Early versus late tracheostomy in patients with acute severe brain injury*

Traqueostomia precoce versus traqueostomia tardia em pacientes com lesão cerebral aguda grave

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Abstract

Objective: To compare the effects of early tracheostomy and of late tracheostomy in patients with acute severe brain injury. **Methods:** A retrospective study involving 28 patients admitted to the ICU of the Federal University of Juiz de Fora University Hospital in Juiz de Fora, Brazil, diagnosed with acute severe brain injury and presenting with a Glasgow coma scale (GCS) score < 8 within the first 48 h of hospitalization. The patients were divided into two groups: early tracheostomy (ET), performed within the first 8 days after admission; and late tracheostomy (LT), performed after postadmission day 8. At admission, we collected demographic data and determined the following scores: Acute Physiology and Chronic Health Evaluation (APACHE) II, GCS and Sequential Organ Failure Assessment (SOFA). **Results:** There were no significant differences between the groups (ET vs. LT) regarding the demographic data or the scores: APACHE II (26 ± 6 vs. 28 ± 8; p = 0.37), SOFA (6.3 ± 2.7 vs. 7.2 ± 3.0; p = 0.43) and GCS (5.4 ± 1.7 vs. 5.5 ± 1.7; p = 0.87). The 28-day mortality rate was lower in the ET group (9% vs. 47%; p = 0.04). Nosocomial pneumonia occurring within the first 7 days was less common in the ET group, although the difference was not significant (0% vs. 23%; p = 0.13). There were no differences regarding the occurrence of late pneumonia or in the duration of mechanical ventilation between the groups. **Conclusions:** On the basis of these findings, early tracheostomy should be considered in patients with acute severe brain injury.

Keywords: Tracheostomy; Pulmonary ventilation; Coma.

Resumo

Objetivo: Comparar os efeitos da traqueostomia precoce e da traqueostomia tardia em pacientes com lesão cerebral aguda grave. **Métodos:** Estudo retrospectivo com 28 pacientes admitidos na UTI do Hospital Universitário da Universidade Federal de Juiz de Fora com diagnóstico de lesão cerebral aguda grave e apresentando escore na escala de coma de Glasgow (ECG) < 8 nas primeiras 48 h de internação. Os pacientes foram divididos em dois grupos: traqueostomia precoce (TP), realizada em até 8 dias; e traqueostomia tardia (TT), realizada após 8 dias. Dados demográficos e os escores *Acute Physiology and Chronic Health Evaluation* (APACHE) II, ECG e *Sequential Organ Failure Assessment* (SOFA) do dia da admissão foram coletados. **Resultados:** Não houve diferenças significativas em relação aos dados demográficos ou aos escores coletados nos grupos TP e TT: APACHE II (26 ± 6 vs. 28 ± 8; p = 0,37), SOFA (6,3 ± 2,7 vs. 7,2 ± 3,0; p = 0,43) e ECG (5,4 ± 1,7 vs. 5,5 ± 1,7; p = 0,87). A mortalidade em 28 dias foi menor no grupo TP (9% vs. 47%; p = 0,04). Pneumonia nosocomial precoce (até 7 dias) foi menos frequente no grupo TP, mas essa diferença não foi significativa (0% vs. 23%, p = 0,13). Não houve diferenças em relação à ocorrência de pneumonia tardia ou ao tempo de ventilação mecânica entre os grupos. **Conclusões:** Baseado nesses achados, a traqueostomia precoce deve ser considerada em pacientes com lesão cerebral aguda grave.

Descritores: Traqueostomia; Ventilação pulmonar; Coma.

