Tracheostomy after cardiovascular surgery: An assessment of long-term outcome

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Supplemental material is available online.

Objective: To ascertain long-term survival, identify risk factors for death, and document complications of tracheostomy after cardiovascular surgery.

Methods: Between January 1, 1998, and September 1, 2001, 188 (1.4%) of 13,191 patients undergoing cardiovascular surgery had tracheostomy for respiratory failure 5 to 79 days (median, 14 days) after surgery. Factors associated with mortality were identified in the hazard function domain, and mode of death and complications of tracheostomy were determined by follow-up.

Results: Survival was 75%, 50%, and 31% at 30 days, 3 months, and 2 years, respectively. The most important risk factors for death were older age ($P = .004$) and variables representing deteriorating hemodynamic ($P < .0001$), respiratory ($P < .0001$), and renal ($P = .0001$) function between the index cardiovascular operation and tracheostomy. The mode of death was isolated respiratory failure in only 21 (16%) of 130 patients, but multisystem organ failure in 71 (55%). Follow-up of 58 survivors identified voice complaints in 13 (24%), tracheal stenosis in 5 (9.2%), and permanent tracheostomy in 3 (6%).

Conclusions: Only one third of patients undergoing tracheostomy after cardiovascular surgery survive, because it is used primarily in those with deteriorating function of multiple organ systems. Although tracheostomy may enhance patient comfort and simplify nursing care, selection algorithms need to be developed if survival is the goal of the intervention.

Tracheostomy for patients admitted to medical intensive care units (ICUs) is associated with favorable short-term outcomes.¹⁻⁴ In contrast, few data are available on the short- and long-term outcome of tracheostomy in the cardiovascular surgery ICU setting.^{5,6} In medical ICUs, a favorable short-term outcome may reflect careful triage; in cardiovascular surgery ICUs, respiratory failure is a less anticipated event for which tracheostomy may be more liberally used. Therefore, the purposes of this study were to determine time-related survival after tracheostomy after cardiovascular surgery, identify risk factors for death and ascertain mode of death, and document early and late complications of tracheostomy. With this information, we sought to identify patients most likely to survive tracheostomy after cardiovascular surgery.

Patients and Methods

Patients

Between January 1, 1998, and September 1, 2001, 188 (1.4%) of 13,191 patients undergoing cardiovascular surgery at The Cleveland Clinic Foundation received 189 tracheostomies (1 patient had 2 tracheostomies 6 months apart, and these were considered as independent occurrences). Cardiac transplant patients and those with ventricular assist devices were not included.

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Received for publication May 20, 2005; revisions received Aug 12, 2005; accepted for publication Sept 9, 2005

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J Thorac Cardiovasc Surg 2006;131:830-7
0022-5223/\$32.00

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doi:10.1016/j.jtcvs.2005.09.038

Abbreviations and Acronyms

CL	= confidence limit
ICU	= intensive care unit
MSOF	= multisystem organ failure
PEEP	= positive end-expiratory pressure

To appreciate the changing nature of patient condition from initial operation to tracheostomy, information was gathered (1) before surgery, through the cardiovascular operation (Tables 1 and 2), and immediately after the operation (initial admission to ICU; Tables 3 and 4) and (2) at tracheostomy, including interim events and changes in measurements and medications occurring between ICU admission and tracheostomy (Tables 5 and 6). Data were collected prospectively and concurrently with patient care and recorded in the Cardiothoracic Anesthesia Database, which has been approved for research by the institutional review board. These data were supplemented by a detailed review of medical records.

Technique of Tracheostomy

Tracheostomy was performed by an open technique, described previously.⁷ With few exceptions, the procedure was performed in the operating room.

Follow-up

Follow-up was 93% complete (175 of 188 patients) and was obtained by review of medical records and telephone interviews

TABLE 1. Preoperative and intraoperative characteristics of tracheostomy patients: categorical variables (n = 189)

Characteristic	No. (%)
Male	103 (55)
Emergency operation	12 (6)
Cardiac status	
Severe LV dysfunction (EF <35%)	43 (23)
Pulmonary hypertension	36 (19)
Previous cardiac operation	71 (38)
Noncardiac comorbidity	
History of smoking	119 (63)
COPD/asthma	41 (22)
Hypertension	117 (62)
Stroke	34 (18)
Renal failure requiring dialysis	7 (4)
Diabetes	45 (24)
Cardiac procedure	
CABG	111 (59)
AV repair or replacement	62 (33)
Myectomy	2 (1)
MV repair or replacement	73 (39)
Thoracic aortic surgery	44 (23)

AV, Aortic valve; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; EF, ejection fraction; LV, left ventricular; MV, mitral valve.

