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Fiber optic bronchoscopy-assisted percutaneous tracheostomy: a decade of experience at a university hospital

Traqueostomía percutánea con asistencia fibrobroncoscópica: una década de experiencia en un hospital universitario

ABSTRACT

Objective: To evaluate the efficacy and safety of percutaneous tracheostomy by means of single-step dilation with fiber optic bronchoscopy assistance in critical care patients under mechanical ventilation.

Methods: Between the years 2004 and 2014, 512 patients with indication of tracheostomy according to clinical criteria, were prospectively and consecutively included in our study. One-third of them were high-risk patients. Demographic variables, APACHE II score, and days on mechanical ventilation prior to percutaneous tracheostomy were recorded. The efficacy of the procedure was evaluated according to an execution success rate and based on the necessity of switching to an open surgical technique. Safety was evaluated according to post-operative and operative complication rates.

Results: The mean age of the group was 64 ± 18 years (203 women and 309 males). The mean APACHE II score was 21 ± 3 . Patients remained an average of 11 ± 3 days on mechanical ventilation before percutaneous tracheostomy was performed. All procedures were successfully completed without the need to switch to an open surgical technique. Eighteen patients (3.5%) presented procedure complications. Five patients experienced transient desaturation, 4 presented low blood pressure related to sedation, and 9 presented minor bleeding, but none required a transfusion. No serious complications or deaths associated with the procedure were recorded. Eleven patients (2.1%) presented post-operative complications. Seven presented minor and transitory bleeding of the percutaneous tracheostomy stoma, 2 suffered displacement of the tracheostomy cannula, and 2 developed a superficial infection of the stoma.

Conclusion: Percutaneous tracheostomy using the single-step dilation technique with fiber optic bronchoscopy assistance seems to be effective and safe in critically ill patients under mechanical ventilation when performed by experienced intensive care specialists using a standardized procedure.

Keywords: Tracheostomy/methods; Respiration, artificial; Ventilator weaning

INTRODUCTION

Tracheostomy has evolved over time from a complex surgical procedure, traditionally performed in the operating room, to an intervention that can be executed percutaneously in the intensive care unit (ICU) at the patient's bedside.⁽¹⁻⁴⁾ Currently, various percutaneous tracheostomy (PT) methods exist, with variable rates of complications.⁽⁵⁾ However, the single-step dilation

technique is the most widely used technique at both national and international levels and has the best safety profile when compared with other PT methods.⁽⁶⁾

The potential advantages of tracheostomy include avoiding oral mucous and laryngeal and vocal cord wounds, facilitating airway suction and mouth care, reducing the need for sedoanalgesia, enabling communication and oral feeding, providing a safe airway, reducing airway resistance and respiratory work, and improving patient comfort.⁽⁷⁾ Recently, Romero et al.⁽⁸⁾ reported that approximately 40% of critical patients without neurological pathology who underwent prolonged translaryngeal intubation (> 15 days) experienced swallowing dysfunction, a condition that can lead to the development of healthcare-associated pneumonia. Various authors have reported reductions in the incidence of pneumonia associated with mechanical ventilation (MV), increases in the days free of MV and shorter stays in the ICU with the execution of early tracheostomy.⁽⁹⁻¹²⁾ However, its true impact on mortality is still disputed.^(13,14)

The development of various PT techniques has facilitated the spread and execution of the procedure in ICUs. Currently, PT is one of the most commonly practiced surgical procedures in critical care patients under MV.^(7,15)

The objectives of the present study were to evaluate the efficacy and safety of PT by means of the single-step dilation technique with the assistance of fibrobronchoscopy in critical care patients under MV.

METHODS

Between October 2004 and September 2014, all patients under MV for whom it was necessary to perform a PT were prospectively evaluated. The criteria for the indication of a tracheostomy were 1) prolonged MV (\geq 2 weeks); 2) failure to wean from MV with the need to re-intubate on two or more occasions; 3) quantitative commitment to be conscious with the inability to protect the airway during the weaning process, in the absence of changes in gas exchange; and 4) neuromuscular pathology in which the need for prolonged MV was anticipated.^(5,7,8) Upon finalizing a decade of follow-up, a retrospective analysis of the prospectively collected database was conducted.

