Tracheostomy does not improve the outcome of patients requiring prolonged mechanical ventilation: A propensity analysis*

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Objective: To examine the association between the performance of a tracheostomy and intensive care unit and postintensive care unit mortality, controlling for treatment selection bias and confounding variables.

Design: Prospective, observational, cohort study.

Setting: Twelve French medical or surgical intensive care units.

Patients: Unselected patients requiring mechanical ventilation for \geq 48 hrs enrolled between 1997 and 2004.

Interventions: None.

Measurements and Main Results: Two models of propensity scores for tracheostomy were built using multivariate logistic regression. After matching on these propensity scores, the association of tracheostomy with outcomes was assessed using multivariate conditional logistic regression. Results obtained with the two models were compared. Of the 2,186 patients included, 177 (8.1%) received a tracheostomy. Both models led to similar re-

sults. Tracheostomy did not improve intensive care unit survival (model 1: odds ratio, 0.94; 95% confidence interval, 0.63–1.39; p = .74; model 2: odds ratio, 1.12; 95% confidence interval, 0.75–1.67; p = .59). There was no difference whether tracheostomy was performed early (within 7 days of ventilation) or late (after 7 days of ventilation). In patients discharged free from mechanical ventilation, tracheostomy was associated with increased postintensive care unit mortality when the tracheostomy tube was left in place (model 1: odds ratio, 3.73; 95% confidence interval, 1.41–9.83; p = .008; model 2: odds ratio, 4.63; 95% confidence interval, 1.68–12.72, p = .003).

Conclusions: Tracheostomy does not seem to reduce intensive care unit mortality when performed in unselected patients but may represent a burden after intensive care unit discharge. (Crit Care Med 2007; 35:132–138)

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

bout one tenth of patients requiring mechanical ventilation (MV) undergo tracheostomy during their intensive care unit (ICU) stay (1–3). Tracheostomy is thought to have many benefits over prolonged translaryngeal intubation including lower risk of laryngeal injury, facilitated weaning from MV, improved patient comfort, and less intravenous sedative administration (4–8). However, those benefits are not

*See also p. 309.

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Studies evaluating the association of tracheostomy with patients' outcomes are scant and conflicting. Tracheostomy seems to improve ICU survival, especially when performed early in the course of mechanical ventilation. But its impact on

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overall survival remains controversial, suggesting that post-ICU mortality could be increased (1, 7, 14).

The absence of generally accepted guidelines may explain these discrepancies. Tracheostomy is far from being standardized with regard to indications for, timing of, and choice of the technique (2, 15). Since the decision to perform a tracheostomy was either left to the discretion of the attending physician or based on poorly defined empirical criteria, the association between tracheostomy and outcomes in the previously mentioned studies could have been confounded by patient characteristics and influenced by in-ICU events that were also related to outcomes. The effect of such treatment selection bias has been called "confounding by indication" (16). The propensity score is a powerful method to control for treatment selection bias. It makes it possible to assess the association of a procedure with specific outcomes in patients with an equal probability of receiving the procedure (17, 18).

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The aim of this study was to use the propensity technique to yield a more accurate estimation of the association of tracheostomy with ICU and post-ICU mortality and to determine whether there was a difference in ICU mortality according to the timing of tracheostomy and in post-ICU mortality according to whether the tracheostomy tube was removed before ICU discharge.

MATERIALS AND METHODS

Study Design and Data Source. We conducted a prospective, observational study in a multiple-center database (OUTCOMEREA) from January 1997 to August 2004. The database, fed by 12 French ICUs, is designed to record daily disease severity and occurrence of iatrogenic events. A random sample of patients older than 16 yrs and having ICU stays >24 hrs was entered into the database each year. Briefly, each participating ICU could choose between two sampling methods: consecutive admissions in *n* randomized beds or consecutive admissions in a randomized month.

Method of Data Collection. Data were collected daily by senior physicians of the participating ICUs. For each patient, the investigators entered the data into a computer case-report form using the data capture software VIGIREA (OUTCOMEREA, Rosny-sous-Bois, France) and imported all records to the OUTCOMEREA database.

