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The Impact of Hospital-Wide Use of a Tapered Cuff Endotracheal Tube on VAP Incidence

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Key words: Ventilator-associated pneumonia; prevention; risk; quality improvement

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Abstract:

Background: Aspiration of colonized oropharyngeal secretions is a major factor in the pathogenesis of VAP. A tapered-cuff endotracheal tube has been demonstrated to reduce aspiration around the cuff.[1] Whether these properties are efficacious in reducing VAP is not known.

Methods: This two-period investigator-initiated observational study was designed to assess the efficacy of a tapered-cuff endotracheal tube to reduce the rate of VAP. All intubated, mechanically ventilated patients over the age of 18 were included. During the baseline period, a standard barrel cuff ETT (Mallinkrodt™ Hi-Lo cuff, Covidien LLC, Mansfield, MA) was used. All endotracheal tubes throughout the hospital were then replaced with a tapered cuff ETT (TaperGuard™ cuff, Covidien LLC, Mansfield, MA). The primary outcome variable was the incidence of VAP per 1,000 ventilator days.

Results: 2,849 patients, encompassing 15,250 ventilator days, were included. The mean monthly VAP rate (mean ± SD) was 3.29 ± 1.79/1000 ventilator days in the Standard Group and 2.77 ± 2.00/1000 ventilator days in the Taper Group (p=0.65). While compliance with the VAP prevention bundle was high throughout the study, bundle compliance was significantly higher during the Standard Group period than in the Taper Group period, 96.5±2.7% and 90.3±3.5% respectively (p=0.01).

Conclusion: In the setting of a rate of VAP very near the average of ICUs in the United States and where there was high compliance with a VAP prevention bundle, the use of a tapered cuff endotracheal tube was not associated with a reduction in the rate of VAP.

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Background:

Ventilator-associated pneumonia (VAP) is a common nosocomial infection in the intensive care unit (ICU). Five to twenty percent of patients who require mechanical ventilation for more than 48 hours will develop VAP with associated mortality rates of 15 – 50%.[2][3] ICU length of stay in patients with VAP is increased by a mean of 6.1 days and the excess costs can be as high as $40,000 per patient.[4][5] These costs are secondary to increased use of antibiotics and mechanical ventilation, as well as prolongation of the length of stay in the ICU. Therefore, the prevention of VAP can reduce both the cost and morbidity associated with mechanical ventilation.

Aspiration of colonized oropharyngeal secretions is one of the primary factors implicated in the pathogenesis of VAP. VAP prevention efforts have centered on reducing the bacterial load of aspirated secretions, and reducing the amount of secretions aspirated.[6] With regard to the former, disinfection of the oropharynx with chlorhexidine coupled with increased attention to oral care has been shown to reduce the risk of VAP.[7] Similarly, elevation of the head of the bed has been demonstrated to reduce the risk of aspiration of oropharyngeal secretions into the lung in intubated, mechanically ventilated patients and has become a nearly universally applied element to prevent VAP.[8][9] Applying each of these interventions as a "bundle" has resulted in marked reductions in the incidence of VAP.[10][11] . However, despite these measures VAP remains a significant problem with a reported incidence of approximately 2 cases per 1,000 ventilator days.[12]

Oropharyngeal secretions pool above the cuff of the endotracheal tube (ETT) and can be aspirated into the trachea despite the presence of the cuff and may represent an important