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Introduction

Tracheostomy is a procedure commonly performed in patients admitted to the ICU with respiratory failure. Tracheostomy has been reported to have advantages over translaryngeal intubation, although there is no consensus regarding such advantages. Among them, the following are of note: easier handling of the airways; greater patient comfort and facility of communication, reducing the need for sedation; possibility of oral feeding; improved respiratory mechanics; reduced trauma in the oral cavity; prevention of ventilator-associated pneumonia (VAP); and easier weaning. However, despite being a safe procedure, tracheostomy can be associated with complications such as infection at the incision site, bleeding, subcutaneous emphysema, pneumothorax, tracheomalacia and tracheal stenosis (the last two can also occur in patients submitted to tracheal intubation).[1-5] Despite these theoretical advantages, few studies have been conducted in an appropriate manner to determine the impact that tracheostomy and its timing have on patient outcomes. At a consensus conference held in 1989, it was suggested that, when ventilatory support is expected to exceed 21 days, tracheostomy is preferable; however, this statement exclusively reflects the opinion of specialists.[6]

In patients with severe neurological injury, which lowers the level of consciousness, early tracheostomy can be especially beneficial. Frequently, such patients are on mechanical ventilation (MV) only due to the need for tracheal intubation to protect the airways. In such cases, tracheostomy can ensure the protection of the airways and allow the withdrawal of MV, avoiding exposure to its risk factors, particularly VAP, and allowing earlier discharge from the ICU.[7] In this study, we retrospectively evaluated the impact of early tracheostomy in patients with acute neurological disease and a decreased level of consciousness.

Methods

We retrospectively analyzed the medical charts of patients admitted to the Federal University of Juiz de Fora University Hospital, located in the city of Juiz de Fora, Brazil, between January of 2004 and August of 2007. We selected patients who underwent MV due to acute neurological disease and presented with a Glasgow coma scale (GCS) score < 8 within the first 48 h of hospitalization. At admission, we recorded demographic data, including age, gender, race and ICU admission diagnosis, as well as determining the following scores: Acute Physiology and Chronic Health Evaluation (APACHE) II; GCS; and Sequential Organ Failure Assessment (SOFA). We registered the time to tracheostomy (in days) for each patient, and the median was 8 days. The patients were then divided into two groups by time to tracheostomy: the early tracheostomy (ET) group (tracheostomy performed within the first 8 days after the initiation of MV); and the late tracheostomy (LT) group (tracheostomy performed after more than 8 days on MV). The adoption of this criterion to separate the groups was due to the fact that studies of the timing of tracheostomy establish widely varying values for tracheostomy to be considered early or late. The choice of the median rather than the mean was due to the non-normal distribution of the sample. All tracheostomies were performed by the same team and using the same technique—open surgery. The timing of the procedure was decided by the attending physician.

The following outcome measures were studied: 28-day mortality; number of ICU-free days; number of ventilator-free days within the first 28 days of hospitalization; occurrence of VAP; and occurrence of early VAP (within the first 7 days on MV).

The statistical analysis was performed using the SigmaStat program, version 2.0 (SPSS Inc., Chicago, IL, USA). Quantitative variables were compared using ANOVA or the Kruskal-Wallis test, depending on whether they presented normal or non-normal distribution, respectively. Categorical variables were compared using Fisher's exact test. Values of $p < 0.05$ were considered statistically significant.

Results

During the study period, 463 patients were admitted to the ICU of the facility. Of those, 28 underwent MV due to neurological disease and presented with a GCS score < 8 within the first 48 h of hospitalization. Of those 28, 11 were in the ET group and 17 were in the LT group. As can be seen in Table 1, the two groups presented similar characteristics in terms of demographic data (age and gender), severity

Table 1 - Characteristics of the study groups at ICU admission.

