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Research Article

Impact of a Low-Pressure Polyurethane Adult Endotracheal Tube on the Incidence of Ventilator-Associated Pneumonia: A before and after Concurrence Study

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Background. Ventilator-associated pneumonia (VAP) is a leading cause of morbidity and mortality in intensive care unit (ICU) patients, encompassing up to 15% of all hospital acquired infections. Our hospital implemented a facility-wide conversion from a low-volume high-pressure polyvinyl cuffed endotracheal tube (PV-cuffed ETT) to a high-volume low-pressure (HVLP) polyurethane-cuffed endotracheal tube (PU-cuffed ETT) in an effort to reduce the incidence of VAP. *Methods*. We completed an IRB approved, retrospective chart review comparing the number of episodes of VAP 12 months preceding and following the introduction of a new ETT. A diagnosis of VAP was made based upon the guidelines of our institution, consistent with the Center of Disease Control and Prevention definition. *Results*. The number of patients developing VAP the year after the ETT conversion reduced to 32 (16.3%) from 68 (24.7%) the year before the conversion ($P = 0.028$). The rate of VAP was reduced by 56% per ventilator day after the implementation of the PU-cuffed ETT ($P < 0.001$). No significant differences were observed in length of hospital stay, length of mechanical ventilation, or mortality before or after the conversion. *Conclusions*. We found that HVLP PU-cuffed ETTs were associated with a statistically significant reduction of VAP in the adult ICUs.

1. Introduction

Ventilator-associated pneumonia (VAP) is a healthcare-associated infection that commonly causes morbidity and mortality in mechanically ventilated patients [1]. VAP is associated with an increased duration of mechanical ventilation, crude death rates of 5% to 65% [2–5], and increased healthcare costs [1, 6–8]. During the past several decades, numerous studies have focused on the role of the endotracheal tube (ETT) in the pathogenesis of VAP. Tracheal intubation impairs the cough reflex, injures the tracheal epithelial surface, facilitates entry of bacteria into the airway by aspiration of subglottic secretions, and allows formation of a bacterial biofilm on the ETT surface. The combination of these factors puts the mechanically ventilated patient at great jeopardy of developing VAP.

Because VAP is multifactorial, it is essential to identify changes in practice that may decrease rates. One important preventive strategy for the pathogenesis of VAP is to minimize subglottic secretions and microaspirations. A preventative strategy to avoid the transmission of subglottic secretions into the lower respiratory tract is to prevent channel formation within the folds of the ETT cuff. The properties of the ETT cuff may have an impact on the passage of secretions from the oropharynx to the lower respiratory tract. Conventional low-volume high-pressure

ETT cuffs are made of polyvinyl (PV) and are 55–80 μm thick. When inflated, excess PV material folds over itself and forms channels between the external cuff surface and the tracheal wall. These channels allow for secretions to pool at the cuff interface and become aspirated into the lungs during the ventilated phase. In contrast to traditional PV-cuffed ETTs, the high-volume low-pressure (HVLP) polyurethane-(PU-) cuffed ETTs are only 10 μm thick (Figure 1). The PU cuff is able to closely adhere to the trachea during inflation and greatly reduces the incidence of contaminated secretions breaching this barrier. These HVLP ETTs with an ultrathin PU cuff do not form channels along the cuff and have been shown *in vitro* to prevent fluid and air leakage [9, 10].

We designed a retrospective study to compare ventilator parameters for patients intubated with the PV-cuffed ETT to the PU-cuffed ETT. The primary objective of the study was to determine if there is a correlation between the use of PU-cuffed ETTs and a reduction in VAP for patients mechanically ventilated >48 hours.