TABLE 2. Preoperative characteristics of tracheostomy patients: continuous variables

Characteristic	Mean $\pm$ SD
Demography	
Age (y)	69 $\pm$ 11
BMI (kg/m ²)	27 $\pm$ 6
Serum chemistries	
Albumin (g/dL)	3.6 $\pm$ 0.68
Creatinine (mg/dL)	1.5 $\pm$ 1.3
Bilirubin (mg/dL)	0.87 $\pm$ 0.83*

BMI, Body mass index. *Median (15th, 85th percentiles): 0.6 (0.4, 1.2).

with patients, their families, or referring physicians by using institutional review board–approved protocols and questionnaires. For patients not traced, a search of the Social Security Death Index was used to determine vital status.^{8,9} The mean and standard deviation of follow-up among survivors was 2.1 $\pm$ 0.99 years; 10% were followed more than 3.5 years. Outcome measures are defined in Appendix 1.

Data Analysis

Descriptive statistics. Categorical variables are summarized by frequencies and percentages, and continuous variables are summarized by means and standard deviations or medians and 15th and 85th percentiles. For consistency, coefficients in multivariable models are presented with 1 SE of the estimates, and probabilities and hazard estimates are accompanied by asymmetric 68% confidence limits (CLs) equivalent to 1 SE.

Survival after tracheostomy. Estimates of survival were obtained by the Kaplan-Meier method and by a parametric method that resolves the number of phases of instantaneous risk and estimates shaping parameters.¹⁰ (For additional details, see <http://www.clevelandclinic.org/heartcenter/hazard>.)

TABLE 3. Characteristics of patients upon admission to the intensive care unit: categorical variables (n = 189)

Characteristic	No. (%)
Medications given during first 24 h in ICU	
Epinephrine	110 (58)
Milrinone	62 (33)
Dobutamine	17 (9)
Norepinephrine	89 (47)
Phenylephrine	11 (6)
Vasopressin	15 (8)
Lidocaine	16 (8)
Amiodarone	18 (10)
Ventilatory settings	
Pressure control	25 (13)
CPAP	25 (13)
Assist control	5 (3)
SIMV	134 (71)

CPAP, Continuous positive airway pressure; ICU, intensive care unit; SIMV, synchronized intermittent mandatory ventilation.

TABLE 4. Characteristics of patients on admission to the intensive care unit: continuous variables

Characteristic	Mean $\pm$ SD
Ventilatory settings	
FIO ₂ (%)	66 $\pm$ 14
PEEP (cm H ₂ O)	5.8 $\pm$ 1.7
Tidal volume (mL per breath)	826 $\pm$ 155
Blood gases	
pH	7.38 $\pm$ 0.073
PaCO ₂ (mm Hg)	42 $\pm$ 7
PaO ₂ (mm Hg)	148 $\pm$ 67
Core temperature (°C)	36 $\pm$ 0.84
Hemodynamics	
Heart rate (beats per minute)	96 $\pm$ 14
Mean systemic arterial pressure (mm Hg)	79 $\pm$ 13
Central venous pressure (mm Hg)	13 $\pm$ 5
Pulmonary artery systolic pressure (mm Hg)	38 $\pm$ 12
Pulmonary artery diastolic pressure (mm Hg)	20 $\pm$ 7
Cardiac index (L $\cdot$ min ⁻¹ $\cdot$ m ⁻²)	2.5 $\pm$ 0.72

FIO₂, Fraction of inspired oxygen; PEEP, positive end-expiratory pressure.

Risk factors for death after tracheostomy. To understand the effect of changing patient condition on factors associated with mortality, a sequential analytic strategy was followed. The first analysis (sequence 1) was of preoperative, intraoperative, and ICU admission variables (Appendix 2). The second analysis (sequence 2) added (1) interim events between ICU admission and tracheostomy and (2) patient condition at tracheostomy.