Quality of the Database. The data capture software immediately conducted an automatic check of most of the variables entered by the investigators. Multiple automatic checking of internal consistency generated queries that were sent to the ICUs before the new data were incorporated into the database. At each participating ICU, the quality control procedure involved having a senior physician from another participating ICU check a 2% random sample of study data. Kappa coefficients ranged from 0.5 to 0.9 for qualitative variables, and interrater correlation coefficients ranged from 0.67 to 1 for clinical variables, severity scores, and organ dysfunction scores.

The lowest κ coefficient was obtained for McCabe score. The lowest interrater correlation was obtained for lactate level on day 3. Otherwise, the κ coefficient was always higher than 0.62 for qualitative variables, and the interrater coefficient ranged between 0.72 and 0.99 for quantitative variables. In particular, it ranged between 0.78 and 0.91 for severity and organ dysfunction scores and was 0.99 for duration of mechanical ventilation, ICU and hospital stay.

Study Population. All patients in the database who received MV for \geq 48 hrs were included. Patients with prior tracheostomy were excluded. Patients who were submitted to tracheostomy represented the exposed population. Controls were selected among the remaining patients.

All participating ICUs followed the recommendations of the Société de Réanimation de Langue Française for airway management and weaning from mechanical ventilation, thus ensuring homogeneous practice. Tracheostomies were performed using either the surgical or the percutaneous technique depending on physicians' preferences and local possibilities. In keeping with a recent survey, surgical techniques were predominant (15). Informed consent before tracheostomy was obtained from all patients or their legal representative.

Since routine collection of clinical and paraclinical data contained in the OUTCOMEREA database does not modify patients' management in anyway and statistical analyses are processed anonymously, informed consent for participation in the study was waived.

Data Collection. The following data were collected: age, gender, McCabe class (class 1, no fatal underlying disease; class 2, underlying disease fatal within 5 yrs; class 3, underlying disease fatal within 1 yr), comorbidities assessed according to the Acute Physiology and Chronic Health Evaluation II definitions (19), severity of illness at ICU admission and daily during the ICU stay assessed using the Simplified Acute Physiology Score II and the Sepsis-related Organ Failure Assessment score, admission category (medical, scheduled sur-

Table 1. Characteristics of the studied patients on admission to the intensive care unit

Variable	Tracheostomy $(n = 177)$	No Tracheostomy $(n = 2009)$	p Value
Age, no. (%), yrs			
<40	9 (5)	247 (12)	
40-70	94 (53)	968 (48)	.02
>70	74 (42)	794 (40)	
Males, no. (%)	117 (66)	1295 (64.5)	.66
SAPS II score, no. (%)			
<36	49 (28)	501 (25)	
36–57	87 (49)	872 (43)	.64
>57	41 (23)	636 (32)	
APACHE II score, mean (SD)	15.3 (7.5)	16.5 (9.2)	.03
McCabe, no. (%)			
1	85 (48)	1039 (52)	
2	83 (47)	742 (37)	.005
3	9 (5)	228 (11)	
Admission category, no. (%)			
Medical	129 (73)	1326 (66)	
Scheduled surgery	22 (12)	253 (13)	.10
Unscheduled surgery	26 (15)	430 (21)	
Transfer from ward	115 (65)	1105 (55)	.01
Chronic coexisting conditions, no. (%)			
Cardiac disease	28 (15.8)	298 (14.8)	.72
Respiratory disease	50 (27.8)	476 (23.7)	.001
Renal disease	3 (1.7)	70 (3.5)	.20
Liver disease	5 (2.8)	138 (6.9)	.22
Immunodeficiency	17 (9.6)	273 (13.7)	.12
Reason for initiation of mechanical	· · ·		
ventilation, no. (%)			
Acute respiratory failure	100 (56.5)	1286 (64)	.05
Coma	9 (5.1)	272 (13.5)	.001
Acute respiratory failure on chronic	0 (012)	=== (1010)	1001
nulmonary disease no (%)			
COPD	11 (6 2)	81 (4)	16
Asthma	$\frac{11}{4}(2.3)$	38(19)	.10
Chronic respiratory disease (non-	$\frac{4}{5}(2.8)$	32(1.6)	.10
	5 (2.0)	52 (1.0)	•44
Neuromuscular disease	48 (27 1)	200(1/(0))	< 001
Cause of acute respiratory failure	40 (27.1)	300 (14.3)	<.001
cause of acute respiratory failure,			
IIO. (%)	90(10k)	400 (20 2)	00
Postoperative	29(10.4)	400 (20.2)	.22
Pheumonia	39(22)	317(15.8)	.03
Congestive neart failure	13(1.3)	230 (11.8) 212 (10.6)	.08
Sepsis	23(13)	212 (10.0)	.30
	0 (3.4)	19 (1)	.003
AKDS	4 (2.3)	54 (2.7)	.13
Cardiac arrest	4 (2.3)	127 (6.3)	.03
Other	59 (33.3)	638 (31.8)	.67

