



Open tracheostomy in patients with dual platelet aggregation inhibitors: case series

Traqueostomía abierta en pacientes con antiagregación plaquetaria dual: Serie de casos

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Abstract

Introduction: Tracheostomy is the most common surgical procedure performed in the intensive care unit (ICU). There is a paucity of evidence regarding complications in patients on dual anti-platelet therapy.

Objective: To describe the complications arising in critically ill patients on dual antiplatelet therapy who are subjected to open tracheostomy.

Method: Descriptive observational study of a retrospective case series of patients admitted to the ICU between June 2011 and December 2016, scheduled to undergo open tracheostomy.

Results: Overall, 52 patients met the inclusion criteria and, of them, 14 were excluded. Postoperatively, 4 patients (10.5%) had major bleeding and 2 (5.3%) had minor bleeding. Only 1 patient (2.6%) required transfusion secondary to tracheostomy-related bleeding. No patient required fiberoptic bronchoscopy due to bleeding. Reintervention was needed in 10.5% of patients (n=4). No tracheostomy-related mortality was reported.

Conclusion: Although 10.5% of patients had major bleeding, there was no impact on mortality. This study showed that, in

patients with recent major cardiovascular events, there is no need to discontinue dual antiplatelet therapy or delay tracheostomy.

Resumen

Introducción: La traqueostomía es el procedimiento quirúrgico más frecuentemente realizado en la Unidad de Cuidado Intensivo. La evidencia respecto a las complicaciones en pacientes con antiagregación plaquetaria dual es escasa.

Objetivo: Describir las complicaciones que se presentan en pacientes críticos en manejo con terapia antiagregante plaquetaria dual, sometidos a traqueostomía abierta.

Método: Estudio observacional descriptivo, serie de casos retrospectiva de pacientes hospitalizados en la Unidad de Cuidado Intensivo desde junio de 2011 hasta diciembre de 2016, programados para traqueostomía abierta.

Resultados: 52 pacientes cumplieron criterios de inclusión, de los cuales se excluyó a 14. No se presentaron complicaciones durante la realización de la traqueostomía. En el posoperatorio, cuatro pacientes (10.5%) presentaron sangrado mayor y dos (5.3%) presentaron sangrado menor. Solo un paciente (2.6%) requirió

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transfusión secundaria a sangrado por traqueostomía. Ningún paciente requirió fibrobroncoscopia por sangrado. En un 10.5% de los pacientes (n=4) hubo necesidad de reintervención. No se reportó mortalidad por causa de la traqueostomía.

Conclusiones: Aunque el 10.5% de los pacientes presentaron sangrado mayor, no hubo impacto en la mortalidad. El presente estudio mostró que en pacientes con evento cardiovascular mayor reciente no es necesario suspender la antiagregación dual ni diferir la realización de la traqueostomía.

Introduction

Tracheostomy is a procedure commonly performed in critically ill patients.¹ Indications are clear, including prolonged mechanical ventilation, need for airway protection, difficulty weaning from mechanical ventilation, persistent Glasgow Coma Score < 8, polyneuropathy, and upper airway obstruction.² Two surgical techniques are used at present: open and percutaneous.³ Situations in which the open technique would be preferred include the use of antiplatelet or anticoagulation therapy.^{4,5} Bleeding occurring within the first 48 hours is associated with factors such as vascular injury, coagulopathy and the use of antiplatelet or anticoagulation therapy. Incidence varies between 5% and 8%.^{6,7} Overall mortality due to tracheostomy complications is lower than 0.5%.^{2,4}

Patients with major cardiovascular events frequently show neurological impairment with indication for tracheostomy.^{8,9} Percutaneous coronary intervention with stent implantation, especially drug eluting stents, is the most frequent form of coronary revascularization performed in patients with ischemic coronary disease or acute coronary syndrome, requiring 1 year of dual antiplatelet therapy to ensure stent patency. Studies have shown that continuation of dual antiplatelet therapy increases the risk of postoperative bleeding, hence the recommendation to discontinue thienopyridines 4 to 5 days before the procedure. However, discontinuation of dual antiplatelet management is the highest predictor of stent thrombosis; the magnitude of the risk is inversely proportional to the time of non-cardiac surgery after revascularization, and it is as high as 5% in the first month after stenting. Mortality from acute coronary syndrome due to stent stenosis is 20%.¹⁰

Few studies have reported complications in critically ill patients undergoing tracheostomy and who have an indication for antiplatelet therapy. At present, international guidelines for the management of patients receiving platelet aggregation inhibitors and/or anticoagulants^{10,11} do not provide recommendations in this clinical context. Consequently, this study seeks to describe the complications seen in critically ill patients undergoing open tracheostomy who are on dual antiplatelet therapy with acetylsalicylic acid (ASA) and clopidogrel. The study is important given the paucity of

information on the subject and also because this is the first study in this country and in Latin America to approach this problem.