Continuous and ordinal variables were retained in their original state to maximize information content. Original measurement scales were calibrated to assumptions of the analysis by transformation, as necessary (linearization).

Selection of factors for both analyses used bootstrap aggregation (bagging).^{11,12} Automated analyses of 1000 random data sets were performed by using $P < .05$ as the criterion for variable retention. The resulting models were aggregated with results expressed as frequency of occurrence of both single factors and closely related clusters of factors. We considered factors or clusters appearing in at least 50% of analyses to be reliably statistically significant. Interaction among variables was then studied in a second bagging process to produce final models.

Modes of death. Primary modes of death were considered as mutually exclusive categories (Appendix 1). A hazard function for each mode was obtained, in an analysis of competing events,¹³ by using both nonparametric and parametric methodology.^{10,14}

Likelihood of recovery after tracheostomy. The equation resulting from the multivariable analysis that included condition at tracheostomy (sequence 2) was solved across time to illustrate patients most and least likely to recover after tracheostomy.

Presentation

Continuous variables are presented as mean $\pm$ SD and, equivalently, as 15th, 50th (median), and 85th percentiles when distributions are skewed. Categorical variables are presented as counts and percentages. Outcome events are accompanied by asymmetric 68% CLs equivalent to ± 1 SE. Model coefficients are presented as

TABLE 5. Characteristics of patients at tracheostomy: categorical variables

Characteristic	No./n (% of n)
Medications	
Paralytics	4/187 (2)
Vasopressors	59/186 (32)
Nitric oxide	0/187 (0)
Antiarrhythmics	108/182 (59)
Inotropes	25/185 (14)
Ventilatory settings	
Pressure control	95/183 (52)
CPAP	56/183 (31)
Assist control	2/183 (1)
SIMV	30/183 (16)
Cardiac rhythm	
Atrial fibrillation	39/189 (21)
Paced	45/189 (24)
Interim events	
Stroke	28/181 (15)
Dialysis	50/185 (27)
Nutrition	
Total parenteral	77/188 (41)
Enteral	104/188 (55)
Infections	
Mediastinitis	8/184 (4)
Endocarditis	10/184 (5)
Pneumonia	116/184 (63)
Empyema	5/184 (3)
Urinary tract	18/184 (10)
Soft tissue	24/184 (13)
Bacteremia	49/184 (27)

CPAP, Continuous positive airway pressure; SIMV, synchronized intermittent mandatory ventilation.

± 1 SE rather than as hazard ratios, in part because the model does not assume proportional hazards across time and in part because linearizing transformations render hazard ratios difficult to interpret. Rather, graphical presentation of results is used to illustrate the multivariable models, values for specific patient variables substituting into them to illustrate various scenarios described in the text.

Results

Survival After Tracheostomy

Survival after tracheostomy was 75%, 50%, and 31% at 30 days, 3 months, and 2 years, respectively (Figure 1). The risk of death was highest in the first month after tracheostomy, and 67 patients (36%) died before hospital discharge (Figure E1).

Risk Factors for Mortality

When only preoperative, operative, and ICU admission variables were considered (sequence 1; Table 7), left heart failure and early milrinone requirement, but not the interval from surgery to tracheostomy, were associated with in-

TABLE 6. Characteristics of patients at tracheostomy: continuous variables

Characteristic	Mean $\pm$ SD
Ventilatory settings	
FIO_2 (%)	41 $\pm$ 6.5
PEEP (cm H_2O)	7.3 $\pm$ 4.0
Tidal volume (mL per breath)	73.3 $\pm$ 176
Rate (breaths per minute)	11 $\pm$ 4.5
Pressure support (cm H_2O)	9.8 $\pm$ 5.5
Minute volume (L/min)	15 $\pm$ 6.3
Blood gases	
pH	7.44 $\pm$ 0.059
$PaCO_2$ (mm Hg)	38 $\pm$ 7.5
PaO_2 (mm Hg)	109 $\pm$ 31
Hemodynamics	
Heart rate (beats per minute)	88 $\pm$ 14
Mean arterial pressure (mm Hg)	75 $\pm$ 11
Central venous pressure (mm Hg)	14 $\pm$ 5.1
Renal function	
Creatinine (mg/dL)	1.9 $\pm$ 1.4

FIO_2 , Fraction of inspired oxygen; *PEEP*, positive end-expiratory pressure.

