Outcome of mechanically ventilated patients who require a tracheostomy*

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Objective: **To estimate the prevalence of, the risk factors associated with, and the outcome of tracheostomy in a heterogeneous population of mechanically ventilated patients.**

Design: **Prospective, observational cohort study.**

Setting: **A total of 361 intensive care units from 12 countries.**

Patients: **A cohort of 5,081 patients mechanically ventilated for >12 hrs.**

Interventions: **None.**

Measurements and Main Results: **A total of 546 patients (10.7%) had a tracheostomy during their stay in the intensive care unit. Tracheostomy was performed at a median time of 12 days (interquartile range, 7–17) from the beginning of mechanical ventilation. Variables associated with the performance of tracheostomy were duration of mechanical ventilation, need for reintubation, and neurologic disease as the primary reason of mechanical ventilation. The intensive care unit stay of patients with or without tracheostomy was a median of 21 days (interquartile range, 12–32) vs. 7 days (interquartile range, 4–12; $p < .001$), respectively, and the hospital stay was a median 36 days (interquartile range, 23–53) vs. 15 days (interquartile range, 8–26; $p < .001$), respectively. Adjusting by other variables, tracheostomy was independently related with survival in the intensive care unit (odds ratio, 2.22; 95% confidence interval, 1.72–2.86). Mortality in the hospital was similar in both groups (39% vs. 40%, $p = .65$).**

Conclusions: **Tracheostomy is a common surgical procedure in the intensive care unit that is associated with a lower mortality in the unit but with a longer stay and a similar mortality in the hospital than in patients without tracheostomy. (Crit Care Med 2005; 33:290–298)**

KEY WORDS: mechanical ventilation; tracheostomy; outcome; survival; mortality; intensive care unit

Tracheostomy is a common surgical procedure performed in mechanically ventilated patients. About 10% of critically ill patients who require mechanical ventilation have a tracheostomy performed (1–3). The introduction into clinical practice of the technique of percutaneous dilational tracheostomy allows this procedure to be performed at the bedside (4). This, together with the fact that use of tracheostomy allows transfer of patients to the ward or to long-term ventilation units, may explain the more frequent and earlier use of tracheostomy.

Despite the common practice of performing a tracheostomy, there are still several questions unanswered concerning this procedure, including in which patients with acute respiratory failure could be indicated a tracheostomy, when is the tracheostomy performed in the actual clinical practice, or what is the outcome of tracheostomized patients? To estimate the prevalence of, the risk factors associated with, and the outcome of tracheostomy, we analyzed a large database of patients who were mechanically ventilated for >12 hrs

METHODS

Patients. A total of 5,183 adult patients who required invasive mechanical ventilation from March 1 to March 31, 1998, in 361 intensive care units from 20 countries from Europe, Latin America, and United States–Canada were included in the study. For the purpose of this study, we excluded patients with previous tracheostomy (n = 102) remaining for the analysis of 5,081 patients. Before data collection, the study protocol was reviewed and approved by institutional review committees of each hospital.

Variables. The following information was collected on each patient receiving mechanical ventilation: demographic data (geographic area divided by cultural and economic similarities in Europe, Latin America, and United States–Canada), sex, age, chronic functional status (classified as normal or limited activity and defined as presence in the last 6 months of any physical condition that impedes a normal activity), date of admission to the intensive care unit, Simplified Acute Physiology Score II (SAPS II) at the time of intensive care unit admission, type of problem (medical or surgical), day of initiating mechanical ventilation, and indication for the initiation of mechanical ventilation. Indication for mechanical ventilation was selected from the following predefined list of categories: a) acute on chronic respiratory failure, which described patients with underlying chronic obstructive or re-

*See also p. 444.