Materials and methods

This is a descriptive observational study of a retrospective case series of adult patients admitted to the intensive care unit (ICU) of the Santa Sofía Hospital in the Department of Caldas between June 2011 and December 2016, who were scheduled for tracheostomy. The bioethics committee of the Health Sciences School of Caldas University granted approval on August 30, 2017 (Minutes No. 012 of 2017). Informed consent was not required because of the retrospective nature of the study. An in-depth review of the clinical records was performed. The inclusion criteria were: 18 years of age or more, use of dual antiplatelet therapy with ASA and clopidogrel and/or heparin given on the day of the procedure and over the following days. Exclusion criteria were: percutaneous tracheostomy, airway bleeding before the procedure, coagulopathy (clotting time 1.5 times higher than the control), thrombocytopenia (platelet count <50,000/ μ L). The following variables were determined as part of bleeding complications: minimal non-relevant bleeding, defined as blood loss easily controlled by the respiratory therapy staff; minor bleeding, defined as blood loss requiring interventions indicated by the ICU physician; major bleeding, defined as blood loss requiring reintervention by a general surgeon, associated or not to a 2g/dL or greater drop in hemoglobin (Hb) and/or transfusion of more than 2U of packed cells. The *Statistical Package for the Social Sciences* (SPSS) version 21 was used for the statistical analysis.

Results

Overall, 52 patients were included. A total of 14 were excluded: 10 patients who underwent percutaneous tracheostomy; 2 patients with airway bleeding before the surgical tracheostomy; 1 case of left thoracotomy and pulmonary decortication due to hemothorax carried out together with the tracheostomy, who went on to develop anemia; 1 case of cardiac arrest and acute myocardial infarction following the tracheostomy who was switched from clopidogrel to ticagrelor. Of the 38 patients selected, 27 were males (71%) and 11 were females (29%); median age men was 64 with an interquartile range of 56 to 64 years for males, and 75 years for females, with an interquartile range of 63 to 83 years.

The 38 patients were admitted to the ICU due to a major cardiovascular event such as unstable angina and acute myocardial infarction, ischemic cerebrovascular disease and ischemic pancreatitis (Table 1).

Per ICU protocol, prophylactic dose low-molecular-weight heparin was discontinued 12 hours before

Table 1. Diagnosis on admission to the ICU.

Diagnosis on admission to the ICU	Frequency (n)	%
Unstable angina	6	15.8
Acute myocardial infarction	20	52.6
Cardiogenic shock	3	7.9
Cardiac arrest from coronary thrombosis	7	18.5
Ischemic cerebrovascular disease	1	2.6
Ischemic pancolitis	1	2.6
Total	38	100

ICU=intensive care unit.
Source: Authors.

the procedure, 24 hours before for therapeutic doses, and 36 hours before the surgery if patients were on fondaparinux. Therapy was restarted 8 to 12 hours following the procedure (Table 2).

There were no complications during the tracheostomy. Postoperatively, 4 patients (10.5%) had major bleeding, 2 (5.3%) had minor bleeding, 25 (65.8%) had minimal non-relevant bleeding, and no bleeding was documented in 7 (18.4%). Five patients required administration of 2 or more units of packed cells within the first 48 hours: 1 patient (2.6%) due to bleeding secondary to the tracheostomy, and the remaining 4 (10.5%) due to anemia not associated with

tracheostomy-related bleeding; 33 patients (86.9%) did not require blood products transfusion (Table 3).

No fiberoptic bronchoscopy was indicated in any patient due to tracheostomy-related complications. In 10.5% of patients (n=4) surgical tracheostomy revision was required due to bleeding in all cases. Of the total number of patients, 79% (n=30) were discharged from the hospital, and 21% (n=8) died during their hospital stay due to other causes.

