

Tapered-cuff Endotracheal Tube Does Not Prevent Early Postoperative Pneumonia Compared with Spherical-cuff Endotracheal Tube after Major Vascular Surgery

A Randomized Controlled Trial

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ABSTRACT

Background: Patients undergoing major vascular surgery often develop postoperative pneumonia that impacts their outcomes. Conflicting data exist concerning the potential benefit of tapered-shaped cuffs on tracheal sealing. The primary objective of this study was to assess the efficiency of a polyvinyl chloride tapered-cuff endotracheal tube at reducing the postoperative pneumonia rate after major vascular surgery. Secondary objectives were to determine its impact on microaspiration, ventilator-associated pneumonia rate, and inner cuff pressure.

Methods: This prospective randomized controlled study included 109 patients who were randomly assigned to receive either spherical- (standard cuff) or taper-shaped (tapered cuff) endotracheal tubes inserted after anesthesia induction and then admitted to the intensive care unit after major vascular surgery. Cuff pressure was continuously recorded over 5 h. Pepsin and α -amylase concentrations in tracheal aspirates were quantified on postoperative days 1 and 2. The primary outcome was the early postoperative pneumonia frequency.

Results: Comparing the tapered-cuff with standard-cuff group, respectively, postoperative pneumonia rates were comparable (42 *vs.* 44%, $P = 0.87$) and the percentage (interquartile range) of cuff-pressure time with overinflation was significantly higher (16.1% [1.5 to 50] *vs.* 0.6% [0 to 8.3], $P = 0.01$), with a 2.5-fold higher coefficient of variation (20.2 [10.6 to 29.4] *vs.* 7.6 [6.2 to 10.2], $P < 0.001$). Although microaspiration frequencies were high, they did not differ between groups.

Conclusion: For major vascular surgery patients, polyvinyl chloride tapered-cuff endotracheal tubes with intermittent cuff-pressure control did not lower the early postoperative pneumonia frequency and did not prevent microaspiration. (ANESTHESIOLOGY 2016; 124:1041-52)

POSTOPERATIVE pneumonia is a nosocomial infection that occurs after surgery, at least 48 h after hospital admission in the absence of previous signs of incubation. Preexisting comorbidities (such as advanced age, diabetes, and chronic obstructive pulmonary disease), surgical incision (*e.g.*, thoracotomy or sternotomy), intraoperative bleeding requiring massive blood transfusion, and long duration of surgery expose patients undergoing major vascular surgery to a high risk of postoperative pneumonia. The postoperative pneumonia rate after such surgery is around 20%, with a sharp increase after 48 h of mechanical ventilation that can reach 40% after major thoracic surgery.¹ Postoperative pneumonia is responsible for a significant economic burden¹ and remains a leading cause of morbidity and mortality, with associated mortality rates ranging between 15 and 45%.¹⁻³

What We Already Know about This Topic

- Patients undergoing major vascular surgery are at high risk of postoperative pneumonia that impacts outcome.
- Although bench studies highlighted better tracheal sealing properties of polyvinyl chloride tapered-cuff endotracheal tubes, their clinical benefits in preventing postoperative pneumonia still need to be demonstrated.

What this Article Tells Us That Is New

- Polyvinyl chloride tapered-cuff endotracheal tubes did not lower the postoperative pneumonia frequency after major vascular surgery.
- Higher tapered-cuff–pressure variability and higher percentage of time with cuff overinflation were documented. The potential clinical impact of such findings warrants further evaluation.

This article is featured in “This Month in Anesthesiology,” page 1A. Supplemental Digital Content is available for this article. Direct URL citations appear in the printed text and are available in both the HTML and PDF versions of this article. Links to the digital files are provided in the HTML text of this article on the Journal’s Web site (www.anesthesiology.org).

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Although postoperative pneumonia often occurs within the first few days after starting mechanical ventilation, it shares common underlying mechanisms with ventilator-associated pneumonia (VAP). Colonization of oropharyngeal secretions with oral or gastric pathogens is commonly viewed as the first step toward postoperative pneumonia and/or VAP. Gravity then pulls them downward, converging toward subglottic area and then to the tracheobronchial tree. Despite implementation of the preventive bundle to thwart postoperative pneumonia and/or VAP, subglottic secretions can still leak through the microchanneled folds that rapidly spread on the surface of any high-volume, low-pressure endotracheal tube's cuff.^{1,4} Subsequent and repetitive microaspiration of subglottic secretions, which carry a high bacterial burden into the distal airways, plays a pivotal role in postoperative pneumonia pathogenesis.¹

Improving cuff design by changing the material or modifying the shape is among the strategies used to enhance its sealing properties. Bench studies showed promising results in terms of reducing air or liquid leakage across the cuff when using a new tapered-shaped cuff compared with the standard-shaped (spherical or cylindrical) cuff.⁵⁻⁷ This new design was based on the concept that a conical shape would provide a better fit between the trachea and the cuff. Currently available data are discrepant concerning the tapered-cuff's efficiency at preventing microaspirations,⁸⁻¹⁰ VAP,¹¹ and bacterial colonization of the tracheal tree¹² in critically ill patients. A recent, two-period, observational study did not show any VAP rate differences before and after implementing the use of tapered-cuff endotracheal tubes.¹¹ However, in that study, adherence to the VAP-prevention bundle was significantly lower during the tapered-cuff period, precluding fair comparison. On the other hand, tapered-cuff endotracheal tubes have never been evaluated in postoperative pneumonia prevention.

We designed this prospective randomized controlled study to assess the effect of tapered-cuff endotracheal tubes on the postoperative pneumonia rate and microaspiration frequency in major vascular surgery patients.

Materials and Methods

Study Design and Patients

This prospective, randomized controlled, single-blind study was conducted in our 26-bed multidisciplinary intensive care unit (ICU) during a 48-month period. The study was approved by the Institutional Ethics Committee *Île-de-France*

V7 (Institutional Review Board of La Pitié-Salpêtrière Hospital, Paris, France; #ID-RCB-2011-A01038-33). Because our protocol did not modify usual patient care, and the two types of endotracheal tubes were also routinely used in the operating room, the institutional review board waived signed consent. Patients and/or their relatives received written information. The study was registered with ClinicalTrials.gov (NCT01457248).