Patients with one or more relative contraindications were considered to be at high risk of experiencing perioperative complications related to PT.⁽⁵⁾ This group

included obese patients (defined by a body mass index $[BMI] \ge 30 \text{kg/m}^2$, patients with coagulation disorders (international normalized ratio [INR] > 2 or platelet recount < 50,000), platelet antiaggregant users and those under anticoagulation (unfractionated or low-molecularweight heparin in doses higher than for prophylactic use), short neck (distance between the cricoid cartilage and the sternal angle less than 2.5cm), inability to hyperextend the neck, and patients with a previous tracheostomy (open surgical or percutaneous). In patients with coagulopathy, an INR of < 1.5 and a platelet recount of > 50,000 using frozen fresh plasma and platelets were achieved prior to the intervention. Anticoagulation treatment with unfractionated heparin was suspended 4 hours before the procedure and was resumed 6 to 12 hours after the procedure. Anticoagulation treatment with lowmolecular-weight heparin was suspended 12 hours before the procedure and resumed 12 hours after if there were no contraindications.

Patients without relevant contraindications were considered to be at low risk for experiencing perioperative complications related to PT.

Patients younger than 16 years old, those with contraindications to PT (Table S1 of the electronic supplementary materials) and those needing emergency tracheostomy were excluded.

All PTs were elective and were performed in the critical care unit (CCU) in a standardized manner using the single-step dilation technique (Blue Rhino Kit, Cook Critical Care, Bloomington, IN, USA). The study was approved by the University of Chile Clinical Hospital's Ethical Committee (CECeI006). In all cases, informed consent was obtained from direct relatives.

The PTs were performed by experienced intensive care specialists with more than one year of training in the technique and more than 30 procedures performed before attending high-risk cases.^(16,17) In all cases, the presence of a respiratory disease specialist was guaranteed for fibrobronchoscopic assistance (1T30 Broncoscope, Olympus Medical Systems Corp, Tokyo, Japan) and airway management. The standardized description of the procedure has been communicated previously and can be reviewed in detail in the electronic supplementary material section (Figures S1 - S3).⁽¹⁸⁾ Inmediately before performing PT, the nursing team applied a safety checklist to ensure proper preparation of each patient (Table S2 of the supplementary electronic materials).

Demographic variables, Acute Physiology and Chronic Health Evaluation II (APACHE II) scores, and days on MV until execution of the tracheostomy were recorded. In all cases, days of intubation were equivalent to days on MV. We performed a comparative analysis of the results from the group of high-risk patients versus the group of low-risk patients.

The efficacy in the execution of the PT was evaluated according to the rate of compliance of the planned procedure until the installation of the tracheostomy cannula and/or the need to switch to open surgical technique.

The safety of the technique was evaluated according to the incidence of perioperative complications. Procedure complications recorded were loss of airway, switch to an open surgical technique, minor and major bleeding, pneumothorax, hemothorax, pneumomediastinum, low blood pressure, hypoxemia and death. Early postoperative complications recorded were displacement of the cannula, major and minor bleeding, infection of the stoma and death. Each of the perioperative complications has been precisely defined in the supplemental electronic material section.^(7,8)

Patients were followed until their decannulation, transfer to another hospital or death.

Statistical analysis

Data are presented as frequencies and percentages for categorical variables and as averages and standard deviations (SD) for continuous variables. Two-way *Student's t* test for comparison of continuous variables and Fisher's exact test for analysis of categorical variables were used. Statistical calculations were performed using SPSS 17.0 (Chicago, Ill., USA). A p-value of < 0.05 was considered statistically significant.

RESULTS

During the study period, 512 patients underwent a PT with fibrobronchoscopic assistance in the CCU of the *Hospital Clínico Universidad de Chile*. One-third of the patients in the study (170 cases) had some relevant contraindication for the execution of a PT, reason for which they were considered "high-risk patients" (Table 1).

