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Benefits of early tracheotomy: underpowered or overestimated?

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To the editor:

With interest we read the recent article from Blot et al. [1] in which they compared 28-day mortality of patients with early tracheotomy against those with prolonged intubation in a prospective randomized unblinded study. This trial is the first multi-centered randomized study on this topic and we would like to complement the investigators for their effort in achieving this trial. The study does not demonstrate any major benefit of early tracheotomy in a general population of intensive care unit-patients, but hints at putative comfort benefits.

As the authors admit their study is severely underpowered. Indeed, the study was prematurely stopped because after about 2 years only 123 patients had been included. Of note, only 10–20% of the patients assessed for eligibility were actually included. One of the major reasons for non-inclusion was the difficulty in anticipating mechanical ventilation lasting >7 days, one of the inclusion criteria of the study. We wonder how many patients in the prolonged intubation group finally reached 7 days of mechanical ventilation after

randomization. If a substantial number of patients were extubated before that time the patients enrolled may not represent the population of interest (those at high risk of prolonged mechanical ventilation). Unfortunately, the authors did not use explicit criteria to predict prolonged mechanical ventilation (such as the presence of shock and multiorgan failure, oxygenation index, high APACHE II scores [2–4]). Another reason for non-inclusion was difficulties in organizing early tracheotomy. How long patients had to await a tracheotomy in the early tracheotomy group in this study? If this was “too” long the potential benefits may have been diluted?

Two secondary endpoints were sedation requirements during the first 28 days and self-reported patient comfort. Sedation requirements were not different between the two study groups, which is in part in line with recent data from our group [5] but opposite to results from others [6]. Unfortunately, however, data on cumulative dose were not given. Although the number of sedation-free days was not different, the administered dose may have been different between the two groups. This could potentially explain the significant difference in self-reported comfort in favor of early tracheotomy.

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