The inclusion criteria were patients older than 18 yr; who were scheduled to undergo major thoracic, thoracoabdominal, or abdominal aorta surgery without pulmonary exclusion requiring intubation with a double-lumen endotracheal tube; and justifying systematic admission to the multidisciplinary ICU for postoperative care. Patients admitted to the ICU with prior tracheostomy, already enrolled in another trial, or who had had pneumonia within 1 month before the planned surgery were excluded.

A computer-generated randomization list gave an allocation table in permuted blocks (fixed block size, 10; allocation ratio, 1:1). Treatment allocation was concealed, using sequentially numbered opaque sealed envelopes. Patients were screened according to the surgery schedule established 1 week before the intervention. Investigators recruited patients satisfying inclusion criteria and provided information on the study whenever possible before randomization. The anesthesiologist took the next assignment envelope (standard cuff or tapered cuff) in the operating room before anesthesia. Standard-cuff patients were intubated with High Contour Brandt endotracheal tube incorporating a polyvinyl chloride (PVC) spherical-shaped cuff (Mallinckrodt Medical, USA). Tapered-cuff patients were intubated with TaperGuard (Covidien, Ireland) (fig. 1). The endotracheal tube size and the insertion technique were chosen according to professional guidelines. The Cormack-Lehane score and difficult airway-management rate were recorded. Endotracheal tube cuff-pressure setup and management are described in Methods (Supplemental Digital Content 1, <http://links.lww.com/ALN/B258>). Briefly, the cuff was inflated to 25 cm H₂O and manually checked with a manometer every 6 h. The different external appearances of the two tracheal tubes

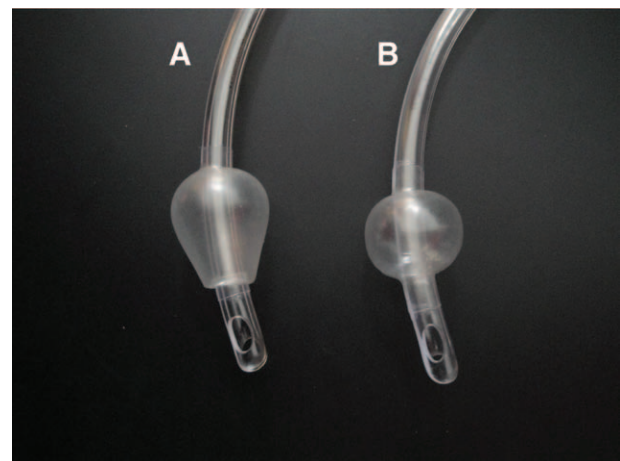


Fig. 1. Polyvinyl chloride endotracheal tubes used in the study: (A) tapered cuff; (B) standard (spherical) cuff.

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rendered blinding of the randomization arm to physicians and nurses impossible. Antibiotic prophylaxis (IV cefamandole; initial dose: 1.5 g, and 750 mg every 2 h) was administered intraoperatively and stopped at the end of surgery. After surgery, all patients were directly admitted to the ICU for postoperative care. They were screened daily for clinical suspicion of postoperative pneumonia for 5 days postextubation or until day 28 if the patient could not be weaned off mechanical ventilation. Tracheal aspirates were sampled within the first hour after the patient's admission (day 1) and 24 h later (day 2) for quantitative pepsin and α -amylase determinations. Cuff pressure was continuously recorded during the 5 h after ICU admission.

The primary endpoint of the study was the frequency of first postoperative pneumonia episodes. The secondary endpoints were as follows: time from intubation to postoperative pneumonia diagnosis; rate of second pneumonia episodes, defined as pneumonia diagnosed after 8 days of antimicrobial treatment for the first pneumonia episode; microaspiration frequency, assessed by tracheal aspirate pepsin and α -amylase concentrations; cuff-pressure variations; lengths of mechanical ventilation and ICU stay, and 28-day mortality.

Diagnosis of Postoperative Pneumonia

Pneumonia diagnosed between intubation and the 5th day post extubation was considered the first postoperative pneumonia episode. Postoperative pneumonia was suspected based on Johanson criteria¹³: new or persistent infiltrates on chest radiography and/or new bedside lung-ultrasound patterns highly evocative of lung infection¹⁴ (see Methods, Supplemental Digital Content 1, <http://links.lww.com/ALN/B258>), associated with two of the three following clinical features: temperature 38.4°C or greater or less than 36.5°C, leukocyte count greater than $11 \times 10^3/\text{ml}$, and/or purulent bronchial secretions. For mechanically ventilated patients, the postoperative pneumonia diagnosis was confirmed when Johanson criteria were associated with a significant concentration of bacteria isolated in lower respiratory tract specimens obtained by fiber-optic bronchoscopy with nonprotected bronchoalveolar lavage or protected mini-bronchoalveolar lavage.¹⁵ A positive sample contained 10^4 or greater colony-forming units per milliliter for nonprotected bronchoalveolar lavage¹⁶ and 10^3 or greater colony-forming units per milliliter for protected mini-bronchoalveolar lavage.¹⁷ For spontaneously breathing patients meeting the Johanson criteria whose lower respiratory tract secretions could not be sampled or ventilated patients meeting those criteria whose lower respiratory tract specimens were negative, a postoperative pneumonia diagnosis was considered possible.^{18,19} Two independent board-certified investigators (attending physicians), blinded to study-arm assignment, made the final pneumonia diagnosis, including the interpretation of chest radiographs and/or lung ultrasounds.

Pepsin and α -Amylase Measurements and Cuff-pressure Recording

On day 1, immediately after surgery, and on mechanical ventilation day 2, pepsin and α -amylase in tracheal aspirates

were measured quantitatively with enzyme-linked immunosorbent assays (Biochemistry and Molecular Biology Laboratory, CHRU, Lille, France). Processing method of tracheal aspirate samples and pepsin and α -amylase quantification techniques were described previously (see Methods, Supplemental Digital Content 1, <http://links.lww.com/ALN/B258>).²⁰ Concentrations of pepsin greater than 200 ng/ml²¹ and α -amylase greater than 1,685 $\mu\text{g/l}$ defined abundant microaspiration.^{20,22,23} Biochemists who measured pepsin concentrations were blinded to study-group assignment.

