Abstract: Some patients who need dual antiplatelet therapy sometimes require tracheotomy. Aim of this study was to compare the rate of complications during and after surgical tracheotomy between patients requiring dual antiplatelet therapy and those without dual antiplatelet therapy. We retrospectively included 79 patients (62% men, mean age 64 ± 14 years) in the period 2007-2011. The following complications were analyzed: need for surgical revision within 24 hours after tracheotomy, need for bronchoscopy within 24 hour after tracheotomy, need for blood transfusion within 24 hours after tracheotomy, death attributed to tracheotomy and any complication attributed to tracheotomy. We compared patients where tracheotomy was performed while receiving dual antiplatelet therapy (n=27, 34%) to patients where tracheotomy was performed without dual antiplatelet therapy (n=52, 66%). Nonsignificant differences between the two groups were observed general characteristics. There were no statistically significant differences in complications after tracheotomy (surgical revision after tracheotomy p=0.63, bronchoscopy after tracheotomy p=0.74, blood transfusion after tracheotomy p=0.59, death attributed to tracheotomy p=1.00 and any complication attributed to tracheotomy p=1.00). The study shows that tracheotomy is safe in cardiac patients on dual antiplatelet therapy.

Keywords: Tracheotomy, complications, antiplatelet therapy, bleeding, intensive care unit.

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1 Introduction

Tracheotomy is a common procedure in the critically-ill patients. Main indications are long-term mechanical ventilation, need to protect the airway, difficult weaning from mechanical ventilation and need for emergency cricothyroidotomy [1,2]. Tracheotomy has some potential advantages over mechanical ventilation via endotracheal tube, namely smaller dead space, protected airway, decreased risk of laryngeal injury and stenosis because of endotracheal tube, improved patient comfort and reduced need for analgesia [1-4]. These advantages have so far failed to translate into improved survival. Tracheotomy can be performed using percutaneous dilatation techniques, usually with bronchoscopic control or using a traditional surgical approach. When using a surgical approach fewer acute complications can be expected compared to percutaneous technique, however, complications, mainly bleeding, can be more severe [1,2,4]. The main advantage of surgical approach over percutaneous is the immediate presence of appropriately trained personnel and surgical instruments (e.g. electrocautery devices), both of which are needed in the event of complications developing during or shortly after the procedure [1-5]. Ultimately, the choice of whether to use a surgical or percutaneous approach depends on institutional policies and availability. An established approach in authors' institution is surgical tracheotomy performed by otorhinolaryngologists in the operating room adjacent to intensive care unit (ICU).

Elective surgical tracheotomy is a safe procedure [1-5]. To decrease the risk of bleeding complications, surgeons mostly encourage the discontinuation of dual oral antiplatelet (DAPT) therapy 4-5 days before surgery. However, in patients with acute coronary syndromes or after percutaneous coronary interventions, discontinuation of DAPT is not advised because of increased risk of acute in-stent thrombosis to about 5% in the first month after stent placement [6-8]. Mortality of patients with acute coronary
syndrome due to acute in-stent thrombosis is around 20% [6-8]. The number of patients in ICU who require DAPT is increasing [1,6,7]. The goal of this study was to compare the rate of complications attributed to tracheotomy between patients requiring DAPT and those without DAPT.

2 Materials and methods

We performed a retrospective study in adult medical ICU patients with surgical tracheotomy performed in the years 2007-2011. Institutional ethics committee approval was obtained (No. 81/12). Inclusion criteria were: intubation, surgical tracheotomy and no need for therapeutic doses of anticoagulant therapy. Clinical data were obtained by chart review regarding antiplatelet therapy, anticoagulant therapy, complications attributable to tracheotomy, gender, age, underlying disease, the indication for admission to the ICU, duration of mechanical ventilation before tracheotomy, total duration of mechanical ventilation and the indication for tracheotomy. Complications of tracheotomy were defined as: need for surgical revision within 24 hours after tracheotomy, need for bronchoscopy within 24 hour after tracheotomy, need for blood transfusion within 24 hours after tracheotomy, death attributed to tracheotomy and any complication attributed to tracheotomy. Surgical tracheotomy was performed in all patients.

Tracheostomy was performed in an operating room that is adjacent to the ICU by ear-nose-throat surgeons, analgesia and sedation was overseen by the attending intensivist. Intravenous analgesia was provided with fentanyl and either midazolam or propophol. Neuromuscular blocking agents were used at the discretion of attending physician. Once trachea was prepared anterior part of usually the 2nd tracheal ring was cut and removed. After insertion of tracheostomy tube the patient was transferred back to the ICU.

DAPT was defined as concomitant therapy with aspirin and one of the following: clopidogrel, prasugrel or ticagrelor. Patients in the DAPT-group could be concomitantly treated with prophylactic dose of low-molecular weight heparin (LMWH). Non-DAPT group included patients who received no antiplatelet therapy and no anticoagulant therapy, only prophylactic dose of LMWH or LMWH and aspirin.

Statistical analysis was performed using SPSS (Software Package 19). P value less than 0.05 was considered as statistically significant. Logistic regression was used to assess the effect of LMWH and aspirin on complications after tracheotomy.

3 Results

Tracheotomies were performed in 79 patients. Twenty-seven patients (34%) were treated with DAPT at the time of tracheostomy, 52 patients (66%) were not receiving DAPT. Indications for admission to the ICU, indications for tracheotomy and characteristics of patients in DAPT and non-DAPT groups are in Tables 1, 2 and 3, respectively.

In the non-DAPT group 36 (69%) patients were treated with prophylactic dose of LMWH (no LMWH on the morning of tracheotomy), 10 (19%) patients were treated with LMWH and aspirin (no LMWH on the morning of tracheotomy, aspirin continued) and 6 (12%) patients received no antiplatelet or anticoagulant therapy.

