



## POINT OF VIEW

### Does early versus late tracheotomy afford benefits in ventilated patients?☆



### ¿Aporta beneficios la traqueotomía precoz frente a la tardía en el enfermo ventilado?

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Since the 1970s,<sup>1</sup> different comparative studies have tried to answer this question. The two randomized, prospective multicenter trials with the largest sample size to date have been published during the last 5 years. In the first of them, Terragni et al.<sup>2</sup> included 419 patients, of which 209 were randomized to early tracheotomy (after 6–8 days of trans-laryngeal intubation [TI]) and 210 to late tracheotomy (after 13–15 days of TI). The primary endpoint was the incidence of ventilator-associated pneumonia (VAP). The authors found no differences between the two groups in terms of either the primary endpoint or mortality after 28 days (secondary endpoint). The overall complications rate was 39%, though the majority were only minor problems. The second and most recent study was published by Young et al. (The Trac-Man randomized trial),<sup>3</sup> and included 909 patients, of which 455 were randomized to early tracheotomy (during the first 4 days of TI) and 454 to late tracheotomy (after 10 days of TI). There were no differences between the two groups in terms of mortality 30 days after randomization (primary endpoint) or as regards in-hospital mortality or mortality after one and two years of follow-up.

In the study published by Terragni et al.,<sup>2</sup> 17% (n = 36) of the patients randomized to early tracheotomy and 20%

(n = 42) of those randomized to late tracheotomy were finally not subjected to tracheotomy, due to blood gas improvement and resolution of the acute disease process that led them to require mechanical ventilation in the first place. The authors underscored that the anticipation of tracheotomy increased the number of patients who were finally tracheotomized. In the study published by Young et al.,<sup>3</sup> 14% (n = 66) of the patients in the early tracheotomy group were not tracheotomized (15 because of recovery), while a full 55% (n = 244) of the patients in the late tracheotomy arm were not tracheotomized—fundamentally due to extubation and discharge from the Intensive Care Unit. As commented by the authors, this situation questions the capacity of clinicians to establish an early prediction of the duration of mechanical ventilation beyond a period of 7 days. Both studies conclude that early tracheotomy should be avoided.

The results of these two large studies are in contrast to the data published in 2004 by Rumbak et al.,<sup>4</sup> who in a randomized, prospective analysis of a smaller patient sample (120 medical critical patients: 60 in each arm) with screening criteria that do not allow generalization of the results, found early tracheotomy (performed after 48 h of ventilation) to be associated to lesser mortality and VAP than tracheotomy performed beyond 14 days of ventilation. Eight of the 60 patients (13%) randomized to late tracheotomy were finally not tracheotomized due to extubation before day 14.

The last article published in relation to this controversial issue is a recent metaanalysis<sup>5</sup> including 11 randomized, prospective trials. The conclusions were that tracheostomy

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performed in the first 7 days of ventilation is associated to a shorter stay in the Intensive Care Unit, though without differences in terms of in-hospital mortality. Consequently, there is no evidence in support of an early tracheotomy strategy. Accuracy in predicting the duration of mechanical ventilation was cited as an important limitation of all the studies evaluated.

In effect, all the published comparative studies present the same limitation, for which no solution is currently available: the lack of a validated instrument for predicting prolonged mechanical ventilation. As a result, patient screening for inclusion has been based on subjective criteria. This situation in turn has led to recruitment problems in some studies, due to difficulties in anticipating the duration of ventilation, or because of clinician reluctance to follow the randomization protocols.<sup>6,7</sup>

In 2014, Figueroa-Casas et al.<sup>8</sup> published the results of a prospective study designed to evaluate the capacity to establish an early prediction of the duration of mechanical ventilation based on clinical judgment. The analysis of the accuracy of clinical prediction during the first 48 h of intubation revealed a sensitivity of 40% for mechanical ventilation lasting over 7 days, versus 29% for mechanical ventilation lasting over 14 days.

In 2007 we started a project designed to develop a predictive model capable of offering help in the clinical decision making process, fundamentally as regards the timing of tracheotomy in ventilated patients, and which was published in this journal in 2012.<sup>9</sup> The study, completed before the estimated sample size was reached, and lacking the required statistical power, was unable to meet the expectations. Other studies in this same line have likewise been unable to define a model applicable to the clinical setting. There is only a predictive equation validated for burn patients,<sup>10</sup> but not applicable to other critical patients.

In view of the current state of this topic, the latest publications<sup>2-4</sup> represent (or should represent) the end of comparative "early versus late tracheotomy" analyses. Future evaluations in this same line cannot draw solid conclusions if no validated predictive instrument is available. The lack of such an instrument results in methodological weaknesses that invalidate the findings of the studies. Furthermore, considering the poor clinical predictive capacity and the lack of a helping instrument, would it be reasonable to plan new projects a priori assuming that

a number of patients are very likely to undergo needless surgery, with the sole justification of having been randomized to a given study arm?

The time has come for a change in direction. If we want to obtain a solid answer to the question of this "Point of view", we first will have to spend years of research in predictive models. This is no easy task. In the meantime, the individualization of decisions remains the best strategy in routine clinical practice.

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