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strictive lung disease that required mechanical ventilation; b) coma, which described patients requiring mechanical ventilation caused by loss of consciousness secondary to organic or metabolic conditions; c) neuromuscular disease, which described patients whose respiratory failure was due to impairment of the peripheral nerves, myoneural junction, or muscle; e) acute respiratory failure, which described patients without a preexisting obstructive or restrictive lung disease requiring mechanical ventilation because of respiratory failure. The patients who fell in the category of acute respiratory failure were further divided into the following subgroups: e.1) acute respiratory distress syndrome as defined according to the criteria of the American-European consensus conference (5); e.2) postoperative state, consisting of patients who required the continuation of mechanical ventilation after surgery because of a serious underlying medical problem, advanced age, or the high risk of the operative procedure; e.3) acute pulmonary edema/congestive heart failure, consisting of patients with dyspnea, bilateral alveolar infiltrates, hypoxemia, and evidence of cardiac disease or patients in cardiogenic shock; e.4) aspiration, defined by visualization of gastric contents in the airways or in a tracheal aspirate; e.5) pneumonia, defined by the development of a new alveolar infiltrate or worsening of previous alveolar infiltrates, accompanied by fever/hypothermia and leukocytosis/leukopenia; e.6) sepsis/septic shock (defined by preestablished criteria) (6); e.7) trauma; and e.8) cardiac arrest, mechanical ventilation due to sudden and unexpected cessation of cardiopulmonary functions. We collected daily assessment of variables related to patient management (usage of sedative and neuromuscular blockers, arterial blood gas analysis, and ventilatory parameters). Daily assessment during the course of mechanical ventilation, for a maximum of 28 days, of the following complications were collected: acute respiratory distress syndrome, barotrauma, pneumonia, sepsis, renal failure, hepatic failure, coagulopathy, metabolic acidosis, and respiratory acidosis. In addition, data were recorded for the date of start of the weaning from mechanical ventilation (the onset was the time that the physician in charge considered the patient was likely to be able to resume spontaneous breathing), date of extubation, need of reintubation within 48 hrs after the extubation, tracheostomy, and date of the tracheostomy. The patients were prospectively followed for a maximum of 28 days of mechanical ventilation or until discharge from the hospital or death, collecting the status at discharge and the destination of the patients who survive (home, nursing home, chronic ventilatory facility, acute facility, or other destination).

Because sepsis, pneumonia, and acute respiratory distress syndrome could be reasons for the initiation of mechanical ventilation, they were considered as complications only if they occurred >48 hrs after mechanical ventilation was started. Acute respiratory distress syndrome was defining according to the criteria of the American-European consensus conference (5). Sepsis and shock were defined according to the criteria of the American College of Chest Physicians/Society of Critical Care Medicine consensus conference (6). Barotrauma refers to the development of at least one of the following: interstitial emphysema, pneumothorax, pneumomediastinum, pneumoperitoneum, or subcutaneous emphysema. Ventilator-associated pneumonia was defined according to the modified Centers for Disease Control and Prevention criteria (7). Renal failure was defined as an acute increase in creatinine of >2 mg/dL (177 μmol/L), double the baseline value in a patient with underlying chronic renal failure, or the need for acute hemodialysis or acute use of any form of dialysis. Hepatic failure was defined as an acute change in bilirubin to >2 mg/dL (34 μmol/L), with transaminase and lactic dehydrogenase levels at least twice the upper limit of normal. Coagulopathy was defined as a decrease in the platelet count of 25% or more from the baseline, with an increase in prothrombin time at least twice the control value. A patient was considered to have any of the above conditions if it was present for at least two consecutive days.

End Points. The study aimed to determine the following end points: 1) to estimate the prevalence of tracheostomy in a large heterogeneous population of mechanically ventilated patients; 2) to know the time at which tracheostomy is performed in the usual clinical practice; 3) to identify the clinical conditions associated with the performance of a tracheostomy; and 4) to assess the outcome estimated as length of stay (both in the intensive care unit and in the hospital) and mortality (both in the intensive care unit and in the hospital) of tracheostomized patients compared with non-tracheostomized patients.

Statistical Analysis. Results are expressed as mean values and SD, median (interquartile range), and proportions as appropriate. We used Student's *t*-test or the Mann-Whitney *U* test to compare continuous variables and the chi-square test to compare proportions. Two-tailed *p* values of <.05 were used to indicate statistical significance.

The Kaplan-Meier method was used to determine the probability of performing a tracheostomy in those patients with acute or chronic pulmonary disease (including chronic obstructive pulmonary disease, asthma, and other chronic pulmonary disease), patients with neurologic disease (coma and neuromuscular disease), and patients with acute respiratory failure.