pathway for colonized secretions to enter the distal airway. Recently, modifications to the design of the cuff of the ETT have been the focus of interventions to reduce the risk of aspiration around the cuff, and thus reduce the risk of VAP. Employing a tapered cuffed, as opposed to the standard barrel shaped cuff, has been proposed to provide a better tracheal seal and reduce the passage of potentially contaminated secretions around the cuff and into the lung. A recent trial employed methylene blue instilled above the endotracheal tube cuff in pigs undergoing abdominal surgery. Significantly less methylene blue staining of mucosa following surgery was observed in pigs intubated with a tapered cuff endotracheal tube compared with those intubated with a standard barrel-shaped cuff endotracheal tube.[13] A tapered-cuff design has been approved by the FDA (TaperGuard™ endotracheal tube, Covidien LLC, Mansfield, MA,) and *in-vitro* and *in-vivo* studies have demonstrated reduced aspiration around the cuff.[1] Whether these properties are efficacious in reducing VAP is not known. These specialized endotracheal tubes are more expensive than standard endotracheal tubes, but represent a "passive" intervention to reduce VAP; they require little to no additional effort on the part of care providers. As a component of institutional efforts to evaluate measures to further reduce the incidence of VAP, we performed a sequential observational study to test the hypothesis that hospital-wide use of a tapered cuff endotracheal tube would result in a significant reduction the rate of VAP(VAP/1000 ventilator days).

Methods:

Study Design: This two-period observational study was approved by our Institutional Review Board with a waiver of informed consent. Each study period was 6 months in duration and included the same calendar months to minimize the impact of seasonal variation on incidence of

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VAP. A transition period, during which the hospital supply of ETTs was changed, was not used for data analysis.

Inclusion Criteria: All patients over the age of 18 admitted to any of our adult Intensive Care Units and who required endotracheal intubation and mechanical ventilation at any time during their ICU stay were included. These 110 ICU beds encompassed multiple specialties including Medical ICU, Surgical ICU, Neurointensive Care, Cardiothoracic ICU, Trauma ICU, and Coronary Care. The VAP prevention bundle and VAP data collection were identical across all ICUs.

Study Procedure: During the baseline 6 month period, July 1, 2010 through December 31, 2010, a standard barrel cuff ETT (Mallinkrodt™ Hi-Lo cuff, Covidien LLC, Mansfield, MA) was used hospital wide. All endotracheal tubes throughout the hospital (including the operating rooms) were then replaced with a tapered cuff ETT (TaperGuard™ cuff, Covidien LLC, Mansfield, MA). This was performed by Resource Management staff who purchase and stock all supplies at the Medical Center. Additionally, our county emergency medical response units (Forsyth County, NC) were supplied with tapered cuff ETT, but intubated patients transferred from other institutions were not reintubated with a tapered cuff ETT, but these patients were included in the study. After a hospital wide audit to ensure removal of the barrel cuffed ETT, the second period of the study commenced on July 1, 2011 and extended through December 31, 2011. The tapered cuff ETT itself is of the same materials and design as the barrel cuff ETT, the difference is solely in the cuff design. This ETT does not have an extra lumen to permit removal of supraglottic secretions, and other than the shape of the cuff when inflated is identical in appearance to the

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standard barrel cuff ETT. Therefore, no staff education concerning the replacement ETT was felt to be necessary, though it was announced that new type of ETT was being studied. Respiratory therapists' procedures for caring for ETTs were unchanged throughout the study period with respiratory therapists checking and documenting the position of the ETT and maintaining ETT cuff pressure at 20 – 25 cm H_2O twice during each 12 hour shift.

Data collection and definition of VAP: Infection Control practitioners trained in data abstraction and reporting were responsible for capturing all instances of VAP during ICU admission. They were not involved in direct patient care, and each suspected case of VAP was reviewed by the Hospital Epidemiologist, a board certified specialist in Infectious Diseases. These individuals did not change during the study period. Criteria for the diagnosis of VAP were concordant with National Healthcare Safety Network (NHSN) criteria (PNU2) which requires bacteriologic confirmation in addition to meeting specific clinical criteria including, for example, new radiographic infiltrates, fever and leukocytosis.[14] However, in our institution, outside the Trauma ICU, instead of the bronchoscopic cultures specified in PNU2, we employ quantitatively cultured tracheal aspirates using a threshold of 10^5 CFU/ml or higher to confirm a diagnosis of VAP. Within the Trauma ICU, bronchoscopic and non-bronchoscopic bronchoalveolar lavage cultures were used, at a threshold of 10^4 CFU/ml to confirm VAP. This was consistent throughout the study.