creased mortality. However, from the time of ICU entry until tracheostomy (the median interval from surgery to tracheostomy was 14 days; the highest probability of receiving it was on day 12), inotropic support generally decreased, antiarrhythmia medication use increased, 28 patients exhibited new neurologic deficits (15%), 50 patients required hemodialysis (27%), and 154 patients developed infections (82%). Patients were more often on pressure-controlled ventilation than on synchronized intermittent mandatory ventilation, and there

Figure 1. Percentage survival after tracheostomy. Each circle represents a death, and vertical bars represent asymmetric 68% confidence limits (CL). Numbers in parentheses are patients remaining at risk. The solid line is a parametric survival estimate enclosed within 68% CLs.

TABLE 7. Incremental risk factors for death after tracheostomy

Risk factor*	P value
Sequence 1: preoperative, operative, and ICU admission variables	
Preoperative	
Older age	.06
At time of ICU admission	
Use of milrinone in first 24 h	.0006
Lower cardiac output	.009
Lower FIO_2	.02
Lower pH	.004
Higher PaO_2	.02
Sequence 2: addition of interim events, status at tracheostomy, and change since ICU admission	
Preoperative	
Older age	.0004
At time of ICU admission	
Use of milrinone in first 24 h	.0009
At tracheostomy	
Higher BUN	.0001
Less pressure support	<.0001
Use of vasopressors	.001
Change from ICU admission to tracheostomy	
Interaction: PEEP change and interval from operation to tracheostomy	.02
Interval from operation to tracheostomy	.8
PEEP change	.6
Higher absolute mean arterial pressure change	<.0001

For details, see Table E1. *BUN*, Blood urea nitrogen; *ICU*, intensive care unit; *PEEP*, positive end-expiratory pressure; FIO_2 , fraction of inspired oxygen. *Variables entered only into the early hazard phase.

was on average an increase in positive end-expiratory pressure (PEEP; $P < .0001$; Tables 3-6).

Therefore, when variables related to these interim events and changing conditions at the time of tracheostomy were added to the analysis (sequence 2; Table 7), factors related to left heart failure and acidosis at ICU admission were no longer risk factors; rather, condition at tracheostomy and change from ICU admission to tracheostomy dominated. These variables included renal dysfunction, nonweaning ventilator mode, and use of vasopressors. If patients received their tracheostomy relatively early (within the first 30 days of operation), the change in the level of PEEP was unimportant; however, if they received tracheostomy late (4-7 weeks) after operation, then an increased PEEP requirement was associated with worse survival (see interaction term in Table 7 and Figure E2).

Modes of Death

In-hospital death. Of the 67 patients who died in the hospital, 49 (73%) died in multisystem organ failure (MSOF), and 7 (10%) died in respiratory failure (Table 8).

TABLE 8. Modes of death after tracheostomy

Mode	In hospital (n = 67)*	After transfer or discharge (n = 63)†
MSOF	49 (73)	22 (45)
Respiratory failure	7 (10)	14 (27)
Heart failure	6 (9.0)	11 (20)
Neurologic	3 (4.4)	2 (3.6)
Gastrointestinal	2 (3.0)	2 (3.6)

MSOF, Multisystem organ failure. *Data are No. (%). †Data are No. (% of 51); mode of death could not be determined in 12 cases.

Families of 43 patients (64%) withdrew support. No patient was decannulated before death.

After hospital transfer or discharge. Of the 63 patients who died after hospital transfer or discharge, the most common mode of death was MSOF (n = 22; 45%; Table 8). Support was withdrawn from 14 patients, and 19 were decannulated before death.

Competing modes of death. The risk of death in cardiac failure at any time after tracheostomy declined with time, whereas MSOF peaked by approximately 2 weeks (Figure 2). The risk of death in isolated respiratory failure peaked 1 month after tracheostomy.

Safety of Tracheostomy

In-hospital complications. There were no operative complications of tracheostomy. Superficial sternal wound infections developed in 3 patients (1.6%; CL, 0.7%-3.2%), and 1 patient (0.5%; CL, 0.07%-1.8%) underwent reoperation for mediastinitis. Two patients (1.1%; CL, 0.4%-2.5%) bled from the tracheal stoma: 1 required transfusion, and the other was readmitted to the ICU for observation.