A recursive partitioning method (Answer Tree Software, Chicago, IL) was used to determine which variables were related to the performance of a tracheostomy. The tree-building process considered the following risk variables: age, SAPS II, sex, previous functional status, principle reason for initiating mechanical ventilation, variables associated with patient management, complications while receiving mechanical ventilation, duration of ventilatory support (including days of weaning), and reintubation. Recursive partitioning identified the threshold value for each variable that provided the best separation of the study population according to performance of a tracheostomy. For continuous variables, potential threshold values are all values represented in the data. For dichotomous variables, the threshold value is the integer value of the two categories. For each variable, the program selected the threshold value that produced two subsets of the greatest purity. The partitioning was started after evaluating each risk variable for its ability to separate cases from controls. The variable that achieved the most precise separation of patients with and without a tracheostomy was selected as the best predictor for the first branch of the tree. The recursive partitioning procedure was repeated for each of the two subgroups that resulted from the first split, again searching all cut-off points of each separation of patients with and without a tracheostomy. The process was repeated for subsequent descendant subsets until no further partitioning was feasible because the subgroup contained fewer than 25 patients or contained only patients with or only patients without a tracheostomy. The purpose of this classification tree was to reveal the structure of the database with respect to distinct combinations of variables that jointly influence the likelihood of performing a tracheostomy. Then, the distinct subgroups identified by the classification tree were modeled using logistic regression. A dummy variable with different subgroups represented by the subsets at the bottom of the classification tree was introduced into a logistic regression analysis to estimate the odds ratios for performing a tracheostomy within each subgroup in relation to subgroups with a lower prevalence of this technique.

Linear regression analysis was used to estimate the adjusted relation between tracheostomy and morbidity (length of stay in the intensive care unit and length of stay in the hospital). Logistic regression analysis was used to estimate the adjusted relation between tracheostomy and mortality. A stepwise approach was used to enter terms into the model, in which mortality was the dependent variable and tracheostomy was one of the independent variables. Other variables entered into the model were those previously published that related to mortality (8). A *p* value of <.10 was used to enter variables in the model, and a *p* value of <.05 was used to keep variables in the model. Linear and logistic regressions were performed with SPSS 11.5 (SPSS, Chicago, IL).

RESULTS

Prevalence and Timing of Tracheostomy. A total of 546 patients (10.7%)

required a tracheostomy during their stay in the intensive care unit. The baseline characteristics of these patients are showed in the Table 1. There were significant differences in the rate of tracheostomy according to geographic area: Europe, 12.2%; Latin America, 9.3%; and United States–Canada, 9.3% ($p = .004$).

Tracheostomy was performed at a median time of 12 days (interquartile range, 7–17) from beginning mechanical ventilation. Figure 1 shows the rate of tracheostomy in relation to the start of mechanical ventilation support. Figure 2 shows the Kaplan-Meier plot of the probability of tracheostomy in patients with acute on chronic pulmonary disease, neurologic disease, and acute respiratory failure. The probability of having a tracheostomy by day 28 of ventilatory support was 48% in patients with acute on chronic pulmonary disease, 55% in patients with neurologic disease, and 46% in patients with acute respiratory failure (38% in acute respiratory distress syndrome, 44% in pneumonia, 29% in sepsis, and 48% in trauma patients).

Variables Associated with Performing a Tracheostomy. In the univariate analysis, we found that patients with tracheostomy were more likely to have had a previous normal functional status (61% vs. 57%, $p = .04$), coma (22% vs. 16%, $p < .001$), neuromuscular disease (5% vs. 1%, $p < .001$), or trauma (13% vs. 1%, $p < .001$) as the main reason for mechanical ventilation and less likely to have postoperative acute respiratory failure (14% vs. 21.5%, $p < .001$) and congestive heart failure (5% vs. 11%, $p < .001$). Patients requiring tracheostomy were more likely to have acute respiratory distress syndrome (7.5% vs. 4%, $p < .001$), ventilator-associated pneumonia (28% vs. 16%, $p < .001$), and sepsis (20% vs. 14%, $p < .001$) during the course of their mechanical ventilation. Duration of mechanical ventilation was longer in the patients with a tracheostomy (median time, 14 days [interquartile range, 7–25] vs. 4 days [interquartile range, 3–8]; $p < .001$). Finally, the need for reintubation was associated with tracheostomy ($p < .001$). Overall, 3,025 patients were extubated and 421 patients (14%) required reintubation within next 48 hrs. From this cohort, 162 patients (38%) had a tracheostomy performed.