Personnel from our Quality Resource Center monitored compliance with the institutional VAP prevention bundle and days of mechanical ventilation. These individuals had no role in the provision of clinical care. These data were collected in all ICU patients Monday through Friday

prospectively by chart review and bedside inspection. Data on weekends and holidays were collected retrospectively by chart review. The institutional VAP prevention bundle consisted of elevation of the head of bed to 30 degrees, swabbing all oral surfaces (buccal, pharyngeal, gingival, tongue and tooth surfaces) for 30 seconds with 15mL 0.12% chlorhexidine gluconate twice daily, brushing teeth twice daily, general oral care every 4 hours, and orogastric in preference to nasogastric tubes. VAP bundle compliance for each intubated patient was recorded daily as compliance with the entire bundle – i.e. failure to perform a single component was defined as failure to comply with the bundle for that patient-ventilator day. Patients in whom there was a documented medical contraindication to a component of the bundle (e.g. a nasogastric tube inserted operatively in a patient undergoing esophageal surgery), were not recorded as non-compliant provided they were compliant with all other bundle components.

In addition to the number of VAPs, and VAP prevention bundle compliance, the number of intubated patients and patient days of mechanical ventilation were captured. This enabled calculation of the VAP rate expressed as VAP per 1,000 ventilator days which was the pre-specified primary outcome. A day of mechanical ventilation was defined as mechanical ventilation at any time on that calendar day.

Role of the sponsor: This was an investigator initiated study. The sponsor (Covidien LLC, Mansfield, MA) provided the tapered cuff endotracheal tubes at a discounted price and provided salary support for data collection. The sponsor was not involved in study design, data collection, or data analysis. The sponsor had no access to study data nor did they have a role in formulating

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study conclusions for this report. They were provided the opportunity to review the manuscript prior to submission for publication.

Statistical analysis: Data were entered into a secure, password-protected computer database and analyzed using SPSS for Windows (version 11, SPSS Inc., Chicago, IL). Results were analyzed initially using descriptive statistics. Comparisons between groups were done using chi square test for proportions, and unpaired Student's t-test for continuous variables. A two tailed p value less than 0.05 was considered statistically significant. From December of 2009 to June 2010, our institutional monthly VAP rate was 5.8 ± 1.47 per 1,000 ventilator days. We estimated that a 6-month trial period would have an 80% power to detect a 50% reduction in the primary outcome of VAP/1,000 ventilator days with an alpha of 0.05.

Results:

2,849 patients, encompassing 15,250 ventilator days, were included in the study. The distribution of ventilator days was 41% Medical ICU, 35% Surgical and Trauma ICU, 11% Cardiothoracic ICU, 10% Neurological ICU, and 3% other ICUs. The distribution of patients across the ICUs did not differ between the study periods. There were 24 VAPs while using the barrel cuff ETT (Standard group), and 21 VAPs while using the tapered cuff ETT (Taper group) (p=0.71) (Table 1). The mean monthly VAP rate (mean ± SD) was 3.29 ± 1.79/1000 ventilator days in the Standard group and 2.77 ± 2.00/1000 ventilator days in the Taper group (p=0.65).

Compliance with the VAP prevention bundle was high throughout the study period. However, VAP bundle compliance was significantly higher during the Standard Group period than in the

Taper Group period, 96.5±2.7 and 90.3±3.5 respectively (p=0.01). The most common reason for VAP bundle non-compliance was failure to perform (or document) every scheduled provision of oral care. This accounted for 76% of all VAP bundle non-compliance. The number of VAPs during each study month, the monthly VAP rate and VAP bundle compliance are displayed in Figures 1, 2 and 3, respectively. There were no significant differences in the number of mechanically ventilated patients or the number of ventilated days (patient days of mechanical ventilation) between periods.

