News Release

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FOR MORE INFORMATION, CONTACT:
Keely Savoie or Brian Kell
ksavoie@thoracic.org or bkell@thoracic.org
ATS Office 212-315-8620 or 212-315-6442 (until May 14)
Cell phones 917-860-5814 or 516-305-9251
ATS Press Room: 504-670-6926 (May 15 to 20)

Poster session time: 1:30-4:00 p.m. May 18
Location: CC-Room 260-260 (Second Level), Morial Convention Center

Early vs. Late Tracheotomy Does Not Reduce Mortality in ICU Patients

ATS 2010, NEW ORLEANS— Early tracheotomy in ICU patients on mechanical ventilation (MV) did not reduce mortality when compared to later tracheotomy in a study of cardiac surgery patients requiring prolonged ventilation in a Paris study.

The findings will be reported at the ATS 2010 International Conference in New Orleans.

Early percutaneous tracheotomy (EPT) in patients requiring prolonged MV remains controversial, as recent studies suggested it might shorten MV duration and lower mortality, while others have not.

"Based on the results of our study, early tracheotomy provided no benefit in terms of MV duration, hospital length of stay, mortality or frequency of infectious complications compared to prolonged intubation possibly followed by late tracheotomy," said researcher Alain Combes, M.D., Ph.D., professor at the Université Pierre et Marie Curie in Paris.

The single-center study randomized 216 adults still requiring MV 4–5 days after cardiac surgery, and projected to remain so for at least seven days, to receive early percutaneous tracheotomy or prolonged intubation (PI) with possible tracheotomy if mechanical ventilation lasted more than 15 days.

Characteristics of the two groups were similar at randomization, although the ET group had more heart transplant patients (21 versus 7 percent) and more patients requiring renal replacement therapy (38 versus 16 percent.) At the end, the number of ventilator-free days was lower in the EPT group, but the difference did not reach statistical significance. However, EPT was associated with less intravenous sedation and analgesia, fewer unscheduled extubations and less reintubations, and with earlier bed-to-chair transfer and resumption of oral nutrition.

“We expected MV duration reduction because tracheotomy was previously shown to reduce sedative and analgesics consumption, which is clearly associated with reduced MV duration and sometimes even with reduced mortality,” said Dr. Combes. “We hypothesized that EPT might reduce MV duration by 6 days, but the true effect of EPT, if it exists, might only be a reduction of 2-3 days, which is not sufficiently clinically relevant, and might require 10 times as many patients for a study to demonstrate a significant effect.”

Dr. Combes did, however, note that tracheotomy is associated with very rare but potential adverse events, like every invasive procedure. “To avoid unnecessary tracheostomies, physicians might consider them only after 7-10 days of MV, when projected MV duration is longer than one week at that time point,” he concluded.

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“Early Versus Late Tracheotomy for Cardiac Surgery Patients Requiring Prolonged Mechanical Ventilation (ETOC Randomized Trial, NCT00347321)” (Session C94, Tuesday, May 18, 1:30- 4:00 p.m., CC-Room 260-262 (Second Level), Morial Convention Center; Abstract 2790)

**Please note that numbers in this release may differ slightly from those in the abstract. Many of these investigations are ongoing; the release represents the most up-to-date data available at press time.*

Early versus late tracheostomy for cardiac surgery patients requiring prolonged mechanical ventilation (ETOC randomized trial, NCT00347321)

J.-L. Trouillet[1], A. Combes[1], E. Vaissier[1], C.E. Luyt[2], A. NIESZKOWSKA[1], R. Makri[1], A. Pavie[3], J. Chastre[4]
[1]APHP Pitie Salpetriere PARIS UNIVERSITAS - Paris/FR, [2]Hôpital La Pitié-Salpétrière - Paris/FR, [3]Hopital de la Pitié Salpétrière - Paris/FR, [4]Hopital Pitie-Salpetriere - Paris/FR

Rationale: Performing early tracheostomy (ET) in ICU patients requiring prolonged mechanical ventilation (MV) remains highly controversial. Indeed, recent studies suggested that ET might reduce MV duration and even mortality, while others did not. The objective of this study was to compare the outcomes of a selected population of severely ill patients requiring prolonged MV after cardiac surgery randomized to ET or to prolonged intubation possibly followed by late tracheostomy.

Methods: This prospective, randomized, controlled study was conducted in a single center in Paris, France. Patients still on MV 4 days after surgery and projected to need MV for >7 days were randomly assigned to immediate early percutaneous tracheostomy (ET, n=109) or to prolonged intubation with tracheostomy performed only if MV lasted >15 days after randomization (PI, n=107). The primary end-point was D1-D60 ventilator-free days (VFD).

Results: Characteristics at randomization were similar between the 2 groups of patients except for higher rates of heart transplant recipients (21% vs. 7%) and renal replacement therapy (RRT) (38% vs. 16.8%) in the ET group. Mean numbers of D1-D60 ventilator-free days were not significantly different between ET and PI groups: 33.0±21.5 days vs. 30.3.±23.1 days, respectively, absolute difference 2.7 days (95% CI, -3.2 to 8.7; p=0.37). No statistically significant differences existed between ET and PI groups in D28 (15 vs. 21%), D60 (25 vs. 28%), and D90 (30 vs. 29%) mortality rates, in the incidence of ventilator-associated pneumonia (21 vs.20%) and other severe infections, respectively. MV durations and length of hospital stays were similar. However, ET was associated with less intravenous sedation and analgesia and with earlier resumption of oral nutrition. No death was linked to the percutaneous tracheostomy procedure.

Conclusion: In a selected population of patients requiring prolonged MV after cardiac surgery, early tracheostomy provided no benefit in terms of MV duration, hospital length of stay, mortality or incidence of infectious complications compared to prolonged intubation possibly followed by late tracheostomy.