Discussion

The management of all the patients in this series included the use of heparin, creating the need to discriminate by types and doses, and the presence of major bleeding, which was 3.6 times more frequent in the group receiving fondaparinux (25%), regardless of its indication, versus other heparins (6.9%). Markota et al¹² conducted a retrospective cohort study in patients subjected to open tracheostomy who were on dual antiplatelet therapy (ASA and any P2Y12 inhibitor), and showed that the addition of heparins did not impact the occurrence of complications in the dual antiplatelet therapy group.

Neither this study nor the others published so far in this context^{5,12,13} have shown evidence of complications due to intraoperative bleeding.

The overall bleeding rate in this series was 10.5% (n=4) for major bleeding and 5.3% for minor bleeding. Markota et al¹² did not report bleeding complications, but reported reintervention during the first 24 hours, with a rate as high as 37% in the group with dual antiplatelet therapy (n=10); in this case series, patients with major bleeding correspond to patients who were reintervened, with a finding of

Table 2. Frequency of bleeding by type of anticoagulation therapy.

Bleeding	None		Minimal non-relevant		Minor		Major	
	n	%	n	%	n	%	n	%
Anticoagulation therapy								
LMWH (anticoagulation)	4	28.6	9	64.3	0	0	1	7.1
LMWH (prophylaxis)	3	20	10	66.8	1	6.6	1	6.6
Fondaparinux (anticoagulation)	0	0	2	66.7	0	0	1	33.3
Fondaparinux (prophylaxis)	0	0	4	80	0	0	1	20
Other anticoagulant	0	0	0	0	1	100	0	0
Total	7	18.4	25	65.8	2	5.3	4	10.5

LMWH=low-molecular-weight heparin.
Source: Authors.

Table 3. Complications.

Complications	Frequency (n)	%
Bleeding		
Major	4	10.5
Minor	2	5.3
Minimal non-relevant	25	65.8
None	7	18.4
Transfusion within the first 48 hours		
Due to tracheostomy-related bleeding	1	2.6
Due to other causes	4	10.5
None	33	86.9
Reintervention due to bleeding		
Yes	4	10.5
No	34	89.5
Fiberoptic bronchoscopy		
Due to tracheostomy-related bleeding	0	0
Due to other causes	5	13.2
No	33	86.8
Death		
Due to the tracheostomy	0	0
Due to other causes	8	21
No	30	79

Source: Authors.

a lower rate. Nam et al¹⁴ reported a major bleeding complication rate greater than 0% and of minor bleeding of 7.7% in patients undergoing percutaneous tracheostomy on dual antiplatelet therapy; in the study by Voigt and Naber⁵ there were no patients with major bleeding, and minor and reintervention rates were 20% in the study

group; Abouzgheib et al¹³ did not report major complications, with 5% minor complications in the clopidrogel group. In the meta-analysis of percutaneous techniques versus surgical tracheostomy techniques,¹⁵ even though there are no statistically significant differences between the 2 surgical techniques, there is a tendency in favor of percutaneous tracheostomy in relation to the occurrence of major bleeding. In contrast with the frequency of bleeding in our series, these findings give rise to a question regarding the selection of the surgical technique, which has traditionally favored the open technique in this special group of patients because it allows direct control of hemostasis. Consequently, further studies are required in order to find proof.

In our study, transfusion frequency because of bleeding was 2.6% for tracheostomy and 10.5% for other causes, while Markota et al¹² reported a frequency of more than 20% in both groups, but did not mention the cause. In addition, our institution has a restricted transfusion policy (Hb threshold between 7 and 8 g/dL with signs of tissue hypoxia), which may have influenced the results. In our study, bronchoscopy was performed only for other causes not related to tracheostomy in 13.2% of patients, with no indication for bronchoscopy in case of bleeding. In our series, mortality attributed to tracheostomy-related major bleeding was 0%, the same as reported by Markota et al¹² and Voigt and Naber⁵ In-hospital mortality in our series was 21%.

Being a descriptive observational study of a retrospective case series, this study has limitations and its findings must be validated in larger studies.

Conclusion

Based on the result of this study, we conclude that delaying the performance of open tracheostomy in patients receiving antiplatelet therapy, or discontinuing the medications, is not warranted because even if the frequency of major bleeding is higher, there is no impact on mortality. However, further studies to validate these findings are required.

Ethical responsibilities

Human and animal protection. The authors declare that no experiments were conducted in humans or animals for this research.

Data confidentiality. The authors declare having followed the protocols of their institution regarding patient data disclosure.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

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Conflict of interest

The authors declare having no conflict of interest.

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