The mean age of the group was 64 ± 18 years; 203 were women, and 309 were men. Mean APACHE II score was 21 ± 3 . In 356 patients (69.5%), indication for MV was respiratory failure due to acute respiratory distress

Table 1 - Relative contraindications in the high-risk patients subgroup

Relative contraindications	Number of patients	
Obesity	90	
Presence of coagulopathy	35	
Use of anticoagulants	15	
Use of anti-platelet agents	11	
Short neck	8	
Previous tracheostomy	6	
Inability to hyperextend the neck	5	

syndrome. In the remainder cases, indication for MV was acute central or peripheral nervous system pathology. Patients remained on average 11 ± 3 days on MV before tracheostomy was performed.

In all patients, the procedure was successfully completed, and the tracheostomy cannula could be installed. There was no need to switch to an open surgical technique in any case.

Regarding procedure complications observed, 18 patients (3.5%) presented some complication during it. Five patients experienced transient desaturation that improved when the fibrobronchoscope was withdrawn from the orotracheal tube and MV was resumed. Four patients developed temporarily low blood pressure related to sedation. Nine patients presented minor bleeding; in six cases, this condition was relieved with compression of the area, while hemostatic sutures were applied in three patients. No patient required red blood cell transfusion. No serious complications or deaths related to the procedure were recorded.

Post-operative complications occurred in eleven patients (2.1%). Seven patients presented minor and temporary PT stomal bleeding, tracheostomy cannula displacement occurred in 2 cases, and 2 patients developed superficial stomal infection. No other types of complications were noted.

Within the subgroup of patients with contraindications relevant to the execution of PT (n = 170), only 7 patients (4.1%) presented some procedure complication: 3 had minor bleeding, 2 presented transient desaturations and 2 had low blood pressure related to sedation. Four patients (2.4%) presented some post-operative complication: 2 patients presented minor bleeding, and 2 experienced displacement of the tracheostomy cannula. No other postoperative complication was documented in this subgroup of patients (Table 2).

Variables	Low risk (N = 342)	High risk (N = 170)	p value
Women	155 (45)	63 (37)	0.34
Age (years)	63 ± 19	65 ± 15	0.91
APACHE II	20 ± 4	21 ± 2	0.29
Operative complications	11 (3.2)	7 (4.1)	0.86
Post-operative complications	7 (2.0)	4 (2.4)	0.90
Overall complications	18 (5.2)	11 (6.5)	0.89

Table 2 - Demographic characteristics and incidence of complications according to subgroup

APACHE II - Acute Physiology and Chronic Health Evaluation II. Results are expressed as N (%) or means ± standard deviations.

DISCUSSION

To our knowledge, this report describes the largest Latin-American study to systematically evaluate post-operative and operative complications of PT by means of the single-step dilation technique with fibrobronchoscopy assistance in critical care patients under MV. Various studies performed in North America and Europe have randomly and prospectively compared PT with open surgical tracheostomy and have consistently reported the equivalence of both procedures in terms of operative complications. However, PT has been associated with a lower rate of stomal infection.^(16,19,20) Observational studies have also evaluated the performance of the percutaneous technique. In 2008, Díaz-Regañón et al.,(21) communicated their experience in 800 critical care patients who underwent PT. The authors reported rates of operative and post-operative complications of 2.1% and 1.85%, respectively. In Turkey, Kilic et al.⁽²²⁾ reported a complication rate of 3.6% for PT. Kornblith et al.⁽²³⁾ published a North American case study of 1000 critical care patients undergoing PT and reported a perioperative complication rate of 1.4%. The variability in the rate of perioperative complications reported in the different studies may be explained by the lack of standardization in the definitions utilized and by the skill level attained in the procedure at the different centers. Recently, Putensen et al.⁽²⁴⁾ employed a meta-analysis to corroborate the reliability of PT when compared to the open suergical technique. Our results are comparable to the international studies published and emphasize the high level of efficacy and safety of PT performed at the patient's bedside using a standardized approach.^(25,26)

The best time to perform a tracheostomy is still a point of controversy. Although the execution of an early PT could be associated with improvement in some clinical outcomes,⁽⁹⁻¹¹⁾ it also increases the risk of performing an unnecessary

procedure.⁽¹³⁾ In daily practice, the best system for adequately define the appropriate time to execute a tracheostomy consists of daily evaluations of the patient's condition by an experienced intensive care specialist. The patients in our study remained an average of 11 ± 3 days on MV before PT was executed. This time interval is in agreement with those reported in various international studies on this topic.^(23,27-29)