During the first 5 h after ICU admission, maximum (P_{max}), minimum (P_{min}), and mean (P_{mean}) cuff pressures were digitally recorded continuously at 100 Hz, with Physiobrace software (Centre d'Investigation Clinique-Innovation Technologique, Centre Hospitalo-Universitaire, France). Cuff pressures were defined as normal (20 to 30 cm H₂O), underinflated (less than 20 cm H₂O), or overinflated (greater than 30 cm H₂O). P_{max} , P_{min} , and P_{mean} cuff pressures and the time in each pressure zone were recorded. The coefficient of cuff-pressure variation was calculated as follows: $[(P_{\text{max}} - P_{\text{mean}}) + (P_{\text{mean}} - P_{\text{min}})]/2$.⁹

Concomitant VAP-prevention Strategies

In the ICU, VAP-prevention strategies were routinely applied to both groups of patients. The measures included the following: cuff pressure measured every 6 h using a manual manometer (Ambu Cuff Pressure Gauge; Ambu A/S, Denmark) and maintained between 20 and 30 cm H₂O; semirecumbent body position maintained between 30° and 45°; enteral nutrition with quantification of residual gastric volume every 6 h; stress-ulcer prevention with a proton-pump inhibitor; and oral decontamination with hexetidine every 6 h. All patients were mechanically ventilated with tidal volume of 6 ml/kg of ideal body weight.²⁴ The end-expiratory-pressure level was set by the patient's treating physician.

Statistical Analyses

The primary outcome analysis evaluated the first postoperative pneumonia episode frequencies for "tapered-cuff" patients *versus* "standard-cuff" patients. The postoperative pneumonia rate after major vascular surgery in our ICU was 48% for patients intubated with standard-cuff endotracheal tubes in 2010. We estimated that, with a 5% risk and 80% statistical power, 112 patients (56 in each group) would be needed to detect a 50% reduction of pneumonia frequency in the tapered-cuff group compared with the standard-cuff group, based on previously published data.^{11,25–30} The primary endpoint analysis was performed on the per-protocol population, defined as randomized patients who were admitted to the ICU immediately after surgery. Patients who were randomized before surgery but transferred to another ward or another ICU outside the study center on day 1 after the intervention were considered lost-to-follow-up early; they were excluded from the analysis.

Categorical variables are expressed as numbers (%) and continuous variables as medians (25 to 75% interquartile range). A two-tailed hypothesis was tested. Differences between

standard-cuff and tapered-cuff groups for patients' characteristics, perioperative factors, primary and secondary outcome measures, inner cuff pressures, and pepsin and α -amylase concentrations were compared using chi-square, Fisher exact, or Mann–Whitney rank sum test, as appropriate. Relative risk and its 95% CI were calculated for the primary outcome. The cumulative rates of patients remaining postoperative pneumonia-free from enrollment to day 28 were analyzed with the Kaplan–Meier method and compared between groups using a log-rank test. Statistical analyses were computed with SPSS v13.0 (SPSS, USA) and SigmaStat v3.5 (SystatS, USA). A P value of less than 0.05 defined significance.

Results

Patients

Among 123 patients undergoing planned major vascular surgery screened for inclusion from October 2011 to September 2013, 114 patients were randomized: 58 assigned to the standard-cuff group and 56 allocated to the tapered-cuff group. Five patients were secondarily excluded from the study within 1 day after surgery (fig. 2), leaving 57 and 52 patients to be analyzed in the standard- and tapered-cuff groups, respectively. Their clinical characteristics at ICU admission are reported in table 1. Other than positive end-expiratory pressure (PEEP), which was higher for the tapered-cuff group, intra- and postoperative risk factors for postoperative pneumonia were comparable for the two groups (table 2).

Postoperative Pneumonia

As shown in table 3, first postoperative pneumonia frequencies did not differ between standard- and tapered-cuff groups (44 vs. 42%, $P = 0.87$, relative risk = 0.97; 95% CI, 0.70

to 1.35). Sixteen standard-cuff patients and 15 tapered-cuff patients had microbiologically confirmed postoperative pneumonia (table 4). Nine standard-cuff patients and seven tapered-cuff patients had possible postoperative pneumonia. The cumulative rate of patients remaining postoperative pneumonia-free from enrollment to day 28 did not differ between groups ($P = 0.71$; fig. 3). As shown in tables 3 and 4, clinical and bacterial postoperative pneumonia characteristics and outcome data were comparable for the two groups.

Tracheal Pepsin, α -Amylase, and Inner Cuff Pressure

Tracheal aspirate pepsin levels exceeded 200 ng/ml in 23% of standard-cuff patients and in 20% of tapered-cuff patients ($P = 0.51$) at ICU admission (day 1) (fig. 4). On day 2, the percentage of patients with pepsin concentration greater than 200 ng/ml remained unchanged for the tapered-cuff group (19%), while it increased, *albeit* not significantly, to 35% for the standard-cuff group ($P = 0.11$). Using the previously validated cutoff of 1,685 μ g/l, tracheal aspirate α -amylase concentrations showed that 37 and 52% of the patients had significant oropharyngeal microaspirations on days 1 and 2, respectively. No significant between-group differences were found for microaspiration rates and absolute α -amylase values on postoperative days 1 and 2 (fig. 5).

The tapered-cuff group's P_{\max} was significantly higher and P_{\min} significantly lower than those of the standard-cuff group (table 5). Comparing the tapered-cuff group to the standard-cuff group, respectively, the coefficient of cuff-pressure variation and the time with cuff overinflation were significantly higher, the time with cuff pressure within the normal range was significantly shorter, and the time with cuff underinflation was longer, but the latter difference did not reach statistical significance ($P = 0.06$). Illustrative cuff-pressure recordings are shown in figure 6.