After hospital transfer or discharge. Ascertainment of tracheostomy-related complications was possible in 109 (90%) of 121 discharged patients. Their most common complaint was a change in the quality or character of the voice (n = 14; 13%; CL, 9.5%-17%). Eleven noted hoarseness, 2 thought their voices were weak, and 1, a singer, had a normal speaking voice but had lost vocal range. Five patients (4.6%; CL, 2.6%-7.7%) had tracheal stenosis, 3 of them with permanent tracheostomies. Three patients (2.8%; CL, 1.2%-5.5%) self-decannulated in a skilled nursing facility. This led to death in 2 and emergency tube replacement in the third. Two patients (1.8%; CL, 0.6%-4.3%) bled from the tracheal stoma; tracheomalacia was documented in 1. One patient (0.9%; CL, 0.1%-3.1%) developed mediastinitis 2 months after tracheostomy and several weeks after hospital discharge, and 1 had a resolving tracheocutaneous fistula 1 year after decannulation.

Figure 2. Instantaneous risk of death (hazard function) in various modes after tracheostomy. For clarity, the horizontal axis has been expanded to depict only the first 6 months after tracheostomy.

Discussion

Principal Findings

Tracheostomy for respiratory failure after cardiovascular surgery is performed in a group of patients at exceptionally high risk of early death. Patients whose condition worsens from the index operation until tracheostomy experience the highest mortality, and the mode of death is most often MSOF. The tracheostomy itself is a safe procedure with few long-term sequelae in patients who survive.

Survival after tracheostomy. Nearly two thirds of patients who received tracheostomy died within the first year: half in the hospital and half after discharge or transfer. This illustrates the severity of the illness and the limited ability to salvage patients who experience MSOF after cardiovascular surgery.

In some acute settings, tracheostomy has been associated with lower mortality in the ICU.¹⁻⁴ However, the long-term prognosis of these patients is likely to be poor.¹⁵⁻¹⁹ Although we had hypothesized that we were using tracheostomy more liberally (without triage) than critical care physicians in medical ICUs, long-term survival seems to be similar in both settings. Nevertheless, the one third of our patients who have survived self-report good functional status.

Risk factors for mortality after tracheostomy. A unique aspect of this study is that the changing condition of the patient was considered in a sequential analysis of risk factors for mortality after tracheostomy. Another is that we have quantified the importance of the changing condition of the patient from time of entry into the ICU until tracheostomy. Specifically, preoperative, intraoperative, and early postoperative risk factors for death were largely superseded by factors reflecting patient condition at tracheostomy. Risk factors based only on the first analysis (sequence 1) were

not highly discriminating. That analysis emphasized that apart from older age, a risk factor previously identified,^{15,17} the primary risk factor for death was hemodynamic status, particularly right or left ventricular failure (Table 7). Variables relating to respiratory state were less reliably associated with outcome.

However, when events that occurred between the index operation and tracheostomy, status of the patient at tracheostomy, and absolute change of multiple hemodynamic and respiratory variables were added to the analysis (sequence 2; Table 7), the importance of changed patient condition with respect to MSOF (respiratory, cardiac, and renal) was appreciated. Except for early use of milrinone, all variables from sequence 1 that related to patient status at the end of the index operation were far less important. It is interesting to note that intervening clinical events (infection, neurologic, renal, and parenteral and enteral nutrition) were not identified directly as risk factors, but were likely reflected in multisystem dysfunction. Clearly, the patient whose condition deteriorates throughout the postoperative period is unlikely to recover after tracheostomy.

Variation in the timing of tracheostomy was not associated with outcome, as was also found by Brook and colleagues² and suggested by others.^{3,4} However, hospital costs may be decreased by early tracheostomy, despite its lack of effect on survival.²

Modes of death. Another important contribution of this study is characterizing the mode of death in a temporal, competing-risks fashion. Most deaths early and late after tracheostomy were from MSOF. Only 10% of in-hospital deaths and 27% of postdischarge deaths were attributable to isolated respiratory failure (Table 8 and Figure 2). Clearly, death from pulmonary failure is delayed by the use of mechanical ventilatory support, but death from cardiac or multisystem failure is less preventable.

Safety of tracheostomy. An open technique of tracheostomy was used for all patients.⁷ This approach proved to be easy, safe, and seldom complicated. It is interesting to note that unlike Curtis and colleagues,⁶ we found no association of tracheostomy with mediastinitis, even though we used an open rather than a percutaneous technique.