SAPS, Simplified Acute Physiology Score; APACHE, Acute Physiology and Chronic Health Evaluation; COPD, chronic obstructive pulmonary disease; ARDS, acute respiratory distress syndrome.

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gery, or unscheduled surgery), whether the patient was transferred from a ward (defined as a stay in an acute-bed ward ≥ 24 hrs immediately before ICU admission), lengths of ICU and post-ICU stays, length of MV, vital status at ICU and hospital discharge, and whether a decision to withhold or withdraw life-sustaining treatments (do-not-resuscitate order) was made. Reasons for initiation of MV and in-ICU events associated with ICU mortality in mechanically ventilated patients were also recorded as described elsewhere (20). Since sepsis, pneumonia, and acute respiratory distress syndrome could be reasons for initiation of MV, they were considered as events only if they appeared after 48 hrs of MV.

End Points. The primary end points were all-cause ICU and post-ICU mortality. The secondary end points were lengths of MV, ICU and post-ICU stays, and occurrence of pneumonia.

Statistical Analyses. Results are expressed as numerical values and percentages for categorical variables, and as means and standard deviations (sD) or medians and quartiles (Q1–Q3) for continuous variables.

Comparisons between patients in the whole cohort were based on chi-square tests for categorical data and on Student's *t*-tests for continuous data.

Since the performance of a tracheostomy was not randomly assigned, treatment selection bias and potential confounding were accounted for by developing two propensity scores for tracheostomy. The rationale and methods underlying the use of a propensity score for a proposed causal exposure variable have been previously described (21, 22). In effect, these propensity scores represented the probability that a patient would receive a tracheostomy.

In the first model, the propensity score was calculated using variables predictive of the performance of a tracheostomy in the ICU. To identify those variables, we searched the Medline database entering the following MeSH terms: tracheostomy, risk factors, and intensive care units. We screened studies by title, then by abstract, and finally by full text. We selected two relevant studies that found the following variables to be associated with the performance of a tracheostomy: pneumonia, aerosol treatments, witnessed aspiration, need for reintubation, duration of MV, and neurologic disease as the reason for initiation of MV (1, 14). All those variables but two (aerosol treatments and witnessed aspiration) were computed in the OUTCOMEREA database and used to calculate the propensity score.

When building a propensity score, the main risk is that there could be an important unmeasured variable not accounted for in the propensity regression. Thus, we fitted a second model in which the propensity score was calculated using variables predictive of the performance of a tracheostomy selected through the Delphi method (23–25). The factors thought to be positively associated with tracheostomy were duration of MV \geq 15 days,

Table 2. Predictive factors for tracheostomy in the intensive care unit in patients matched on propensity scores

Variable	Model 1		
	Tracheostomy $(n = 169)$	No Tracheostomy $(n = 572)$	p Value
Pneumonia, no. (%) Duration of MV, median (Q1–Q3) Need for reintubation, no. (%) MV for neurologic disease, no. (%)	$ \begin{array}{r} 105 \ (62.1)^a \\ 19 \ (12-29)^a \\ 7 \ (4.1) \\ 51 \ (30.2) \end{array} $	322 (56.3) 17 (9–24) 9 (1.6) 155 (27.1)	.56 .22 .98 .99
	Model 2		
Variable	Tracheostomy $(n = 160)$	No Tracheostomy (n = 422)	p Value
Duration of MV \geq 15 days, no. (%)	95 (59.4)	229 (54.3)	.77
Need for reintubation, no. (%)	4 (2.5)	6 (1.3)	.25
MV for neurologic disease, no. (%)	46 (28.8)	126 (27.8)	.67
Chronic respiratory disease, no. (%)	46 (28.8)	101 (22.3)	.11
Do-not-resuscitate order, no. (%)	18 (11.3)	61 (13.4)	.48
Cause of acute respiratory failure, no. (%)	04 (1F)	00 (10 1)	10
Postoperative	24 (15) 10 (6 2)	$\frac{\delta 2}{22} (18.1)$.10
Congestive neart failure Cardiac arrest	4 (2.5)	32(7.1) 8(1.8)	.99 .46

MV, mechanical ventilation; Q1–Q3, interquartile range.