Recursive partitioning method found that variables associated with tracheostomy were: duration of mechanical ventilation, reintubation, and neurologic disease (coma and neuromuscular disease as reason of mechanical ventilation) (Figure 3). The probability of tracheostomy, estimated by logistic regression analysis, in each subgroup derived from recursive partitioning analysis is shown in Table 2.

Outcomes. Patients with a tracheostomy had a longer stay both in the intensive care unit (median, 21 days [interquartile range, 12–32] vs. 7 days [interquartile range. 4–12]; $p < .001$) and in the hospital (median, 36 days [interquartile range, 23–53] vs. 15 days [interquartile range, 8–26]; $p < .001$) than those without a tracheostomy. Linear regression analysis showed that tracheostomy was independently related to both of these outcomes ($p < .001$).

Mortality in the intensive care unit of patients who have a tracheostomy was lower than in patients without tracheostomy (20% vs. 32%, respectively, $p < .001$). Adjusting by other variables, tracheostomy was independently related with survival in the intensive care unit (odds ratio, 2.22; 95% confidence interval, 1.72–2.86). Hospital mortality was similar in both groups (39% vs. 40%, $p = .65$). There were significant differences to where the patients were discharged from

Table 1. Baseline characteristics of the patients (n = 546) who required tracheostomy

Age in yrs, mean (SD)	59 (17)
Simplified Acute Physiology Score II, mean (SD)	43 (15)
Female sex, n (%)	208 (38)
Medical problem, n (%)	342 (62)
Surgical problem, n (%)	204 (37)
Previous functional status normal, n (%)	336 (61)
Main reason for mechanical ventilation, n (%)	
COPD	51 (9)
Asthma	3 (0.5)
Coma	120 (22)
Neuromuscular disease	27 (5)
Chronic pulmonary disease—not COPD	9 (2)
Acute respiratory failure	335 (61)
Acute respiratory distress syndrome	26 (5)
Postoperative	76 (14)
Congestive heart failure	29 (5)
Aspiration	17 (3)
Pneumonia	79 (14.5)
Sepsis	32 (6)
Trauma	72 (13)
Cardiac arrest	12 (2)

COPD, chronic obstructive pulmonary disease.

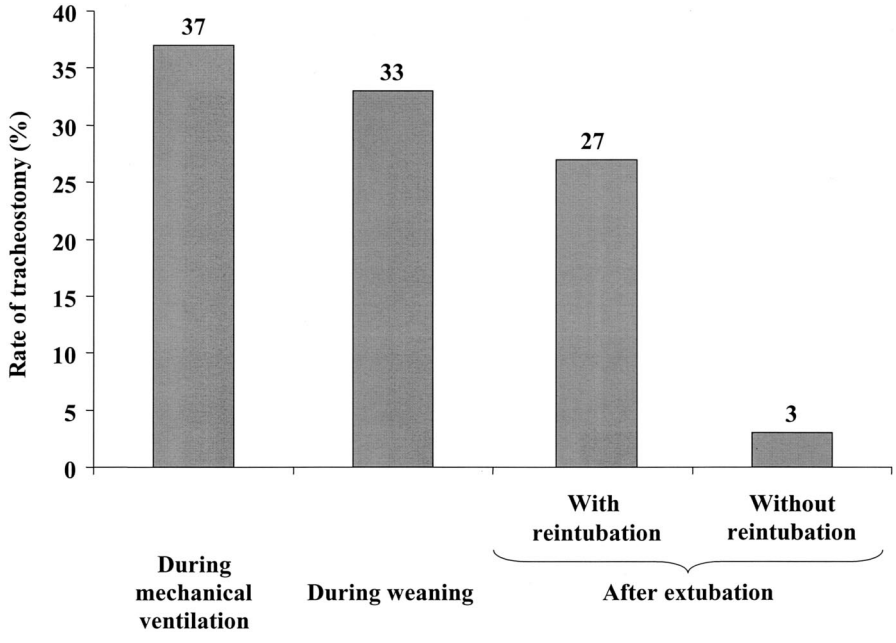

Figure 1. Rate of tracheostomy according to the timing of ventilatory support.

the hospital between patients with and without a tracheostomy ($p < .001$) (Fig. 4).