Long-term sequelae of tracheostomy were few. Surprisingly, most long-term survivors had no complaints after decannulation; among those who did, the most frequent was a change in voice. These few late posttracheostomy complications contrast with vocal sequelae in more than one quarter of patients after percutaneous dilatational tracheostomy.²⁰

Limitations

This study centers on the experience of a single high-volume institution and has typical institutional biases regarding patient selection. Data collected from long-term

ventilator facilities were often limited to mode of death. Assumptions regarding the mode of death of transferred patients whose families decided to terminate life support relied on noninstitution physician assessment.

Survival after tracheostomy was a primary end point. There are other outcomes to consider, including patient comfort, advancement of oral nutrition, decreased use of sedation, improved patient–family communication, and simplified nursing and respiratory care. However, because none of these end points could be easily abstracted and quantified, analyses were not possible. In addition, the date of death for patients who died of respiratory failure is somewhat artificial, reflecting in part family wishes to terminate support of chronically ventilator-dependent patients.

Recommendations

Indications for tracheostomy generally have been based on the duration of invasive mechanical ventilation, independently of the underlying disease. They reflect historical data that tracheostomy reduced laryngotracheal injury from protracted orotracheal intubation.^{4,21–23} Are there indications for tracheostomy that can be based on survival as the important outcome? Figure 3 illustrates the survival, derived from our analysis, of 3 typical, but hypothetical, patients with different clinical scenarios (Table 7). The greatest survival benefit of tracheostomy after cardiovascular surgery is realized by relatively young patients with no early milrinone requirement and with, at the time of tracheostomy, normal blood urea nitrogen, no vasopressors with higher blood pressure, and improved respiratory mechanics (less PEEP and lower pressure support requirements; patient A). A minimal survival benefit is realized by the older patient with persistent cardiac, pulmonary, and renal dysfunction at tracheostomy (patient C), and variable survival benefit is realized for patients intermediate between these, such as patient B.

Other possible, but less tangible, benefits of tracheostomy include simplified nursing care, improved pulmonary toilet, reduced occurrence of pneumonia, superior airway security, and expedited ventilatory weaning.²⁴ In addition, tracheostomy may promote early transfer to a chronic ventilation facility to allow more efficient allocation of resources, may reduce the need for sedation, and facilitates communication between patient and family. Unfortunately, none of these indications is well documented or easily investigated.

Conflicting information exists regarding whether tracheostomy is lifesaving.^{15,19} Indeed, decisions regarding tracheostomy after cardiovascular surgery should consider not only survival, but also patient comfort and nursing issues. However, consideration for tracheostomy earlier in the postoperative course may prevent some patients from deterio-

Figure 3. Illustration of the survival values of tracheostomy in 3 typical patients. These are solutions of the multivariable analysis (Table 7; sequence 2). Values for variables are as follows:

Variable	A	B	C
Preoperative			
Age at ICU admission (y)	60	75	75
Use of milrinone in first 24 h	No	No	Yes
At tracheostomy			
BUN (mg/dL)	29	20	40
Pressure support (cm H ₂ O)	10	0	0
Use of vasopressors	No	No	Yes
Change from ICU to tracheostomy			
Interval from operation to tracheostomy (d)	14	14	4
PEEP difference	↓ 5	↓ 5	0
Mean arterial pressure change	0	0	↓ 10

BUN, blood urea nitrogen; ICU, intensive care unit; PEEP, positive end-expiratory pressure.

rating to the point of no return, thus decreasing the number of futile or merely supportive tracheostomies.

We thank Marvin Leventhal for representing the efforts of the Cardiothoracic Anesthesia Database team; Tanya Ashinhurst for registry assistance; Angela York, Linda DiPaola, MS, and Christopher Pierce, PhD, for data management; and Tess Parry for editorial assistance.