Characteristic	ET group (n = 11)	LT group (n = 17)	p
Age, years[a]	55 ± 17	54 ± 20	0.98
Male gender[b]	4 (36)	12 (71)	0.12
Acute Physiology and Chronic Health Evaluation II[a]	26 ± 6	28 ± 8	0.47
Sequential Organ Failure Assessment[a]	6.3 ± 2.7	7.2 ± 3.0	0.43
Glasgow coma scale[a]	5.4 ± 1.7	5.5 ± 21.7	0.37
Timing of tracheostomy, number of ICU days[c]	4.73 ± 2.28	16.94 ± 7.68	< 0.001
	4 (1-8)	14 (9-28)	< 0.001
Diagnosis[d]			
Cerebrovascular accident	7	9	
Meningitis	0	3	
Epilepsy	1	2	
Neurotoxoplasmosis	1	1	
Anoxic encephalopathy	1	0	
Demyelinating disease	1	1	
Exogenous intoxication	0	1	

ET: early tracheostomy; and LT: late tracheostomy. Results expressed as: [a]mean ± SD; [b]n (%); [c]mean ± SD and median (interquartile range); and [d]n.

(APACHE II and SOFA scores), coma severity (GCS score) and neurological diagnosis.

The 28-day mortality rate was lower in the ET group than in the LT group (9% vs. 47%; p = 0.049; Figure 1). In contrast, the difference between the groups (ET vs. LT) regarding in-ICU mortality was not statistically significant (46% vs. 65%; p = 0.44; Figure 1).

There was a tendency toward faster weaning among the ET group patients, as evidenced by the greater number of ventilator-free days within the first 28 ICU days, although there was no statistical significance in relation to the LT group patients (median = 4 days [range: 0-26 days] vs. median = 0 days [range: 0-25 days]; p = 0.23). There was no difference between the groups (ET vs. LT) regarding the number of ICU-free days within the first 28 days of hospitalization (median = 0 days [range: 0-21 days] vs. median = 0 days [range: 0-25 days]; p = 0.72; Figure 2).

None of the ET group patients developed VAP within the first 7 days of MV, compared with 4 (23%) of the LT group patients (p = 0.13). Taking into consideration the entire hospitalization stay, 6 (54%) of the ET group patients and 12 (70%) of the LT group patients developed VAP (p = 0.44; Figure 3).

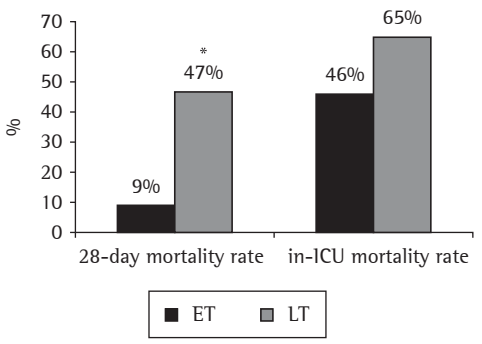

Figure 1 - 28-day and in-ICU mortality rates in the early tracheostomy (ET) and late tracheostomy (LT) groups. *p = 0.049.

Discussion

Tracheostomy remains one of the most commonly performed procedures in the ICU. One group of authors, in a prospective observational study conducted at 349 units in 23 countries and including 4,968 patients on MV, observed that 12.5% of those patients were submitted to tracheostomy.[8] A similar result had been found in 1998 by the same group, who observed that 11% of the patients on MV were submitted to tracheostomy.[9] The timing of tracheostomy, however, remains a matter of controversy, and the recommendations are still based on the experience of specialists rather than on scientific evidence. For instance, in a document