DISCUSSION

The main findings of our study are that tracheostomy is a frequent procedure performed in mechanically ventilated patients. Tracheostomy is more frequently performed in patients who have prolonged mechanical ventilation, require re-intubation after a failed extubation, and have a neurologic condition as the precipitating event for mechanical ventilation. Patients with tracheostomy had, after adjusting for variables related with survival, a lower mortality in the intensive care unit but a similar mortality in the hospital compared with patients without a tracheostomy.

The lower intensive care unit mortality of patients with a tracheostomy could be due to several reasons. This technique is performed in patients who are recovering from acute respiratory failure and who are not able to be weaned from the ventilator. In patients with a bad long-term prognosis, such an acute neurologic event, the tracheostomy could facilitate the transfer of patients from the intensive care unit to the ward. This may also explain our finding that hospital mortality was similar in patients with and without a tracheostomy. This finding is the opposite to that of Kollef et al. (1), who showed lower hospital mortality in patients with a tracheostomy. However, in this study, about half of the patients with a tracheostomy were transferred to a skilled nursing facility, and the outcome of these patients is not reported. Recently, a retrospective study designed to determine the survival and functional outcome of 549 patients with tracheostomy who were studied over a 3-yr period reported that the overall survival and functional status were poor in this cohort of patients (9).

Although tracheostomy was associated with a lower mortality in the intensive care unit, patients with a tracheostomy had a longer stay in the unit compared with those patients without a tracheostomy. Previous studies have reported that patients with a tracheostomy have a longer duration of mechanical ventilation and stay in the intensive care unit or in the hospital (1, 9–11). One of the reasons for the longer stay could be the inability of the patients to be weaned from mechanical ventilation. Although there is no study that shows an improvement in weaning from mechanical ventilation with tracheostomy compared with translaryngeal intubation, use of a tracheostomy has been reported to reduce the work of breathing and level of intrinsic positive end-expiratory pressure in patients requiring a low level of ventilatory support (12, 13).

Few studies have evaluated the characteristics of the patients who have a tracheostomy. Kollef et al. (1) found the following variables independently associated with patients undergoing tracheostomy: nosocomial pneumonia, aspiration, aerosolized treatments, and reintubation. We used a recursive partitioning analysis

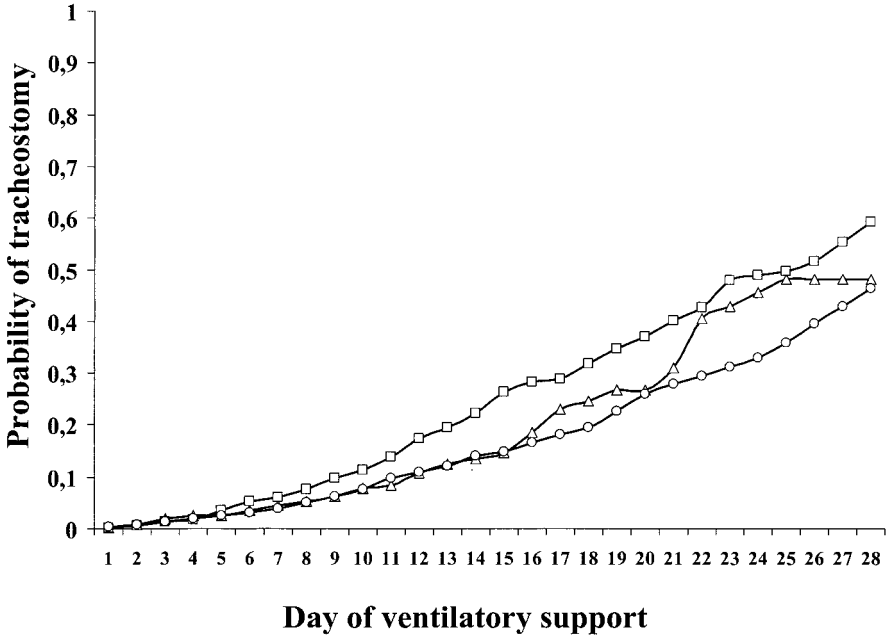

Figure 2. Kaplan-Meier plot of the probability of tracheostomy according to main reason of mechanical ventilation. *Triangles*, acute on chronic pulmonary disease; *squares*, neurologic disease; *circles*, acute respiratory failure. Log rank test, $p < .001$.