Discussion:

The use of a tapered-cuff endotracheal tube did not result in a significant reduction in the rate of VAP. Our compliance with measures to reduce VAP was high, but it was significantly higher in the Standard period than in the Taper period. The reason for this difference is not clear, but consistency of performance of interventions to improve quality has been reported to wane over time if efforts directed at maintaining performance are not sustained.[15] It is possible that reduced compliance with the VAP prevention bundle masked a significant reduction in VAP in the Taper period. However, compliance rates of 80-90%, as observed in the Taper period, have been reported to still be associated with reduced rates of VAP.[8] Further, an analysis of our VAP rates and VAP bundle compliance from July 2008 through June 2010 found only a weak correlation between VAP bundle compliance and VAP incidence (r^2=11.2)(unpublished data). Collectively, while this lessens the probability, it does not preclude that the observed difference in VAP bundle compliance obscured a clinically relevant reduction in VAP attributable to the use of a tapered cuff endotracheal tube.

The rates of VAP observed in the present study, 2.77 – 3.29/1,000 ventilator days, were much lower in comparison to other studies reporting successful interventions to reduce VAP including elevation of the head of the bed, chlorhexidine oral rinsing, silver-coated endotracheal tubes, and subglottic secretion removal, in which VAP rates of 10 – 15/1,000 ventilator days or higher were observed.[16][17][18][19] Whether significant reductions in VAP consequent to use of a tapered cuff ETT might be observed in settings with a higher baseline rate of VAP cannot be determined from the present study. Importantly, however, the rates reported in the present study closely mirror the median rates reported by NHSN for 2010 which range approximately from 0 to 5/1,000 ventilator days depending upon the type of ICU.[12] Several studies have suggested that publicly reported rates of VAP may not accurately reflect clinical VAP.[20][21] However, a study of patients in our institution indicated that, while specific patients may differ, the rate of pneumonia was similar whether bronchoscopic or NHSN criteria were used.[22]

While this study was designed to be powered to detect a 50% reduction in the rate of VAP, this was predicated on a historical rate of VAP of 5.8 ± 1.47 per 1,000 ventilator days present in early 2010 during study planning. The observed baseline rate was only 3.29/1,000 ventilator days. With this baseline rate of VAP a study duration of 3 years would be required to have an 80% power to detect a 50% reduction. This underscores the difficulty of executing adequately powered studies of VAP prevention in the setting of successful baseline efforts to reduce VAP rates.

Of note, in contrast to the bronchoscopic quantitative cultures used in the NHSN PNU2 definition of VAP, quantitative tracheal aspirates with a threshold of 10^5 CFU/ml were employed

to confirm VAP. However, this criterion has been shown to result in VAP rates virtually identical with the rate found if using a bronchoalveolar lavage quantitative culture threshold of 10^4 CFU/ml.[23][24]

Another limitation of this study is that transfer patients were not reintubated with a tapered cuff ETT. Patient referral and transfer patterns in our institution were not known to change over the study period and while unlikely, an unappreciated increase in these patients with an attendant higher VAP incidence may have masked a decrease in VAP in patients intubated with a tapered cuff ETT. While all mechanically ventilated adult patients were included, the limited data elements collected for the study precludes ascertainment of the impact of time-related changes in the demographic characteristics, severity of illness, or comorbidities on the incidence of VAP.

Only VAP occurring in an ICU was captured. However, all patients who were mechanically ventilated were initially cared for in an ICU and only a small minority is ultimately transferred to a step down unit for longer term ventilator management. Only one VAP was observed in the stepdown unit during the study period. Thus, comparison of VAP rates in the Standard and Taper groups should not be affected by this limitation.

In conclusion, in the setting of a rate of VAP very near the average of ICUs in the United States and where there was high compliance with a VAP prevention bundle, the use of a tapered cuff endotracheal tube was not associated with a significant reduction in the rate of VAP.