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Appendix 1: Definitions of Outcome Measures

Infections

Mediastinitis. Fever, sternal instability, and purulent drainage from the sternal wound requiring reoperation

Endocarditis. Fever associated with valve vegetations on echocardiogram and positive blood cultures

Pneumonia. Positive sputum culture and infiltrates on chest radiograph associated with fever, copious sputum production, and/or leukocytosis, for which antibiotic therapy is instituted

Empyema. Purulent material in the pleural space confirmed by cultures from chest tube drainage or thoracentesis

Urinary tract infection. Positive urine cultures for which antibiotics are prescribed

Soft tissue infection. Purulent drainage with positive cultures and institution of therapy, exclusive of mediastinal wounds

Bacteremia. Bacteria grown from blood cultures, for which antibiotic therapy is instituted

Complications

Superficial sternal wound infection. Drainage or cellulites for which antibiotics are given and/or for which the wound is opened and packed at bedside

Mediastinitis. Fever, sternal instability, and purulent drainage from the sternal wound for which the patient is returned to the operating room

Bleeding. Bleeding from the airway any time after tracheostomy requiring reoperation or transfusion

Voice. Self-assessment of a change in the strength or character of one's voice after decannulation

Self-decannulation. Unplanned removal of tracheostomy by the patient, resulting in adverse sequelae such as a readmission to the hospital, translaryngeal reintubation, hypoxia, or death

Tracheal stenosis. Dyspnea, stridor, or both, with stenosis at the stoma or below documented by fiber-optic visualization of the airway

Tracheomalacia. Persistent leak around the tracheostomy balloon, or dyspnea, and malacia documented by fiber-optic examination of the airway

Tracheocutaneous fistula. Persistent stoma more than 6 months after decannulation

Modes of Death

Neurologic. Stroke or intracerebral bleed documented by the consulting neurologist and head computed tomographic scan

Cardiac. Isolated persistent cardiogenic shock defined by some combination of acidosis ($\text{pH} < 7.35$), low cardiac index ($< 2.0 \text{ L} \cdot \text{min}^{-1} \cdot \text{m}^{-2}$), ejection fraction less than 30%, or dependence on inotropes

Respiratory. Isolated persistent respiratory failure defined by PaO_2 less than 60 mm Hg, PaCO_2 greater than 50 mm Hg; persistent diffuse infiltrates on chest radiograph or pneumonia; inability to wean from the ventilator; and, in 1 case, pulmonary embolus

Gastrointestinal. Isolated intra-abdominal catastrophe such as gastrointestinal bleeding, ischemia, or perforated viscus

Multisystem organ failure. Failure of 3 or more of the following organ systems:

1. Circulatory: defined by persistent cardiogenic shock
2. Respiratory: as defined previously
3. Renal: defined as serum creatinine greater than 3.0 mg/dL, anuria, or new-onset dialysis (hemodialysis or continuous venovenous hemodialysis)
4. Liver, defined by bilirubin greater than 6 mg/dL or aspartate aminotransferase greater than 500 units/L
5. Gastrointestinal, manifest as bleeding, ischemia, or intra-abdominal sepsis
6. Immunologic, defined as persistent culture-positive infection and sepsis

Appendix 2: Variables Used in Analyses

Preoperative

Demography. Sex, age at operation (years), height (centimeters), and weight (kilograms)

Clinical condition. Emergency operation

Cardiac status. Left ventricular function

Cardiac comorbidity. Pulmonary hypertension and number of previous cardiac operations

Noncardiac comorbidity. Serum albumin (grams per deciliter), blood urea nitrogen (milligrams per deciliter), creatinine (milligrams per deciliter), bilirubin (milligrams per deciliter), hematocrit (percentage), chronic obstructive pulmonary disease/asthma, history of heart failure, hypertension, history of smoking, stroke, diabetes (diet controlled, oral hypoglycemic treatment, insulin treatment), and dysrhythmia

Cardiac Procedure

Coronary artery bypass grafting, aortic valve replacement, mitral valve repair, mitral valve replacement, thoracic aortic surgery, cardiopulmonary bypass time, and aortic clamp time

Experience

Date of operation (years since January 1, 1997)

Upon Admission to the Intensive Care Unit

Cardiac status. Cardiac output (liters per minute), cardiac index (liters per minute per square meter), central venous pressure (millimeters of mercury), heart rate (beats per minute), pulmonary artery diastolic pressure (millimeters of mercury), pulmonary artery systolic pressure (millimeters of mercury), and mean systemic arterial pressure (millimeters of mercury)