TP presents advantages compared to open surgical technique, as it has been shown that its implementation significantly reduces the delay for its execution. This benefit might be associated with shorter MV duration, shorter stays in ICU, and lower costs.^(9-11,30-35) Additionally, performing a PT in the ICU avoids the need to transfer critically sick patients out of the unit, simultaneously avoiding the risks implied with that course of action.⁽³⁶⁾

However, for many years, PT was restricted to a select group of patients, as a considerable proportion of critical care patients presented some of the "classical" contraindications for its execution. In recent years, some authors have challenged several of these supposed contraindications for PT, showing it is feasible and safe in carefully selected high-risk critical care patients when the procedure is performed by experienced professionals.^(17,18,37,38) In our study, the rate of post-operative and operative complications in the subgroup of high-risk patients was not different from the rate of complications observed in the subgroup of low-risk patients. These results are in agreement with those reported recently by other investigators.^(17,23,39,40) However, it is very important to emphasize that none of the high-risk patients were included in the present study during practitioner's learning curve. It is probable that a combination of events, including the application of a safety checklist for patient preparation, the standardization of the procedure, and the experience acquired by the clinical team with a single-step dilation technique, are associated with the absence of significant

differences in the perioperative complications observed among the subgroups of high- and low-risk patients in the present study.

Our study has several limitations. It represents the experience of a single center, is observational, does not include a control group, and lacks of long-term monitoring for assessing late post-operative complications. However, it is a 10-year systematic and prospective study, including a significant number of consecutive patients, which makes the results generalizable to daily clinical practice in centers with professionals who have experience with

RESUMEN

Objetivo: Evaluar eficacia y seguridad de la traqueostomía percutánea, mediante dilatación única con asistencia fibrobron-coscópica, en pacientes críticos sometidos a ventilación mecánica.

Métodos: Entre los años 2004 y 2014, se incluyeron prospectivamente 512 enfermos consecutivos con indicación de traqueostomía según los criterios clínicos de nuestro centro. Un tercio de los pacientes fueron de alto riesgo. Se registraron variables demográficas, puntaje APACHE II, y días de ventilación mecánica previo a traqueostomía percutánea. La eficacia del procedimiento fue evaluada mediante tasa de éxito en su ejecución y necesidad de conversión a técnica abierta. La seguridad fue evaluada por tasa de complicaciones operatorias y postoperatorias.

Resultados: La edad media del grupo fue 64 ± 18 años (203 mujeres y 309 varones). El puntaje APACHE II fue 21 ± 3 . Los pacientes permanecieron en promedio 11 ± 3 días en ventilación mecánica antes de la realización de la traqueostomía percutánea. Todos los procedimientos se completaron exitosamente,

the procedure. The systematic approach exposed in this study could increase the safety of PT in high-risk critical care patients.

CONCLUSION

In conclusion, percutaneous tracheostomy with the single-step dilation technique and fibrobronchoscopy assistance appears to be effective and safe in critical care patients under mechanical ventilation when performed by experienced intensive care specialists using a standardized approach.

sin necesidad de convertir a técnica abierta. Dieciocho pacientes (3,5%) presentaron complicaciones operatorias. Cinco pacientes experimentaron desaturación transitoria, cuatro presentaron hipotensión relacionada a la sedación, y nueve presentaron sangrado menor, pero ninguno requirió transfusión. No se registraron complicaciones graves, ni muertes asociadas al procedimiento. Once pacientes (2,1%) presentaron complicaciones postoperatorias. Siete presentaron sangrado menor y transitorio del estoma de la traqueostomía percutánea, 2 sufrieron desplazamiento de la cánula de traqueostomía y 2 desarrollaron infección superficial del estoma.

Conclusión: La traqueostomía percutánea mediante la técnica de dilatación única con asistencia fibrobroncoscópica, parece ser efectiva y segura en enfermos críticos sometidos a ventilación mecánica, cuando es realizada por intensivistas experimentados mediante un abordaje estandarizado.

Descriptores: Traqueostomía/métodos; Respiración artificial; Desconección del ventilador

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