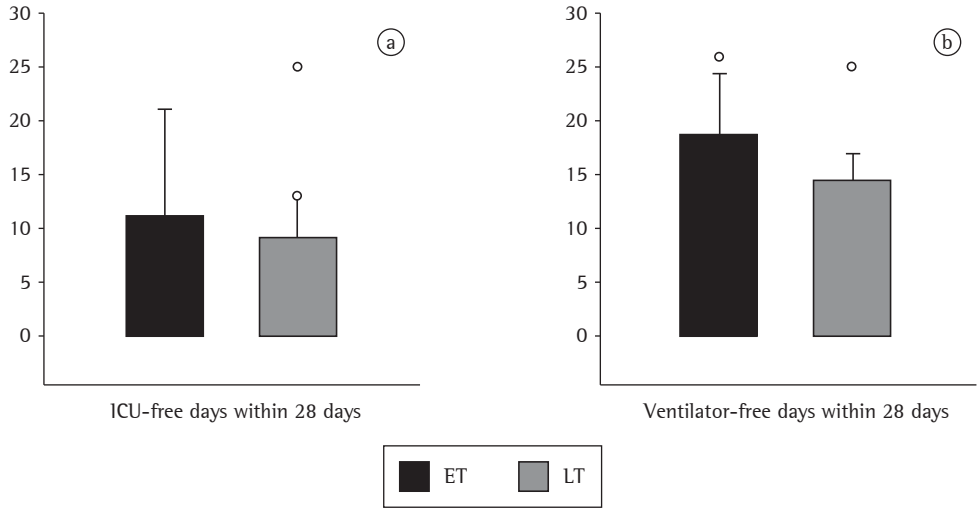

Figure 2 - Number of ICU-free days and ventilator-free days within the first 28 days of hospitalization in the early tracheostomy (ET) and late tracheostomy (LT) groups. There were no statistically significant differences between the groups.

published in 2001, the American College of Chest Physicians, the American Association for Respiratory Care and the American College of Critical Care Medicine proposed that tracheostomy should be considered when, after an initial period of stabilization of the patient submitted MV, the clinical impression is that the ventilatory support will be prolonged and that tracheostomy will bring one or more of the following benefits: reduction in the need for sedation for patients to tolerate tracheal intubation; reduction in airway resistance in patients with borderline respiratory mechanics; psychological benefit due to the possibility of speaking and receiving oral feeding; and facilitation of active mobilization.[10]

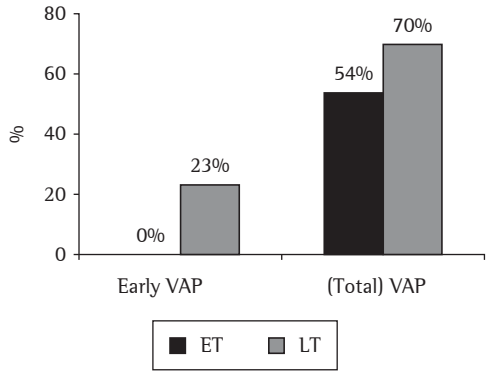

Figure 3 - Occurrence of ventilator-associated pneumonia (VAP) within the first 7 days on mechanical ventilation and occurrence of VAP in the sample as a whole—early tracheostomy (ET) vs. late tracheostomy (LT) groups.

In recent years, some studies have attempted to define the appropriate timing of tracheostomy more accurately. However, some of their findings point in opposite directions. For instance, one group of authors evaluated 120 patients for whom VM was estimated to be required for more than 14 days. Those patients were divided into two groups: early tracheostomy (within 2 days) and late tracheostomy (within 14-16 days). The patients undergoing early tracheostomy had better outcomes: the duration of MV was shorter (7.6 vs. 17.4 days; $p < 0.001$); the occurrence of VAP was lower (5% vs. 25%; $p < 0.005$); and, most importantly, the mortality rate was lower (32% vs. 62%; $p < 0.005$).[11] Conversely, in a very similar study, 123 patients expected to remain on MV for more than 7 days were evaluated. The patients were randomized to undergo early tracheostomy (within the first 4 days of MV) or prolonged intubation. Early tracheostomy was found to offer no advantages, and there were no differences between the groups regarding mortality, occurrence of VAP, duration of MV or length of ICU stay.[12] In 2005, a meta-analysis investigated the impact that the timing of tracheostomy, whether early (within 7 days) or late, has on the outcomes of patients on MV. Only five randomized prospective studies met

the inclusion criteria of the meta-analysis, which indicates the scarcity of data on the subject. As the principal findings, the authors observed that early tracheostomy had no significant impact on mortality (relative risk = 0.79; 95% CI: 0.45 to 1.39; p = 0.42) or on the occurrence of VAP (relative risk = 0.90; 95% CI: 0.66 to 1.21; p = 0.48). However, early tracheostomy was associated with a shorter duration of MV (Δ = −8.5 days; 95% CI: −15.3 to −1.7 days; p = 0.03) and a shorter ICU stay (Δ = −15.3 days; 95% CI: −24.6 to −6.1 days; p = 0.001).[13]

