge		
Death	9	19
Rehabilitation center	3	11
Care home	2	4
At home	1	7

Table 4. Red packed cells transfusion 72h post-PDT

	Dual platelet therapy (n=15)	Control (n=41)	p value
Red packed cells transfusion (mean)	1.5	1.95	ns
None	10	30	
1 unit	0	1	
2 units	5	10	

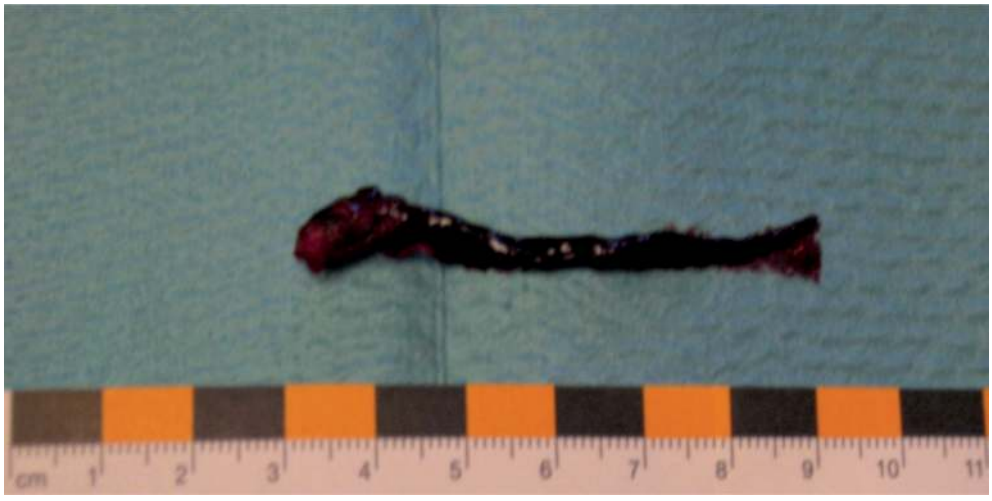
Legend: ns=non significant

Table 5. Clinical data and scores in patients depended on transfusion decision during the first 72h post PDT

	No transfusion (n=40)	Transfusion (n=16)	p value
Age (years)	66.4±13.1	68.4±9.8	ns
Scores			
CRUSADE	42±17	58±16	0.003
SAPS II	34±8	37±8	ns
Hemoglobin (g/dl)	10.9±2.1	9.2±0.6	0.003
Platelet count (100,000/ul)	221±106	221±120	ns
aPTT (sec.)	45±15	48±18	ns
INR	1.2±0.2	1.2±0.3	ns
Creatinine (mg/dl)	1.5±1.6	2.6±1.5	0.02

Legend: ns=non significant

Figure 1. Evacuated thrombotic mass from right main bronchus 48h past PDT



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