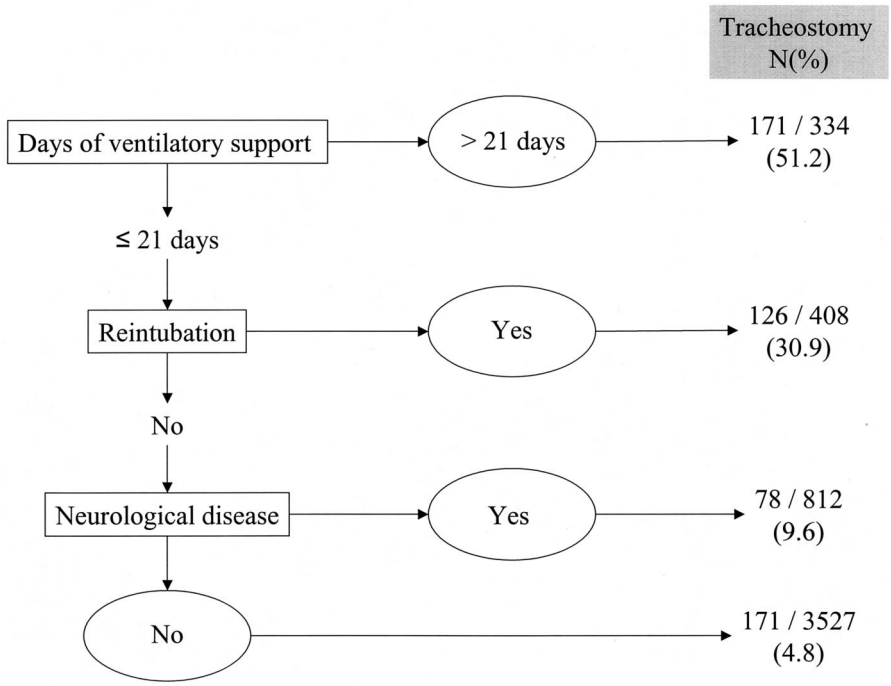

Figure 3. Tree-building of risk factors for tracheostomy obtained by the recursive partitioning method.

Table 2. Risk subgroups for tracheostomy derived from the recursive partitioning analysis

Node	Risk Subgroup	n	Tracheostomy, %	Odds Ratio (95% Confidence Interval)
1	Duration of ventilatory support for >21 days	334	51.2	20.59 (15.81–26.81)
2	Duration of ventilatory support for ≤21 days and reintubation	408	30.9	8.77 (6.76–11.37)
3	Duration of ventilatory support for ≤21 days and no reintubation and neurologic disease	812	9.6	2.09 (1.58–2.76)
4	Duration of ventilatory support for ≤21 days and no reintubation and no neurologic disease	3527	4.8	1

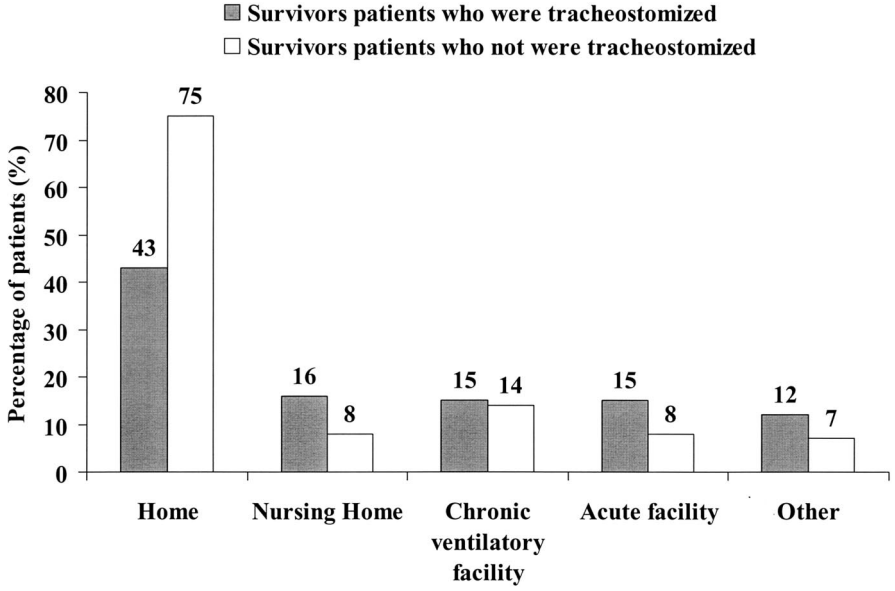

Figure 4. Destiny of the surviving patients at discharge from hospital.