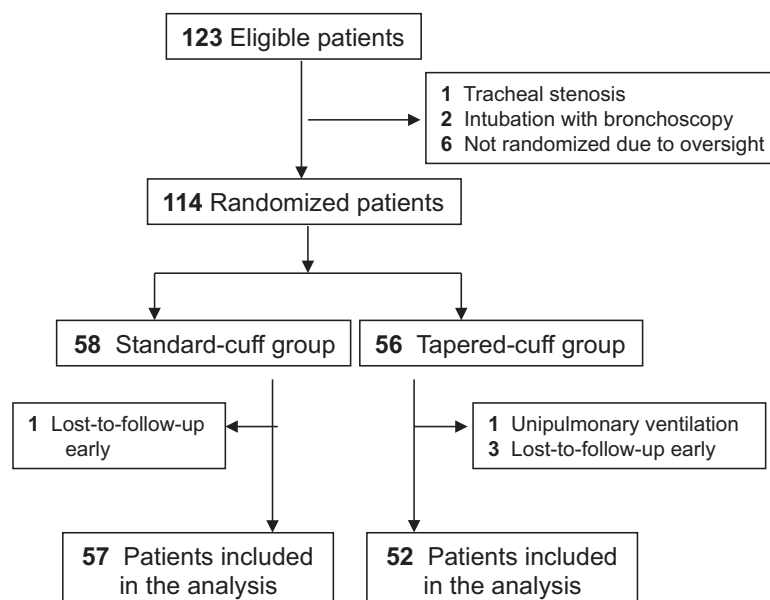


Fig. 2. Study flow chart. Lost-to-follow-up early was defined as patients who had been randomized in the operating room but on day 1 after surgery had been transferred to another intensive care unit or ward outside the study center.

Table 1. Patient Characteristics at ICU Admission According to Randomized Cuff Group

Characteristics	Standard Cuff (n = 57)	Tapered Cuff (n = 52)
Age, yr	66 (59–73)	64.0 (58–70)
Male sex, n (%)	39 (68)	38 (73)
Body mass index	24.8 (21.5–29.5)	24.9 (22.9–28.7)
Simplified Acute Physiology Score II	31 (24–40)	29 (21–42)
Sepsis-related Organ Failure Assessment score	5 (2–8)	6.0 (3–8)
McCabe & Jackson score	1.0 (1.0–2.0)	1.0 (1.0–1.5)
Vascular surgery category, n (%)		
Ascending aorta or aortic arch aneurysm	16 (28)	15 (29)
Thoracic or thoracoabdominal aorta aneurysm	12 (21)	8 (15)
Abdominal aorta aneurysm	7 (12)	4 (8)
Aortic dissection	1 (2)	1 (2)
Vascular prosthesis infection	7 (12)	9 (17)
Other	14 (25)	15 (29)
Shock at ICU admission, n (%)	27 (47)	20 (38)
Diabetes, n (%)	7 (12)	9 (17)
Chronic obstructive pulmonary disease, n (%)	20 (35)	18 (35)
Immunodeficiency, n (%)	5 (9)	8 (15)

Values are expressed as median (25–75% interquartile range) or number (%).

ICU = intensive care unit.

Table 2. Risk Factors for Postoperative Pneumonia According to Randomized Cuff Group

Factors	Standard Cuff (n = 57)	Tapered Cuff (n = 52)	P Value
Intraoperative			
Surgical approach, n (%)			0.88
Sternotomy	22 (39)	22 (42)	
Thoracotomy or thoracotomy	5 (9)	5 (10)	
Laparotomy or sternotomy	27 (47)	21 (40)	
Lumbar incision	3 (5)	4 (8)	
Duration of surgery (h)	5.0 (3.7–6.5)	4.5 (3.8–6.0)	0.66
Blood transfusion (units)	4 (2–9)	4 (2–6)	0.15
Fluid loading, ml	4,000 (3,500–5,000)	4,000 (3,000–5,000)	0.51
Cardiopulmonary bypass, n (%)	21 (37)	16 (31)	0.55
Circulatory arrest, n (%)	6 (11)	7 (13)	0.7
Cardiopulmonary bypass duration, min	158 (126–181)	125 (94–167)	0.13
TEE, n (%)	30 (53)	26 (50)	0.85
Intraoperative prophylactic antibiotics	56 (98)	49 (94)	0.30
Endotracheal tube size (mm)	7.5 (7.5–8)	7.5 (7.5–8)	0.73
Cormack–Lehane score			0.40
1	49/56 (88)	40/51 (78)	
2	4/56 (7)	9/51 (18)	
3	1/56 (2)	1/51 (2)	
4	2/56 (4)	1/51 (2)	
Difficult tracheal intubation	2/57 (4)	0	0.50
Difficult bag-mask ventilation	1/57 (2)	2/51 (4)	0.60
Postoperative			
PEEP (cm H ₂ O)	5.0 (5.0–6.0)	5.6 (5.0–6.3)	0.03*
Muscle relaxant used, n (%)	5 (9)	5 (10)	0.58
Proton-pump inhibitor used, n (%)	52 (91)	49 (94)	0.62
Nasogastric tube, n (%)	52 (91)	48 (92)	0.87
Residual gastric volume, ml/day	97 (5–177)	48 (1–132)	0.32
Enteral nutrition (days)	0 (0–1)	0 (0–2)	0.24
Patients with trunk position < 30°, n (%)	21 (37)	18 (35)	0.91
Postoperative antibiotics, n (%)	1 (2)	3 (6)	0.35

Data are expressed as median and 25–75% interquartile range or number (%).

* $P < 0.05$.

PEEP = positive end-expiratory pressure; TEE = transesophageal echocardiography.