^aOnly pneumonia and duration of mechanical ventilation before tracheostomy were considered.

Table 3. Odds ratios for intensive care unit mortality associated with tracheostomy in patients matched on propensity scores

	OR	95% CI	p Value
Model 1			
All patients	0.94	0.63 - 1.39	.74
Patients with early tracheostomy ^a	0.41	0.10 - 1.80	.24
Patients with late tracheostomy b	0.97	0.65 - 1.50	.90
Model 2			
All patients	1.12	0.75 - 1.67	.59
Patients with early tracheostomy ^a	0.78	0.21 - 2.91	.71
Patients with late tracheostomy b	1.16	0.77 - 1.75	.49

OR, odds ratio, CI, confidence interval.

^aWithin 7 days of mechanical ventilation; ^bafter 7 days of mechanical ventilation.

Table 4. Odds ratios for postintensive care unit mortality associated with tracheostomy in patients matched on propensity scores

	OR	95% CI	p Value
Model 1			
All patients	2.57	1.20 - 5.48	.01
Patients decannulated before discharge	1.43	0.42 - 4.90	.56
Patients not decannulated before discharge	3.73	1.41 - 9.83	.008
Model 2			
All patients	2.12	1.003 - 4.40	.049
Patients decannulated before discharge	0.86	0.26 - 2.86	.80
Patients not decannulated before discharge	4.63	1.68 - 12.72	.003

OR, odds ratio, CI, confidence interval.

need for reintubation, neurologic disease as the primary reason for initiation of MV, and underlying chronic respiratory disease. The factors thought to be negatively associated with tracheostomy were do-not-resuscitate order, postoperative state, congestive heart failure, or cardiac arrest as indications for initiation of MV.

Assuming an ICU mortality of 25% in unexposed patients and that tracheostomy would

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occur in >150 patients, we calculated that three controls per patient with tracheostomy would be necessary to unmask a difference in the odds ratio of mortality of 1.5 with an α risk of 5% and a power of 80%.

Using an algorithm (available at http:// www.outcomerea.org/ehtm/matchmacro.pdf), we matched patients who received a tracheostomy during their ICU stay to other mechanically ventilated patients who did not on the basis of each of the two propensity scores (model 1 and model 2). Specifically, we sought to match each patient with tracheostomy with controls who had the closest propensity score (within 0.005 on a scale of 0-1). We imposed that the time to tracheostomy from the start of MV in the exposed patients be less than or equal to the length of MV of their respective controls.

Comparisons between matched patients were first based on univariate conditional logistic regression (for pneumonia, only episodes occurring in the exposed patients after tracheostomy and after an equivalent length of MV in their respective controls were considered). Multivariate conditional logistic regression was then used to examine the association between the performance of a tracheostomy and ICU and post-ICU mortality, adjusting for the confounding variables (i.e., risk factors for ICU and post-ICU mortality previously described) (20, 26) that had $p \leq .10$ in univariate analysis. Only patients discharged alive to the ward and free from mechanical ventilation were considered for post-ICU mortality analyses. Wald chi-square tests were used to determine the significance of each variable. Adjusted odds ratios (ORs) and 95% confidence intervals (CIs) were calculated for each parameter estimate.

We considered p < .05 as significant. Analyses were computed using the SAS 8.2 software package (SAS Institute, Cary, NC).

RESULTS

Study Population. Of the 4,374 OUT-COMEREA database patients, 76 had a tracheostomy on ICU admission and were excluded. Among the remaining 4,298 patients, 2,186 (50%) received mechanical ventilation for \geq 48 hrs, of whom 177 (8.1%) received a tracheostomy. The median time to tracheostomy was 20 (14–32) days from the start of mechanical ventilation. Patients' baseline characteristics and reasons for initiating mechanical ventilation are listed in Table 1.

Matching. One hundred sixty-nine exposed patients were matched to 572 controls in model 1, and 160 exposed patients were matched to 422 controls in model 2. There were no differences in variables predictive of tracheostomy between patients with and without trache-

ostomy after matching on propensity scores (Table 2).