to identify the patients who were more likely to have a tracheostomy. We found, with this methodology, three groups of patients with a high likelihood of having a tracheostomy: patients who required prolonged ventilatory support (defined as >21 days), patients with <21 days of ventilatory support but requiring reintubation, and patients whose primary reason for mechanical ventilation was a neurologic disease independently of duration of ventilatory support or reintubation.

The optimal timing for a tracheostomy is a controversial issue. The Consensus Conference on Artificial Airways in patients receiving mechanical ventilation (14) gives the following recommendations supported only by expert opinion: tracheostomy should be performed in patients who are anticipated to need an artificial airway for >21 days and discouraged if the anticipated need is <10 days, with daily assessments for intermediate situations (14). In our study, the median time for a tracheostomy was 12 days. A variable associated with the timing of a tracheostomy was the reason for mechanical ventilation. Thus, at day 12, the probability of receiving a tracheostomy was higher in patients with neurologic disease (17%) than in patients with chronic pulmonary disease (12%) or acute respiratory failure (11%). An interesting observation was that tracheostomy was performed more frequently during weaning from mechanical ventilation and after a reintubation, indicating that the main reason for the procedure was weaning failure. Maziak et al. (15) concluded, in a systematic review of the literature, that there is insufficient evidence to support the proposal that the timing of a tracheostomy affects the duration of mechanical ventilation or the extent of injury to the airway in critically ill patients. Most recently, Brook et al. (16), in an analysis of a cohort of 90 patients who had a tracheostomy, found that patients with an early tracheostomy (performed by day 10 of mechanical ventilation) had a mean duration of mechanical ventilation lower than patients with a late tracheostomy (performed after day 10 of mechanical ventilation), but the timing of tracheostomy was not associated with hospital mortality. Similar results have been reported in a recent randomized trial including 44 burn patients with a predicted ventilatory support of >14 days (17).

Possible limitations of this study are related to the inherent characteristics of the observational design of this study. First, it could be a selection bias because, as we have pointed out previously, patients with higher possibility to survive their hospital stay are the ones who have a tracheostomy. To solve this bias, a case-matched study in which patients with tracheostomy are matched for every variable related with the outcome with a control without tracheostomy could be performed. We have previously reported this analysis (18) with the same results that we have observed in the present study. Attributable mortality of tracheostomy was lower in the intensive care unit but similar in the hospital. However, we only found controls for the 68% of the tracheostomized patients, and the cases without controls were patients who had worse outcome. For this reason, to avoid a higher bias, we decided to perform a logistic regression analysis adjusting for variables related with mortality in mechanically ventilated patients. The use of case-mix adjustment analysis should therefore not be regarded as a guarantee that a study is unbiased, and we have to consider that variables associated with performance of the tracheostomy could simply reflect clinician biases and choices rather than biological differences.

Another limitation from our study is that we did not ask the investigators the indications and preferences to perform a tracheostomy. Although we observed significant differences between geographic areas, we believe that these differences are not clinically relevant and have not influenced our results because this vari-

Tracheostomy is a common surgical procedure in the intensive care unit that is associated with a lower mortality in the unit but with a longer stay and a similar mortality in the hospital than in patients without tracheostomy.

able was not independently related with the performance of tracheostomy. This is an observational study and we report what the clinicians do in their regular practice. Furthermore, our results are similar to other authors whose studies were performed in a single institution.

In conclusion, tracheostomy is a common surgical procedure in the intensive care unit and is associated with a lower mortality in the intensive care unit but a longer stay and similar hospital mortality compared with patients without a tracheostomy. Further studies are needed to provide evidence on the indications, timing, and cost-effectiveness of this technique (19).

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APPENDIX

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