A significant limitation to the interpretation of most studies of the timing of tracheostomy is the inclusion of patients with different diagnoses, that is, with different indications for ventilatory support, as was the case in the studies mentioned.[12,13] The advantages of tracheostomy are not uniform across the different diagnoses, and patients with certain conditions obviously gain more benefit from this procedure. This has already been noticed in routine practice, and, in some situations, tracheostomy tends to be performed early, as shown in one study of a cohort of 5,081 patients in which tracheostomy was found to be performed, on average, 12 days after tracheal intubation.[14] A multivariate analysis showed that physicians consider the procedure to be indicated if one or more of the following factors are present: more than 21 days of MV and occurrence of reintubation or neurological disease as the cause of MV (coma or neuromuscular disease).[14] Ideally, there should be an investigation to determine the most appropriate timing of tracheostomy for each one of the principal indications for MV. Therefore, we chose to evaluate the impact of early tracheostomy on the management of patients on MV and with severely impaired consciousness, which is characterized by the persistence of a GCS score < 8. Such patients are intubated in order to ensure airway safety and alveolar ventilation, preventing upper airway obstruction—due to tongue depression, to the accumulation of secretions or to irregularities in the breathing pattern—from compromising gas exchange and, thereby, worsening the brain injury. Some patients, however, maintain good neural command and can safely be maintained on spontaneous ventilation. They are not extubated only due to the lack of an appropriate level of consciousness, remaining on MV and being exposed to its complications, particularly the risk of VAP. Such patients can benefit from early tracheostomy, which, by ensuring upper airway patency, allows the withdrawal of MV.

Our findings show the benefits of performing tracheostomy early in individuals with neurological disease and severely impaired consciousness. The 28-day mortality rate was lower in the ET group than in the LT group (9% vs. 47%; p = 0.049). There was no statistically significant difference between the groups regarding mortality by the end of the ICU stay, although the rate was lower among the ET group patients (46% vs. 65%; p = 0.44). The small size of our sample might have contributed to the lack of a significant difference. In addition, the patients presented with extremely severe clinical and neurological conditions, as evidenced by the high APACHE II and SOFA scores and the low GCS scores, which limits the impact of any specific therapeutic measure. These are patients who often develop severe sequelae, which leave them exposed to complications while still in the hospital, and those complications can lead to death.

Two additional findings (fewer cases of VAP within the first 7 days of MV and a greater number of ventilator-free days within the first 28 days of hospitalization) suggest that early tracheostomy provides benefits, although the differences were not statistically significant. None of the ET group patients developed early VAP, whereas 23% of the LT group patients did (p = 0.23). Despite the apparently considerable difference between the two groups, it was not statistically significant, probably due to the small number of patients evaluated. Later, over the course of hospitalization, the percentage of VAP was high in both groups (54% vs. 70%), these data being consistent with those reported in the literature, which indicates a cumulatively high risk in patients who remain on MV, particularly in those with a decreased level of consciousness, and reflecting the reality of our ICU, which has a high rate of nosocomial infection.[15-18] Tracheostomy might have contributed to the earlier withdrawal of MV, a finding suggested by the greater number of ventilator-free days within the first 28 days of hospitalization. We believe that the possibility of earlier withdrawal of MV, reducing the exposure of patients to its risks, particularly that of VAP, is the principal