Patient status. Ventricular rate (beats per minute), ventilatory support (mode), positive end-expiratory pressure (centimeters of water), tidal volume, fraction of inspired oxygen, core temperature (degrees centigrade), pH, PaCO_2 , PaO_2 , and HCO_3^-

Medications given in intensive care unit (first 24 hours). Amiodarone, dobutamine, epinephrine, lidocaine, milrinone, norepinephrine, phenylephrine, and vasopressin

At Tracheostomy

Cardiac status. Cardiac rhythm, central venous pressure (millimeters of mercury), heart rate (beats per minute), mean systemic arterial pressure (millimeters of mercury), cardiac output (liters per minute), and cardiac index (liters per minute per square meter)

Patient status. Ventricular rate (beats per minute), ventilatory support (mode), positive end-expiratory pressure (centimeters of water), fraction of inspired oxygen, tidal volume, mandatory ventilation, pressure control, pressure support, pH, PaCO_2 , HCO_3^- , and PaO_2

Medications. Inotropes, antiarrhythmics, nitric oxide, paralytics, and vasopressors

Infection. Bacteremia, empyema, endocarditis, mediastinitis, pneumonia, soft tissue infection, and urinary tract infection

Neurologic. Stroke, encephalopathy, and spinal injury

Renal. Dialysis dependence, blood urea nitrogen (milligrams per deciliter), and creatinine (milligrams per deciliter)

Nutrition. Total parenteral nutrition and enteral feed

Interval. Operation to tracheostomy (days)

TABLE E1. Incremental risk factors for death after tracheostomy

Risk factor*	Coefficient $\pm$ SE	P value	Reliability (%)†
Sequence 1: preoperative, operative, and ICU admission variables			
Preoperative			
Older age‡	0.23 $\pm$ 0.12	.06	32
At time of ICU admission			
Use of milrinone in first 24 h	0.63 $\pm$ 0.18	.0006	80
Lower cardiac output§	−0.88 $\pm$ 0.34	.009	66
Lower FIO ₂	1.7 $\pm$ 0.71	.02	37
Lower pH¶	−27 $\pm$ 9.4	.004	37
Higher PaO ₂ #	0.11 $\pm$ 0.051	.02	39
Sequence 2: addition of interim events, status at tracheostomy, and change since ICU admission			
Preoperative			
Older age‡	0.43 $\pm$ 0.12	.0004	52
At time of ICU admission			
Use of milrinone in first 24 h	0.62 $\pm$ 0.19	.0009	57
At tracheostomy			
Higher BUN**	0.53 $\pm$ 0.14	.0001	94
Less pressure support (cm H ₂ O)††	0.11 $\pm$ 0.029	<.0001	53
Use of vasopressors	0.63 $\pm$ 0.19	.001	55
Change from ICU admission to tracheostomy			
Interaction: PEEP change and interval from operation to tracheostomy‡‡	−0.012 $\pm$ 0.0052	.02	85
Interval from operation to tracheostomy§§	−0.0069 $\pm$ 0.023	.8	
PEEP change	−0.012 $\pm$ 0.021	.6	
Higher absolute mean arterial pressure change	0.076 $\pm$ 0.015	<.0001	70

BUN, Blood urea nitrogen; ICU, intensive care unit; FIO₂, fraction of inspired oxygen; PEEP, positive end-expiratory pressure. *Variables entered only into the early hazard phase. †Percentage of bootstrap models in which the variable appeared. ‡Exp(age/50) exponential transformation. §Cardiac output/5. ||(60/FIO₂) inverse transformation. ¶Ln(pH) logarithmic transformation. # (PaO₂/130)² squared transformation. **BUN/50. ††(10/Pressure support) inverse transformation. ‡‡PEEP difference · exp(interval from operation to tracheostomy/17). §§Exp(interval from operation to tracheostomy/17) exponential transformation. |||(Mean arterial pressure difference)² squared transformation.

Figure E1. Instantaneous risk of death (hazard function) enclosed within 68% confidence limits.

Figure E2. Interplay of the timing of tracheostomy and the change in ventilatory states at tracheostomy compared with those at intensive care unit admission as they affected 1-year survival. This is an illustration of the multivariable equation for death (Table 7; sequence 2). The *top curve* (with confidence limits equivalent to 1 SE) shows the effect of decreased positive end-expiratory pressure (PEEP), whereas the *bottom curve* shows the effect of increased PEEP.