In the DAPT group, 21 patients (78%) were treated with DAPT and prophylactic dose of LMWH (no LMWH on the morning of tracheotomy).

There were no statistically significant differences between DAPT group and non-DAPT group in need for

| Indication for admission to the ICU | DAPT group | Non-DAPT group |
|-----------------------------------|------------|---------------|
| Survivors of cardiac arrest (%)   | 78         | 12            |
| Sepsis (%)                        | 0          | 50            |
| Acute myocardial infarction (%)   | 22         | 9             |
| Exacerbation of chronic obstructive pulmonary disease (%) | 0 | 17 |
| Intoxication (%)                  | 0          | 10            |
| Polyneuropathy (%)                | 0          | 2             |

Legend: ICU = intensive care unit, DAPT = dual antiplatelet therapy.
Surgical tracheotomy performed with and without dual antiplatelet therapy

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surgical revision within 24 hours after tracheotomy (10 (37%) vs. 23(40%), p=0.63), need for bronchoscopy within 24 hour after tracheotomy (3 (11%) vs. 9 (16%), p=0.74), need for blood transfusion within 24 hours after tracheotomy (8 (30%) vs. 11 (21%), p=0.59) death attributed to tracheotomy (0 vs. 0 p=1.00) and any complication attributed to tracheotomy (15 (56%) vs. (58%), p=1.00). The addition of LMWH did not significantly predict complications after tracheotomy (need for surgical revision within 24 hours after tracheotomy: OR 0.11, 95% CI 0.008-1.741, p=0.12, need for bronchoscopy within 24 hour after tracheotomy: OR 3.15, 95% CI 0.445-22.34, p=0.94, need for blood transfusion within 24 hours after tracheotomy: OR 0.76, 95% CI 0.075-7.75, p=0.82, death attributed to tracheotomy: OR 0.96, 95% CI 0.089-6.74, p=0.82 and any complication attributed to tracheotomy: OR 0.76, 95% CI 0.14-26.94, p=0.62). Likewise, the addition of aspirin in non-DAPT group did not significantly predict complications after tracheotomy (need for surgical revision within 24 hours after tracheotomy: OR 1.2, 95% CI 0.24-6.38, p=0.79, death attributed to tracheotomy: OR 0.92, 95% CI 0.39-3.74, p=0.88 and any complication attributed to tracheotomy: OR 0.79, 95% CI 0.09-6.32, p=0.82).

4 Discussion

This study demonstrates that complications after surgical tracheotomy in patients on DAPT are rare and that no significant differences exist between the group of patients with and without DAPT. To date, limited data exists on the use of DAPT in patients where tracheotomy was performed, either by percutaneous or surgical method [8]. To our knowledge, this is the first study focused on patients with DAPT and concomitant surgical tracheotomy.

More data exist on percutaneous tracheotomy and thrombocytopenic patients. In a study by Sharma et al [9] no difference was discovered between thrombocytopenic (platelet count <100x109 cells/L) and nonthrombocytopenic patients. Beiderlinden et al [10] studied the risk for
complications after percutaneous tracheotomy and found significantly higher risk for bleeding in thrombocytopenic patients (platelet count <50x10^9 cells/L). In a study by Kluge et al [11] 5% of thrombocytopenic patients (mean platelet count 26x10^9 cells/L) suffered from bleeding and required surgical intervention.

Regarding thrombocytopenia associated with coagulopathy Auzinger et al [12] presented data from 25 patients with liver disease and coagulopathy (platelet count <50x10^9 cells/L or international normalized ratio (INR) >1.5). Clinically relevant bleeding complications were low, so they concluded that percutaneous tracheotomy is not contraindicated in this patient subset. Blankenship et al [13] compared patients with coagulopathy (INR >1.5) and thrombocytopenia (platelet count <20x10^9 cells/L) with a control group. Non-significant differences were observed regarding bleeding and conversion to surgical tracheotomy. Regarding thrombocytopenia and surgical tracheotomy only limited data exists from a study by Blot et al [14], suggesting that tracheotomy can be safely performed in neutropenic and thrombocytopenic patients requiring mechanical ventilation.

There are several potential advantages of surgical tracheotomy compared to percutaneous technique. In case of a failed percutaneous tracheotomy or complications during percutaneous tracheotomy it is a rescue technique [15]. It is one of the oldest continuously practiced surgical procedures, performed by surgeons trained in solving possible complications. Percutaneous technique is a relatively new procedure, practiced at the bedside mostly by intensivists, who require surgical backup in case of complications [2,5,15]. Using a surgical approach potentially allows for better local hemostasis, being able to visualise operating field [2,15]. A low rate of complications in this study could be at least partially attributed to tracheotomy being performed by otorhinolaryngologists, who were aware of the fact that patients required DAPT and could have adjusted surgical technique to a more careful approach.

This study has several limitations. It was a retrospective study observing a relatively small cohort. DAPT group received different drugs (clopidogrel, prasugrel or ticagrelor) with different characteristics regarding bleeding risk. Addition of prophylactic dose of LMWH in DAPT group contributed to heterogeneity of patients in DAPT group. Non-DAPT group was even more heterogeneous (no antiplatelet and no anticoagulant therapy, only prophylactic dose of LMWH or prophylactic dose of LMWH with aspirin). However, no significant differences were observed between different groups.

The authors conclude that tracheotomy is a safe procedure for cardiac patients who require DAPT. Tracheotomy in patients treated with DAPT has a low complication rate, comparable to patients not treated with DAPT. DAPT may not be a contraindication for surgical tracheotomy, however, studies with larger sample size are needed to validate this finding.

Conflict of interest statement: Authors state no conflict of interest

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