factor responsible for the greater survival among the patients undergoing early tracheostomy. However, this is only an assumption, since our findings do not allow us to draw this conclusion. Similar findings have previously been described. One group of authors retrospectively evaluated 30 patients who had undergone neurosurgery and were submitted to tracheostomy. Comparing those undergoing tracheostomy within the first 7 days (mean = 5.3 ± 1.7 days) with the remaining patients (mean = 10.6 ± 2.7 days of MV), those authors observed that early tracheostomy was associated with a shorter duration of MV (9.8 ± 5.9 days vs. 16.0 ± 5.4 days; p = 0.007) and a lower occurrence of colonization of the airways by multidrug-resistant pathogens (42% vs. 72%; p = 0.098).[19] In another retrospective study, which evaluated 49 patients on MV after neurosurgery, it was observed that choosing to perform tracheostomy early, in comparison with performing it only after the attempt at extubation fails, was associated with earlier weaning and earlier discharge from the ICU.[20] In contrast, in another study, involving 55 patients on MV due to severe craniocerebral trauma and comparing the outcomes of these patients by the timing of tracheostomy (within the first 7 days on MV vs. after day 7 on MV), there were no differences between the groups regarding the occurrence of VAP, the duration of MV or the mortality rates, although those undergoing early tracheostomy were found to be discharged from the ICU earlier.[21] The only randomized prospective study evaluating whether early tracheostomy would have a positive impact in patients with brain injury was published in 2004. That study included patients in whom CT scans of the skull revealed cerebral contusion and who presented with a GCS score ≤ 8 on post-admission days 1 and 5. The patients were then randomized into two groups: patients submitted to tracheostomy on the fifth day of MV (n = 31) and patients maintained on prolonged intubation (n = 31). Although the patients undergoing early tracheostomy remained on MV for a shorter period (14.5 ± 7.3 vs. 17.5 ± 10.6 days; p = 0.02), there was no difference between the groups regarding mortality.[7] In one meta-analysis, studies evaluating the impact of early tracheostomy in trauma patients were initially reviewed, and, subsequently, the findings were individualized among the patients who had severe brain injury. Five prospective randomized studies met the inclusion criteria, of which two evaluated only patients with severe brain injury. The meta-analysis showed that early tracheostomy resulted in no benefits for the trauma patients as a whole, there being no reduction in the mortality rate, the length of ICU stay or the occurrence of VAP. However, taking only the two studies of patients with brain injury into consideration, early tracheostomy was associated with a shorter duration of MV and a shorter ICU stay.[22] All of those studies, most of which were retrospective and included a small number of patients, indicate, with small variations among them, some significant benefit of early tracheostomy in patients with severely impaired consciousness and, therefore, to some extent, corroborate our findings.

Our study has significant limitations, particularly because it was retrospective and involved a small number of patients. In view of the retrospective nature of the study, the allocation to early or late tracheostomy was not randomized and might have been influenced by the impression of the physician in charge of the case, who was responsible for the decision regarding the timing of the procedure. Therefore, although the two groups were homogeneous regarding the severity scores, the GCS scores and the neurological diagnoses, the possibility of a selection bias cannot be ruled out. In addition, since this was a retrospective study, we could not define the precise timing of tracheostomy, and the distinction between early and late tracheostomy was empirical, based on the median number of days on MV prior to the procedure being performed. Consequently, in the two groups, there were patients undergoing tracheostomy at very close time points, a few days before or after the cut-off point. This limitation might have prevented differences between the groups from appearing and therefore underscores our findings. The principal consequence of the small size of the sample was to limit the capacity to demonstrate statistical significance in the differences found. As a result, our findings only raise the issue of the possible benefits of early tracheostomy in these patients, without confirming such benefits.

In conclusion, tracheostomy can offer advantages in the management of patients on MV, particularly those requiring airway control, as is the case of those with severely impaired

consciousness. In this population, it seems that tracheostomy can facilitate weaning, safely reducing patient exposure to the risks of MV, and therefore has a positive impact on mortality. Controlled, prospective studies involving a larger number of participants with severe brain injury are needed in order to elucidate the true role of early tracheostomy in the management of patients on MV due to neurological disease and with severely impaired consciousness.

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