Outcomes. Overall, ICU and post-ICU mortality in patients with and without tracheostomy were 27.68% vs. 37.15% (p = .01) and 15.25% vs. 4.83% (p < .001), respectively. Hospital mortality in patients with and without tracheostomy was similar: 42.94% vs. 41.98% (p = .8). Patients

with tracheostomy had more pneumonia (61.02% vs. 31.61%, p < .001) and longer lengths (days) of ICU stay (46 [29–67] vs. 10 [6–18], p < .001), post-ICU stay (13 [1–35] vs. 4 [1–17], p < .001), and MV (33 [22–54] vs. 7 [3–13], p < .001) than patients without tracheostomy.

After we controlled for treatment selection bias and confounding variables, tra-

Table 5. Differences in risk factors for intensive care unit mortality in patients matched on propensity scores

	Model 1		
Variable	Tracheostomy $(n = 169)$	No Tracheostomy $(n = 572)$	p Value
Factors present at the start of mechanical			
ventilation			
SAPS II score, no. (%)	40 (20)	12/ (92/4)	
<00 26 57	49 (29) 92 (49 E)	134(23.4) 262(46)	01
50-57 \\S7	04 (40.3) 28 (22 5)	203 (40)	.01
APACHE II score mean (SD)	153(22.3)	165 (88)	10
Admission category no. (%)	13.3 (1.0)	10.3 (0.0)	.10
Medical	123 (73)	375 (65.6)	
Scheduled surgery	2123(73) 21(12)	60 (12)	03
Upscheduled surgery	21(12) 25(15)	128(22/4)	.05
Reason for initiation of mechanical	23 (13)	120 (22.4)	
ventilation po (0/)			
Ventilation, no. (%)	00 (58 6)	272 (65.2)	05
Comp	99 (30.0) 10 (6)	76 (12.2)	.05
Neuropuscular disease	10(0) 41(24.3)	70 (13.3)	.001
Cause of acute respiratory failure	41 (24.3)	19 (13.0)	<.001
110. (%) Trauma	6 (2 5)	2(0, 4)	006
Cording preset	(3.3)	2(0.4) 21 (5 4)	.000
Eactors occurring during the ICU stay	4 (2.4)	51 (5.4)	.10
ractors occurring during the ico stay,			
Shock	106 (62 7)	402 (70 5)	0.02
ADDC	100(02.7) 160(04.7)	403 (10.3)	0.02
ANDS Songie	100(94.7) 152(00)	402 (80.8)	<.001 002
Pnaumonia	102(50) 103(61)	$\frac{433}{48}$	- 002
Renal failure	103(01) 104(615)	430 (75.2)	<.001 001
Henatic failure	112 (66 3)	328 (57 3)	10
Coagulonathy	27 (16)	31 (5.4)	< 001
Coaguiopathy	21 (10)	51 (5.4)	<.001
	M	odel 2	
	Tracheostomy	No Tracheostomy	
Variable	(n = 160)	(n = 422)	p Value
Factors present at the start of mechanical			
ventilation			
SAPS II score po (%)			
SAI 5 II SCOLE, 110. (70)	47 (20.2)	03 (99)	
<50 36_57	$\frac{41}{76}$ (47.2)	205 (48.6)	10
>57	38 (23.6)	124(29.4)	.10
APACHE II score mean (SD)	154(74)	169 (87)	10
Reason for initiation of mechanical	10.7 (1.7)	10.0 (0.1)	.10
ventilation no (%)			
Acute respiratory failure	97 (60)	279 (66)	05
Factors occurring during the ICU stav	51 (00)	213 (00)	.00
no (%)			
ARDS	153 (95)	298 (70)	< 001
Pneumonia	95 (59)	193 (46)	01
i neamonia	55 (55)	100 (10)	.01

SAPS, Simplified Acute Physiology Score; APACHE, Acute Physiology and Chronic Health Evaluation; ARDS, acute respiratory distress syndrome.