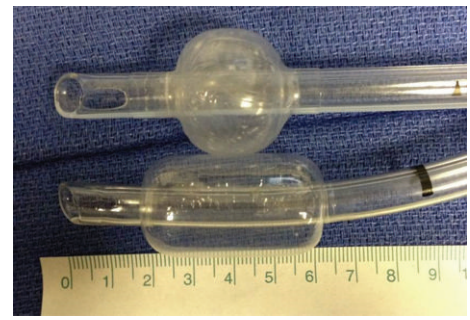

Figure 1: Comparison of cuff dimensions of a high-volume low-pressure ETT (bottom) and a high-pressure low-volume ETT (top). Both ETTs are size 7. The ruler is in centimeters.

2. Methods

2.1. Study Design. In July 2007, our tertiary, level 1 trauma hospital with 115 adult intensive care unit (ICU) beds implemented a facility-wide conversion from a PV-cuffed ETT (Mallinckrodt, Hazelwood, MO, USA) to a HVLP PU-cuffed ETT (Kimberly-Clark MICROCUFF, Neenah, WI, USA). The conversion included all of the adult medical and surgical intensive care units, operating rooms, and crash carts. The purpose of this conversion was to evaluate whether a new ETT design reduced the incidence of VAP. The conversion was undertaken after discussion about the recently published literature and after a consensus was reached between the operating room, ICU staff, and hospital administration to utilize a uniform ETT across all departments.

After attaining the University of South Florida Institutional Review Board approval, data were obtained from medical records of patients admitted to the adult ICUs the year prior to the conversion (July 2006–June 2007) and the year after the conversion (July 2007 to June 2008). We analyzed subjects who received mechanical ventilation for >48 hours. We excluded all patients that were transferred to our hospital intubated with an endotracheal tube other than the standard PV-cuffed ETT (before the conversion) or HVLP PU-cuffed ETT (after the conversion).

2.2. Collected Parameters. The following information was collected from the medical records of selected control patients and from the database of VAP patients: patient demographics (age, gender, height, and weight), baseline respiratory history (smoker, asthma, and COPD), comorbidities, total number of ICU days, length of mechanical ventilation, type of endotracheal tube, length of hospital stay, morbidity/mortality, and documentation of tracheal damage if possible. Total ventilator days, episodes of VAP, location of attribution, and microbes isolated were monitored and recorded prospectively and kept in a database under the supervision of the Infectious Disease Department. The VAP rates reported in our study were prospectively derived from all ventilated patients at our hospital. Annual VAP rates per ICU were calculated by dividing the total number of VAP episodes by the total ventilator days.

2.3. Sample Size and Medical Record Selection Criteria. As part of our hospital's routine surveillance, our Department of Infectious Disease maintains a prospective database of all patients that develop VAP. The database is used to identify trends and to help drive evidence-based patient care. We identified a total of 100 patients who developed VAP during our 2-year study timeframe.

In order to formulate two appropriate control groups, we used ventilator shift billing charges to identify all patients that were admitted to an adult ICU and received mechanical ventilation for >48 hours. A single billing shift charge is accrued for every 12 hours of mechanical ventilation. The medical audit office at our hospital generated a list of patients charged for 4 or more consecutive ventilator shifts. Based upon these criteria, a total of 4162 patients were mechanically ventilated with an ETT for at least 48 hours without any incidence of VAP in the same study timeframe. In order to complete the study in a timely manner, we reviewed a random selection of case-matched patients to serve as our control group. Statistically, a ratio of 4 case-matched controls for every 1 VAP case provides a maximum power without superfluous data collection. Ratios higher than this are not considered worthwhile because of increased cost of gathering data [11]. Based on this statistical assumption, we reviewed 400 case-matched control subjects and 100 patients that developed VAP. For the control cohort, a randomized, computer-generated selection of cases was used. The number of control patients for the two selected years was unequal but selected proportionally (4 : 1) to the number of VAP cases before and after the ETT conversion.

For patients with multiple ICU admissions, only the first admission was considered for analysis. Standardized daily ICU nursing notes were reviewed to corroborate the length of mechanical ventilation. The nursing notes include how the patient was ventilated. We excluded all patients admitted to the ICU with a diagnosis of pneumonia on or before the first day of mechanical ventilation. Therefore, the samples include only patients who had hospital-acquired

pneumonia developed while receiving mechanical ventilation and matched controls without developing VAP.