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Table 1 Summary Data

	Standard Group	Taper Group	
Ventilated Patients	1387	1462	p=0.13
Ventilator Days	7266	7984	p=0.20
VAPs	24	21	p=0.71
VAP/1,000 Ventilator Days (monthly mean ±SD)	3.29±1.79	2.77±0.2.00	p=0.65
VAP Bundle Compliance (monthly mean ±SD)	96.5±2.7	90.3±3.5	p=0.01

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Figure Legends:

Fig. 1: The number of VAPs during each study month during each study period.
Standard period ▭ Taper period ▬

Fig. 2: The VAP rate (VAPs/1,000 ventilator days) during each study month during each study period.
Standard period ▭ Taper period ▬

Fig. 3: The VAP prevention bundle compliance rate during each study month during each study period.
Standard period ▭ Taper period ▬

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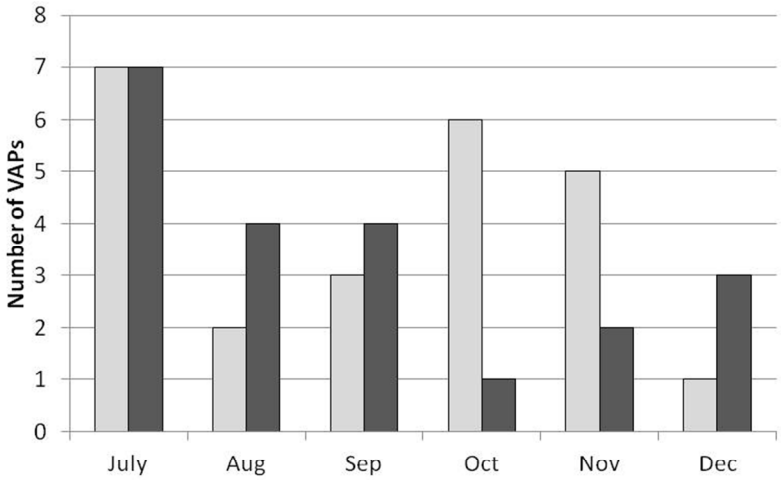

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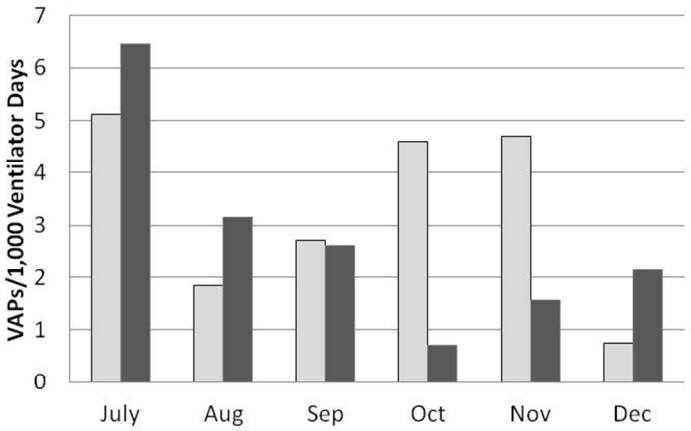

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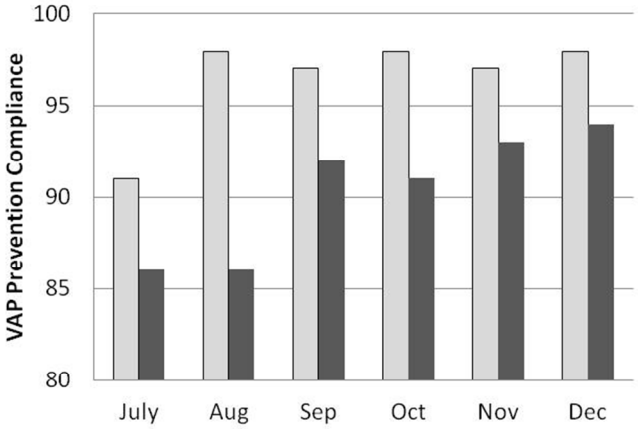

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