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Table 6. Differences in risk factors for postintensive care unit mortality in patients matched on propensity scores

	М	odel 1	p Value
Variable	Tracheostomy $(n = 98)$	No Tracheostomy $(n = 330)$	
SOFA score at discharge, median (Q1–Q3)	1 (0–2)	2 (1–3)	.02
	М	Model 2	
Variable	Tracheostomy $(n = 96)$	No Tracheostomy $(n = 297)$	p Value
Transfer from ward, no. (%) SOFA score at discharge, median (Q1–Q3)	62 (64.6) 1 (0–3)	164 (56.2) 2 (1–3)	.02 .08

SOFA, Sepsis-related Organ Failure Assessment; Q1–Q3, interquartile range.

Only patients discharged alive from the intensive care unit and free from mechanical ventilation were considered for analysis.

cheostomy was not associated with improved ICU survival in either model 1 or model 2, irrespective of whether tracheostomy was performed early (within 7 days of MV) or late (after 7 days of MV). Adjusted ORs and 95% CIs are shown in Table 3. On the other hand, tracheostomy was associated with increased postintensive care unit mortality in patients discharged free from MV with their tracheostomy tube in place but not in patients discharged after removal of their tracheostomy tube. Adjusted ORs and 95% CIs are shown in Table 4. Differences in risk factors for ICU and post-ICU mortality between matched patients with and without tracheostomy are listed in Tables 5 and 6.

Finally, patients with tracheostomy in model 1 had longer lengths (days) of ICU stay (45 [29–67] vs. 20 [13–30], p <.001), post-ICU stay (13 [1–34] vs. 7 [1–21], p <.001), and MV (33 [22–50] vs. 17 [9–24], p <.001) than patients without tracheostomy, but tracheostomy was not associated with the development of subsequent pneumonia (OR, 1.50; 95% CI, 0.52–4.34; p = .46). Results obtained with model 2 were similar.

DISCUSSION

Our results suggest that tracheostomy has no positive impact on survival when performed in unselected mechanically ventilated patients. It does not seem to reduce ICU mortality but may set patients discharged free from MV with their tracheostomy tube in place at high risk for post-ICU mortality. This emphasizes the utmost importance of targeted indications for tracheostomy and suggests the need for specialized step-down units for optimal post-ICU care.

The first major finding that tracheostomy does not favorably influence survival runs counter to previous reports. In 1999, Kollef et al. (1) inferred that tracheostomy was associated with a decreased hospital mortality. However, potential confounding factors were not taken into account, thus precluding drawing any conclusion. Recently, Frutos-Vivar et al. (14) showed a protective effect of tracheostomy in the ICU. Confounding factors were considered but patients were heterogeneous as to the indications for tracheostomy, leading to possible bias in the estimation of the effect of tracheostomy. In our study, we extensively dealt with baseline confounding and treatment selection biases. Potential confounders related to mortality were taken into account and analyzed within each cluster of exposed and not exposed patients, allowing an accurate estimation of the independent effect of tracheostomy. By using the propensity technique, we achieved an even distribution of all measured confounders and were able to assess the effects of tracheostomy in homogeneous patients who had the same probability of receiving the procedure, thus ensuring a greater reliability of the results. It must be noticed that we studied an unselected population. Yet, the prognosis may differ according to the type of patients. This is particularly true for elderly patients, who seem to have the worse outcomes (27, 28). Patients with neuromuscular disease and patients with chronic obstructive pulmonary disease may also have different outcomes. Whether specific subgroups of patients do benefit from tracheostomy is an important outcome measurement for future investigations.

Apart from mortality, this study addresses three other main issues. First, since the timing could be of prognostic interest (7, 29, 30), we evaluated whether patients with early tracheostomy had lower ICU mortality than patients with late tracheostomy. No difference was found. This could be ascribable to the fact that early placement of a tracheostomy is not always judicious. In the study by Rumbak et al. (7), for instance, eight patients (35% of survivors) in the delayed tracheostomy group no longer needed tracheostomy by the time this procedure was indicated by protocol. Second, we assessed the relationship between tracheostomy and pneumonia, taking into account only pneumonia occurring after tracheostomy was performed or after an equivalent length of MV in the respective controls. Thus, we avoided misinterpretation due to pneumonia occurring at different time points during the course of MV. The risk of pneumonia was not modified by tracheostomy. Third, we brought evidence that tracheostomy increases lengths of MV, ICU, and post-ICU stays. This may be due to the median time before tracheostomy (20 days), which is somewhat longer than usually reported (1, 14). But longer lengths of stays more probably reflect the great deal of difficulties encountered when trying to discharge those patients from ICU or hospital.