2.4. Standard Measures to Prevent VAP. Identical strategies for VAP prevention were implemented during the 2-year study period and were documented by an ICU nurse in the medical record on a standardized hospital-wide daily checklist. All patients that were intubated received a ventilator bundle protocol and epidemiological surveillance. The components of the ventilator bundle included head of bed elevated at 30 degrees unless contraindicated, 2% chlorhexidine oral care every two hours, application of 2% mupirocin ointment to the anterior portion of the nares, periodic verification of intracuff pressure, leaks, obstruction, or malposition, sedation "holiday," DVT prophylaxis, and stress ulcer prophylaxis.

2.5. Definitions. The diagnosis of VAP was established by the standards set by the Centers for Disease Control and Prevention [12]. The VAP diagnosis criteria included temperature of greater than 100.4°F, a white blood cell count greater than 12,000 cells/mm^3, new onset of purulent bronchial sputum, chest radiograph showing new or progressive infiltrates, and significant quantitative cultures or respiratory secretions by tracheal aspirate (>10^4 cfu/mL). A diagnosis of VAP was considered when it was identified after 48 hours of mechanical ventilation. A ventilation day was considered a 24-hour period where mechanical ventilation was required.

2.6. Statistical Analysis. All data were analyzed to represent outcomes before and after the implementation of the PU-cuffed ETT. VAP rate was calculated by dividing the total number of VAP episodes by the total ventilator days of the respected years. The VAP rate was then normalized to depict the number of VAP episodes per 1000 ventilator days. All other data were analyzed using SPSS 17.0 (SPSS Inc., IL, USA). The normality and variance of the group distributions for continuous variables were first assessed using the Kolmogorov-Smirnov test, and comparisons were then completed using the Mann-Whitney U test. Categorical variables were analyzed using either chi-square or Fisher's exact tests. Results are expressed as mean ± SD (medians for nonparametric) for continuous variables and as frequencies and percentages for categorical variables. A P value of <0.05 was considered statistically significant.

3. Results

Of the 500 medical records reviewed (100 VAP and 400 controls), 29 were withdrawn from the final analyses because they were transferred to our hospital already intubated with an ETT other than the PV-cuffed ETT or PU-cuffed ETT for the proper timeframe of the study.

Patients were evenly distributed between the groups based on demographics and baseline characteristics (Table 1); however, there was a significant difference in weight between the patients before and after the ETT conversion (76.9 kg versus 81.7 kg ($P = 0.016$)). There were no significant differences in comorbidities, mortality, or hospital days between the two groups. The median number of ICU days was significantly less in the year after the conversion to the PU- ETTs compared to the year before (11 days versus 17 days ($P = 0.002$)). The generalized admittance diagnosis for all reviewed patients is represented in Table 1.

Table 2 represents the patients developing VAP before and after the conversion to the PU-cuffed ETT. In the year after the conversion to PU-cuffed ETTs, the number of cases of VAP was reduced to 32 (16.3%) episodes from 68 (24.7%) episodes in the year prior to the conversion ($P = 0.028$). There was no significant difference between the groups with respect to hospital days, ICU days, mortality, ventilation days, or days until VAP was developed. The polymicrobial infections from the bronchoalveolar fluid are also described in Table 2.

VAP occurrences and total ventilator days are presented per ICU in Table 3. After the conversion to the PU-cuffed ETTs, there were 14119 vent days and 13239 vent days prior to the ETT conversion. When normalized, this equates to a VAP rate of 2.27 episodes per 1000 vent days versus 5.14 episodes per 1000 vent days the year prior, resulting in an overall reduction in VAP incidence by 56%.

4. Discussion

The national average of the incidence of VAP is approximately 10% with a VAP rate of 4.3/1000 ventilator days. Our VAP rate prior to the implementation of the PU-cuffed ETT was 5.14/1000 vent days. Within the first 12 months after our hospital-wide conversion to PU-cuffed ETTs, we experienced a reduction of VAP in every ICU that was reviewed, an overall 56% reduction on annual VAP incidence and four months with a 0% VAP rate.