Table 3. Clinical Postoperative Pneumonia Characteristics and Outcome Data According to Randomized Cuff Group

Characteristics	Standard Cuff (n = 57)	Tapered Cuff (n = 52)	P Value
First postoperative pneumonia episodes, n (%)	25 (44)	22 (42)	0.87
Day(s) until the first postoperative pneumonia episode	3 (2–5)	4 (2–6)	0.35
CPIS (first postoperative pneumonia)	7 (6–8)	7 (6–9)	0.83
Procalcitonin (first postoperative pneumonia), ng/ml	4.1 (0.5–8.7)	1.6 (0.4–3.4)	0.27
Second postoperative pneumonia episodes, n (%)	8 (14)	10 (19)	0.47
Days until the second postoperative pneumonia episode	9 (8–19)	10 (7–25)	0.83
Duration of mechanical ventilation, h	29 (9–97)	27.5 (12–306)	0.46
ICU length of stay, days	7 (4–14)	9 (5–20)	0.21
Length of hospital stay, days	22 (13–30)	20 (12–32)	0.91
28-day mortality, n (%)	2 (4)	1 (2)	1.0

Values are expressed as median (25–75% interquartile range) or number (%).

CPIS = Clinical Pulmonary Infection Score; ICU = intensive care unit.

Table 4. Microorganisms Causing Postoperative Pneumonia According to Randomized Cuff Group

Pneumonia	Standard Cuff (n = 25)	Tapered Cuff (n = 22)	P Value
Microbiologically confirmed, n (%)	16 (64)	15 (68)	0.76
Polymicrobial (≥ 2) microorganisms, n	4	2	
Identified microorganisms, n	20	17	
Gram positive, n	4	3	
<i>Staphylococcus coagulase</i> negative	0	1	
<i>Streptococcus</i> spp	3	1	
<i>Enterococci</i> spp	1	1	
Gram negative, n	13	10	
<i>Enterobacteriaceae</i>	9	8	
<i>Pseudomonas aeruginosa</i>	2	1	
<i>Acinetobacter</i> spp	1	0	
<i>Stenotrophomonas</i> spp	1	0	
<i>Haemophilus</i> spp	0	1	
Mixed oropharyngeal flora, n	3	3	
<i>Herpes simplex</i> virus 1	0	1	
Possible pneumonia, n (%)	9 (38)	7 (32)	0.76

Values are expressed as n (%). Possible pneumonia is microbiologically undocumented pneumonia, defined as patients meeting the Johanson criteria, who had a negative lower respiratory tract specimen or from whom lower respiratory tract specimen could not be obtained.

spp = species.

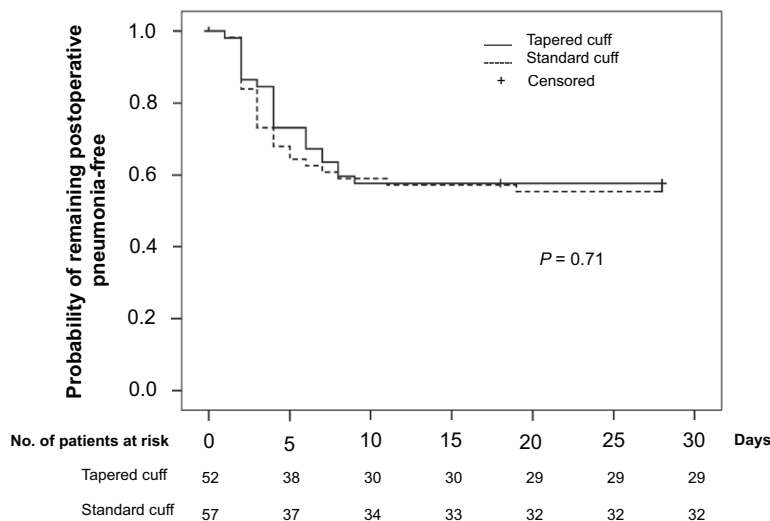


Fig. 3. Kaplan-Meier curve showing the probability of remaining postoperative pneumonia-free (log-rank test: $P = 0.71$). +One tapered-cuff patient censored before day 28 because of tracheostomy performed on day 18.