The second major finding was that tracheostomy increased post-ICU mortality in patients weaned from MV who did not have their tracheostomy tube removed before discharge. One explanation is that these patients could not be decannulated because they had the most serious impairment of their respiratory function. As a consequence, they were more likely to die after ICU discharge and the tracheostomy tube *per se* was not responsible for the excess of mortality. In this view, that patients discharged after decannulation did not subsequently experience increased mortality may simply reflect the fact that weaning from MV could have been achieved without tracheostomy. Another explanation is poor tracheostomy care in the wards, which could be responsible for complications such as obstruc-

tion of the cannula, and subsequent increased mortality. In some countries, patients are transferred to specific units while still on MV (7). In France, very few specific units are available and most patients are transferred to general wards. Our study suggests the need to develop specific units and provide nurses with practical clinical guidance on how to care for a patient with a tracheostomy in a safe and effective manner. Recent articles described how to implement strategies to ensure optimal care of tracheostomized patients by educated and supported teams of nurses (31, 32). However, the real utility of such units has still to be evaluated in the absence of clear benefits or indications for tracheostomy.

Some limitations merit consideration. First, we did not assess secondary outcomes such as patient comfort, which may be a valuable indication for tracheostomy. Second, we performed an observational study, not a randomized controlled trial. Although by using the propensity technique we adjusted for treatment selection bias, the possibility of an important missing variable in the propensity regression leading to inappropriate subsequent matching cannot be entirely excluded. However, two distinct models were developed with two different techniques of relevant variable selection, and the conclusions obtained with both models were quite similar. Thus, it is unlikely that an important missing variable would have changed the results. Third, since this is a multiple-center study, results may be subject to inconsistent institutional practices. However, physicians of the participating ICUs followed current recommendations for tracheostomy, and neither the timing of tracheostomy nor the technique used altered patients' outcomes (12, 13, 27). So, the fact that mainly surgical procedures were performed in our population was very unlikely to have confounded the results.

CONCLUSIONS

As the use of tracheostomy seems to increase in patients requiring prolonged MV (33), it must be kept in mind that the ICU is not an isolated environment and that all the decisions we make in the ICU do have an important impact on future care needs.

Tracheostomy does not seem to favorably influence ICU survival but may represent a burden after ICU discharge. Consequently, the decision to proceed with tracheostomy should be cautious, and efforts should be made to identify patients who might clearly benefit from this technique to avoid unnecessary and unwanted prolonged MV.

Finally, it must be emphasized that successful weaning from MV can often be achieved without tracheostomy (7, 34).

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REFERENCES

- Kollef MH, Ahrens TS, Shannon W: Clinical predictors and outcomes for patients requiring tracheostomy in the intensive care unit. *Crit Care Med* 1999; 27:1714–1720
- Fischler L, Erhart S, Kleger GR, et al: Prevalence of tracheostomy in ICU patients. A nation-wide survey in Switzerland. *Intensive Care Med* 2000; 26:1428–1433
- Esteban A, Anzueto A, Alía I, et al: How is mechanical ventilation employed in the intensive care unit? An international utilization review. *Am J Respir Crit Care Med* 2000; 161:1450–1458
- Whited RE: A prospective study of laryngotracheal sequelae in long-term intubation. *Laryngoscope* 1984; 94:367–377
- Stauffer JL, Olson DE, Petty TL: Complications and consequences of endotracheal intubation and tracheotomy: A prospective study of 150 critically ill adult patients. *Am J Med* 1981; 70:65–76
- Diehl JL, El Atrous S, Touchard D, et al: Changes in the work of breathing induced by tracheotomy in ventilator-dependent patients. *Am J Respir Crit Care Med* 1999; 159: 383–388
- Rumbak MJ, Newton M, Truncale T, et al: A prospective, randomized, study comparing early percutaneous dilational tracheotomy to prolonged translaryngeal intubation (delayed tracheotomy) in critically ill medical patients. *Crit Care Med* 2004; 32:1689–1694
- Nieszkowska A, Combes A, Luyt CE, et al: Impact of tracheotomy on sedative administration, sedation level, and comfort of mechanically ventilated intensive care unit patients. *Crit Care Med* 2005; 33:2527–2533
- Heffner JE: Medical indications for tracheostomy. *Chest* 1989; 96:186–190
- Marsh HM, Gillespie DJ, Baumgarener AE: Timing of tracheostomy in the critically ill patient. *Chest* 1989; 96:190–193
- 11. Heffner JE, Miller KS, Sahn SA: Tracheos-

tomy in the intensive care unit. Part 2: Complications. *Chest* 1986; 90:430-461

- Antonelli M, Michetti V, Di Palma A, et al: Percutaneous translaryngeal versus surgical tracheostomy: A randomized trial with 1-yr double-blind follow-up. *Crit Care Med* 2005; 33:1015–1020
- Angel LF, Simpson CB: Comparison of surgical and percutaneous dilational tracheostomy. *Clin Chest Med* 2003; 24:423–429
- Frutos-Vivar F, Esteban A, Apezteguía C, et al, for the International Mechanical Ventilation Study Group: Outcome of mechanically ventilated patients who require a tracheostomy. *Crit Care Med* 2005; 3:290–298
- Blot F, Melot C, for the Commission d'Epidémiologie et de Recherche Clinique: Indications, timing, and techniques of tracheostomy in 152 French ICUs. *Chest.* 2005; 127:1347–1352
- Greenland S, Neutra R: Control of confounding in the assessment of medical technology. *Int J Epidemiol* 1980; 9:361–367
- Rosenbaum PR, Rubin DB: The central role of the propensity score in observational studies for causal effects. *Biometrika* 1983; 70: 41–55
- Rosenbaum PR, Rubin DB: Reducing bias in observational studies using subclassification on the propensity score. J Am Stat Assoc 1984; 79:516–524
- Knaus WA, Draper EA, Wagner DP, et al: APACHE II: a severity of disease classification system. *Crit Care Med* 1985; 13:818–829
- Esteban A, Anzueto A, Frutos F, et al, for the Mechanical ventilation International Study Group: Characteristics and outcomes in adult patients receiving mechanical ventilation: a 28-day international study. JAMA 2002; 287:345–355
- Joffe MM, Rosenbaum PR: Invited commentary: Propensity scores. Am J Epidemiol 1999; 150:327–333
- Hosmer D, Lemeshow S: Applied logistic regression. New York, Wiley, 1989
- Dalkey N, Helmer O: An experimental application of the Delphi method to the use of experts. *Management Science* 1963; 9:458-467
- Critcher C, Gladstone B: Utilizing the Delphi technique in policy discussion: A case study of a privatized utility in Britain. *Public administration* 1998; 76:434–449
- Dunn WN: Public Policy Analysis: An Introduction. 2nd ed. Englewood Cliffs, NJ, Prentice Hall, 1994
- Azoulay E, Adrie C, De Lassence A, et al: Determinants of postintensive care unit mortality: A prospective multicenter study. *Crit Care Med* 2003; 31:428–432
- Kurek CJ, Cohen IL, Lambrinos J, et al: Clinical and economic outcome of patients undergoing tracheostomy for prolonged mechanical ventilation in New York state during 1993: Analysis of 6,353 cases under diagnosis-related group 483. *Crit Care Med* 1997; 25:983–988
- 28. Baskin JZ, Panagopoulos G, Parks C, et al: A.

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Clinical outcomes for the elderly patient receiving a tracheotomy. *Head Neck* 2004; 26: 71–75

- Moller MG, Slaikeu JD, Bonelli P, et al: Early tracheostomy versus late tracheostomy in the surgical intensive care unit. *Am J Surg* 2005; 189:293–296
- Griffiths J, Barber VS, Morgan L, et al: Systematic review and meta-analysis of studies of the timing of tracheostomy in adult patients undergoing artificial ventilation. *BMJ*. 2005; 330:1243–1246
- Russell C: Providing the nurse with a guide to tracheostomy care and management. Br J Nurs 2005; 14:428–433
- Lewis T, Oliver G: Improving tracheostomy care for ward patients. *Nurs Stand* 2005; 19: 33–37
- Cox CE, Carson SS, Holmes GM, et al: Increase in tracheostomy for prolonged mechanical ventilation in North-Carolina, 1993–2002. Crit Care Med 2004; 32: 2219–2226
- 34. Coplin WM, Pierson DJ, Cooley KD, et al: Implications of extubation delay in braininjured patients meeting standard weaning criteria. Am J Respir Crit Care Med 2000; 161:1530–1536

APPENDIX

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