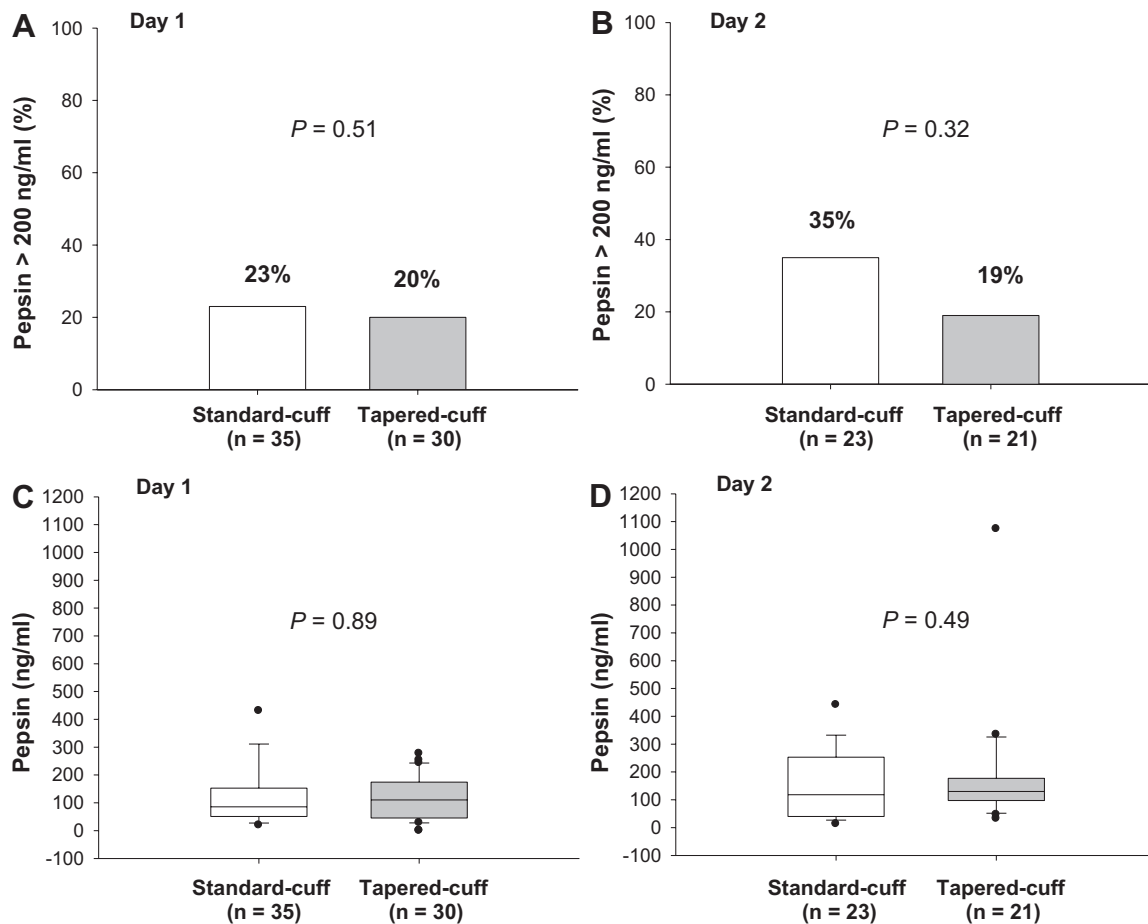


Fig. 4. Pepsin concentrations measured in the tracheal aspirates of standard-cuff and tapered-cuff patients. (A and B) Percentages of patients whose pepsin levels were greater than 200 ng/ml at admission (day 1) and 24 h later (day 2). (C and D) Box plots of pepsin levels on days 1 and 2, respectively: internal horizontal lines are the medians, lower and upper box limits are the 25 to 75% interquartile range, respectively, T-bars represent the ranges, and • are outliers.

Discussion

The results of this study showed that using tapered-cuff endotracheal tubes in major vascular surgery patients did not prevent the first postoperative pneumonia episode, failed to prevent intraoperative gastric or oropharyngeal microaspiration, generated higher variability of cuff inner pressure, increased the time with cuff overinflation, and decreased the time with normal cuff pressure.

Rationale for Using a Tapered-cuff Endotracheal Tube

The rationale for designing a tapered-shaped cuff was based on the assumption that a continuum of minimum-to-maximum diameter sections might better fit the tracheal walls than a standard cuff with single fixed diameter. Improving the fit between trachea and cuff walls would expand the surface area with few or no folds, thereby reducing the number of microchannels toward distal airspace, which might ultimately result in improved tracheal sealing.

Bench-study findings comparing a tapered cuff to either spherical- or cylindrical-shaped cuffs highlighted better sealing properties in terms of liquid and gas leakages.^{6,7} However,

obvious methodological limitations of such *in vitro* studies preclude any generalization of their observations to clinical settings. In addition, when polyurethane tapered cuffs were tested in similar settings, the tapered cuff's superiority was not confirmed.^{6,7} Perioperative sealing properties of tapered cuffs were assessed in a clinical study conducted on patients in a prone position for lumbar surgery. D'Haese *et al.*⁸ used bronchoscopic examination to assess colored-dye leakage across the cuff. Although their results suggested significantly less tracheal aspiration of the dye with tapered-cuff endotracheal tubes, some methodological limitations should be noted. Prone positioning can increase the risk of gastric content aspiration and impact the determinants of tracheal sealing, and evaluations concerned short 10- to 120-min periods. Aspiration was diagnosed based on bronchoscopic detection of liquid-dye-volume leakage, as its viscosity is much lower than that of oropharyngeal secretions.

The first postoperative pneumonia episode after major aorta surgery is thought to be most closely related to intraoperative risk factors for microaspiration, potentially prevented by improving perioperative tracheal sealing. In contrast, the second episode is

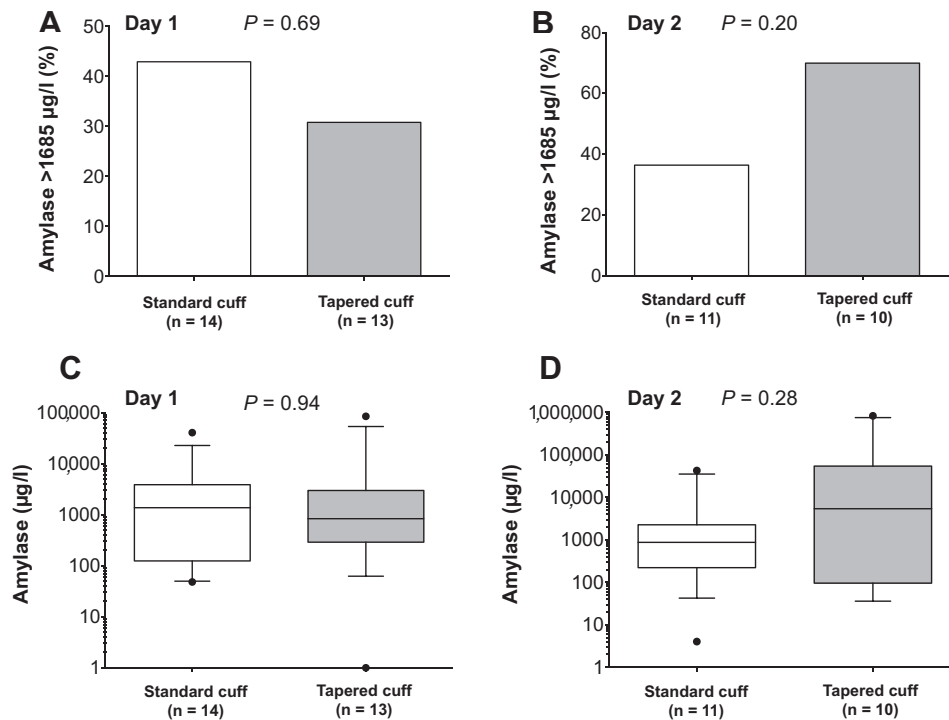


Fig. 5. α -Amylase concentrations measured in the tracheal aspirates of standard-cuff and tapered-cuff patients. (A and B) Percentages of patients whose α -amylase levels were greater than 1,685 $\mu\text{g}/\text{ml}$ at admission (day 1) and 24 h later (day 2), respectively. (C and D) Box plots of α -amylase levels on days 1 and 2, respectively: internal horizontal lines are the medians, lower and upper box limits are the 25 to 75% interquartile range, respectively, T-bars represent the ranges, and • are outliers.

Table 5. Inner Cuff-pressure-monitoring Characteristics According to Randomized Cuff Group

Characteristics	Standard Cuff (n = 32)	Tapered Cuff (n = 44)	P Value
Duration of acquisition, h	5.0 (3.4–6.1)	5.0 (4.0–6.6)	0.51
Cuff pressure, cm H ₂ O			
Mean	26 (23–28)	25 (22–30)	0.97
Maximum	43 (36–48)	65 (45–98)	< 0.001
Minimum	23 (18–25)	18 (15–22)	0.016
Cuff pressure, % of time			
Normal, 20–30 cm H ₂ O	97.1 (73.5–99.9)	68.4 (41.5–80.4)	< 0.001
Underinflated, < 20 cm H ₂ O	0 (0–0)	0 (0–18.5)	0.057
Overinflated, > 30 cm H ₂ O	0.6 (0–8.3)	16.1 (1.5–50)	0.001
Coefficient of cuff-pressure variation	7.6 (6.2–10.2)	20.2 (10.6–29.4)	< 0.001

Values are expressed as median (25–75% interquartile range).

mostly associated with prolonged invasive mechanical ventilation and other factors leading to VAP and/or hospital-acquired pneumonia, which are more independent of intraoperative events. For this study, we considered the first postoperative pneumonia episode, diagnosed between intubation and day-5 postextubation, to be mainly attributable to intraoperative microaspiration events. In contrast, because pneumonia developing after day-5 postextubation could reflect other factors driving late hospital-acquired pneumonia rather than endotracheal tube and microaspiration events, its episodes were not considered herein. All patients remaining pneumonia-free 5 days postextubation were discharged from the ICU but were followed until day 28; none was readmitted to the ICU for pneumonia.

This randomized, controlled trial investigating the potential advantage of PVC tapered-cuff endotracheal tubes to prevent the first postoperative pneumonia episode was conducted on patients undergoing major vascular surgery because this population carries a high risk of postoperative lung infection. Although initially subjected to short-term ventilation for surgery,³¹ these patients were exposed intraoperatively to numerous risk factors for microaspiration (*e.g.*, surgery duration, body position, and transesophageal echocardiography) that might have been prevented by intraoperative use of a tapered-cuff endotracheal tube.¹ Moreover, patient-related factors (age, chronic obstructive pulmonary disease, diabetes, and immunodeficiency) increase the risk of developing postoperative pneumonia. As expected,

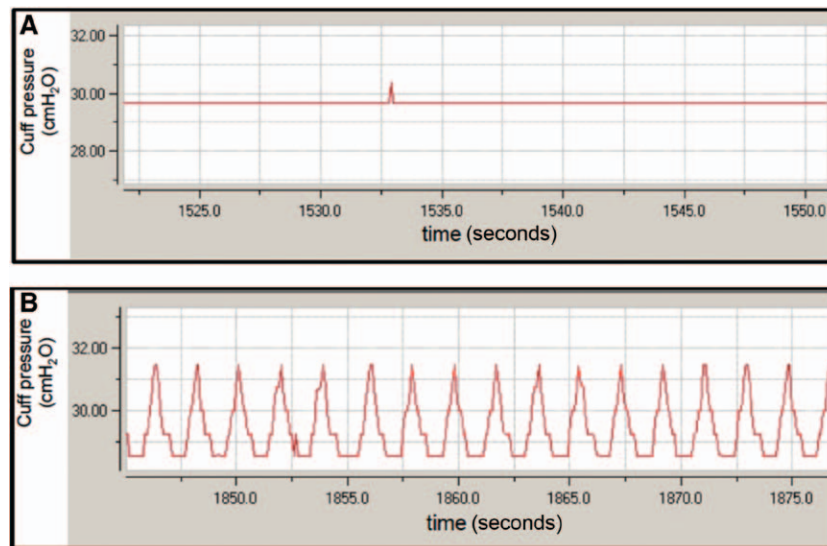


Fig. 6. Representative cuff-pressure recordings of a (A) standard (spherical) cuff or (B) tapered cuff during mechanical ventilation. Tapered-cuff pressures varied more widely.

around 40% of patients developed early postoperative pneumonia. Similar postoperative pneumonia rates, ranging from 30 to 48%, were reported after cardiothoracic surgery.^{32–37} Among patients meeting Johanson criteria, 66% had microbiologically confirmed pneumonia and 34% had possible pneumonia. The negative respiratory samples of 9 of the 16 patients with possible pneumonia could reflect antibiotic use (intraoperative prophylaxis or aorta-prosthesis-related sepsis) before specimen collection. However, intraoperative antibiotic use did not differ significantly between the two study groups.

Unfortunately, our results showed that tapered-cuff endotracheal tubes did not prevent early postoperative pneumonia. Similarly, two recent prospective studies showed that the use of tapered-cuff endotracheal tubes did not lower the VAP rate for critically ill patients intubated for various causes of respiratory failure.^{11,12} The inability to prevent VAP likely reflects the inability to prevent intraoperative microaspiration during major vascular surgery. Last, tapered-cuff endotracheal tubes cannot reduce the risk factors resulting from comorbidities, elevated disease severity scores, and massive blood transfusion, all frequently observed in patients undergoing major vascular surgery.

Our microaspiration results agree with those of two randomized controlled trials that enrolled medical ICU patients and showed that tracheal aspirate pepsin levels did not differ between tapered- and cylindrical-cuff groups.^{9,10} However, those studies used polyurethane cuffs, which could explain the lack of benefit of cuff shape on sealing properties, as reported in *in vitro* studies.^{6,7} To the best of our knowledge, tracheal sealing properties of PVC tapered cuffs have never been assessed through tracheal pepsin or α -amylase level measurements. Because pepsin is a gastric marker, monitoring its tracheal aspirate level might have underestimated the true oropharyngeal microaspiration frequency. Therefore, we also measured tracheal α -amylase, an oropharyngeal marker, which confirmed

that overall (oropharyngeal and gastric) microaspiration events did not differ between standard- and tapered-cuff groups.

Another factor that might explain the failure to prevent postoperative pneumonia is the significantly higher coefficient of cuff-pressure variation with the tapered-cuff, compared with the standard cuff (table 5). As shown in a bench study,³⁸ tapered cuffs had the lowest tracheal wall contact area compared with other-shaped cuffs. This small contact area might lead to cuff slippage and, hence, to cuff-pressure fluctuation over time. As a consequence, the times with cuff overinflation and underinflation were longer for the tapered-cuff group. These effects are potentially detrimental: cuff underinflation-induced microaspiration might enhance the risk of postoperative pneumonia, whereas cuff overinflation might produce trachea-wall ischemia.³⁹ Although no adverse effects (e.g., postextubation stridor or tracheal stenosis) were observed herein, our findings suggest that close monitoring and continuous cuff-pressure control would be required if tapered-cuff endotracheal tubes were to be used.

Methodological Limitations of the Study

The current study has some limitations. First, the cuff material might impact its tracheal sealing properties. Although two bench studies found that polyurethane tapered cuffs had no benefits for microaspiration reduction, their preventive role in postoperative pneumonia remains to be investigated further. Second, in many previously published studies, the control group was composed of patients intubated with cylindrical-cuff endotracheal tubes.^{9,11,12} Our control patients were intubated with standard (spherical)-cuff endotracheal tubes. Given that PVC spherical-cuff endotracheal tubes are used worldwide, with proven good performances,⁴⁰ have been compared in multiple clinical trials,^{40–44} and are routinely used in our surgical center as standard practice for patients undergoing major vascular surgery, we considered that such control group management would not introduce bias into our trial. Third, although statistically significant

(5 vs. 5.6 cm H₂O, $P = 0.03$), the mean PEEP level difference observed between groups was much lower than that demonstrated to affect tracheal sealing.^{7,45} For this reason, we think that such a low PEEP level difference (0.6 cm H₂O) did not induce major bias into our trial. Last, the lack of continuous cuff-pressure control might have blunted the potential benefit of tapered-cuff endotracheal tubes in terms of sealing properties. Indeed, it was shown that continuous cuff-pressure control using a mechanical device reduced cuff-pressure fluctuation and the time in underinflation for a series of critically ill patients intubated with tapered- or cylindrical-cuff endotracheal tubes.¹⁰ Although available data on the benefits of continuous cuff-pressure control for microaspiration events and VAP prevention are contradictory,^{10,21,46,47} two monocenter randomized controlled trials have reported that continuous control of cuff pressure either mechanically or electronically may prevent VAP.^{21,47} Therefore, it cannot be excluded that the better sealing properties of the tapered-cuff endotracheal tube may have been offset by intermittent cuff-pressure control. The lack of randomized controlled multicenter trial explains why, to date, no recommendations for routine use of continuous cuff-pressure control as a VAP-preventive measure have been issued.⁴⁸ Some caveats had been raised concerning the use of certain automated cuff-pressure controllers, leading to worse tracheal sealing and potentially cause trachea-wall injury.⁴⁹ Additional studies are required to assess the impact of continuous cuff-pressure control on efficiency of tapered- and spherical-cuff endotracheal tubes to prevent gastric aspiration and postoperative pneumonia.

In conclusion, our results did not show that PVC tapered-cuff endotracheal tubes using intermittent manometer control of cuff pressure was superior to standard-cuff endotracheal tubes to prevent postoperative pneumonia in major vascular surgery patients. The higher cuff-pressure variability and higher percentages of time with tapered-cuff overinflation and underinflation represent a potential caveat that deserves further investigation. The impact of continuous cuff-pressure regulation on the ability of tapered cuffs to prevent microaspiration, postoperative pneumonia, and/or VAP needs to be evaluated.

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Competing Interests

The authors declare no competing interests.

Reproducible Science

Full protocol available from Dr. Monsel: antoine.monsel@aphp.fr. Raw data available from Dr. Monsel: antoine.monsel@aphp.fr.

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Appendix

Members of the Tapered Endotracheal Tube to prevent Respiratory Infections (TETRIS) Study Group:

The TETRIS study group members are authors of this article and the following investigators: Liliane Bodin, M.D., Romain Deransy, M.D., M.Sc., Pierre Garçon, M.D., Hatem Douiri, M.D., Ismael Khalifa, M.D., Antoine Pons, M.D. (Multidisciplinary Intensive Care Unit, Department of Anesthesiology and Critical Care, La Pitié-Salpêtrière Hospital, Assistance Publique–Hôpitaux de Paris, Paris, France); Wen-Jie Gu, Ph.D. (Clinical Research Department, La Pitié-Salpêtrière Hospital, Assistance Publique–Hôpitaux de Paris, Paris, France); Fabien Koskas, M.D., Ph.D., Julien Gaudric, M.D. (Department of Vascular Surgery, La Pitié-Salpêtrière Hospital, Assistance Publique–Hôpitaux de Paris, Paris, France).

ANESTHESIOLOGY REFLECTIONS FROM THE WOOD LIBRARY-MUSEUM

Peale's Central Figures in *The Court of Death*: Death, the Corpse, Old Age, and Faith



Raised in a Vermont family of church deacons and clergymen, nitrous oxide pioneer Gardner Q. Colton (1814–1898) so relished selling tickets for showings of *The Court of Death* that in 1858 he bought that allegorical oil painting from its American painter, Rembrandt Peale (1778–1860). In a central close-up (above) of the chromolithograph that Colton mass-produced for sale, pharaoh-like Death (1) passes judgment over the youthful Corpse (2), on whose chest rests the right foot of Death. Approaching Death is the figure—uniting supposed features of the bard Homer with the body of Peale's father—of Old Age (3), who, supported by Faith (4), can triumph over Death. Over a rocky surface, Peale arches the Corpse (modeled after an actual cadaver and after Peale's brother) with "oblivion's listless stream" washing over its head and feet to show that, "We know not whence man cometh, nor whither he goeth." In 1863, less than 4 years after first selling copies of Peale's masterwork, Colton would found his namesake dental association for using unoxxygenated nitrous oxide anesthetics to "wash away" patients' experiences or memories of dental extraction. (Copyright © the American Society of Anesthesiologists, Inc.)

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