The prevention of subglottic space secretions has been shown to reduce VAP [13–15]. The PU-cuffed ETTs implemented in our hospital are specifically designed to prevent the formation of cuff folds, thus preventing fluid and air leakage [9] and channeling of secretions from the oropharynx into the lungs.

Miller and colleagues reported a significant reduction in VAP rates after a short-term evaluation of the same PU-cuffed ETT followed by a rise in VAP incidence after returning to the conventional polyvinyl tubes [16]. In another study, a HVLP PU-cuffed ETT with a lumen for subglottic secretion drainage was evaluated in a randomized clinical trial of 280 subjects and was found to reduce the incidence of early- and late-onset VAP when compared with a PV-cuffed ETT without subglottic secretion drainage [17]. Cox regression analysis showed that polyvinyl cuffed tubes were a risk factor for global VAP (hazard ratio (HR) 3.3; $P = 0.001$), early onset VAP (HR 3.3, $P = 0.02$), and late onset VAP (HR 3.5; $P = 0.01$). In addition, a prospective, single-blinded, randomized pilot study revealed that the PU-cuffed ETTs reduced the frequency of early postoperative pneumonia in cardiac surgical patients [18]. Our study, however, demonstrates a significant reduction of VAP incidence on a larger scale with a PU-cuffed ETT.

Table 1: General demographics, comorbidities and other characteristics during the two year analysis.

Characteristic	Before conversion ($N = 275$)	After conversion ($N = 196$)	P value
Male sex *n* (%)	174 (63.6)	116 (59.2)	0.275
Admit age (median)	56	57	0.273
Height (inches) (median)	68	67	0.811
Weight (kg) (median)	80.7	76.9	**0.016***
Hospital days (median)	21	20	0.369
ICU Days (median)	17	11	**0.002***
Days ventilated with ETT (median)	6	5	0.219
Mortality (%)	54 (19.6)	45 (23.0)	0.383
Co morbidities *n* (%)			
Immunodeficiency	28 (10.2)	28 (14.3)	0.175
CAD	68 (24.7)	48 (24.5)	0.953
CHF	41 (14.9)	33 (16.8)	0.571
Asthma	13 (4.7)	7 (3.6)	0.540
COPD	27 (9.8)	29 (14.8)	0.100
Interstitial lung	13 (4.7)	10 (5.1)	0.852
CRF	36 (13.1)	19 (9.7)	0.258
Hepatopathy	30 (10.9)	21 (10.7)	0.947
Encephalopathy	23 (8.4)	12 (6.1)	0.361
Alcohol abuse	44 (16.0)	35 (18.9)	0.415
Smoker	60 (21.9)	53 (27.0)	0.198
Diabetes	77 (28.0)	49 (25.1)	0.489
Cancer	25 (9.1)	18 (9.2)	0.959
Generalized admitting diagnosis *n* (%)			
TBI	70 (26.0)	52 (28.0)	
Trauma	20 (7.0)	24 (10.0)	
Bowel obstruction	4 (1.0)	4 (2.0)	
Burn	14 (5.0)	7 (4.0)	
Cancer	8 (3.0)	11 (6.0)	
Cardiac	59 (22.0)	34 (17.0)	
Organ transplant	20 (7.0)	9 (4.0)	
Drug overdose	8 (3.0)	6 (3.0)	
Other	71 (26.0)	50 (26.0)	

*Statistically significant P value. Before and after conversion is relative to the introduction of the HVLP PU-cuffed ETT. Patients in the before and after groups comprise Controls plus VAP (4 : 1).

This study has several limitations. First, the data was collected retrospectively. Therefore, the information was dependent upon the availability and the accuracy of the medical record. However, as stated previously, we noticed such a drastic decrease in VAP incidence with the use of PU-cuffed ETTs that a randomized prospective study to further evaluate the differences between PU-cuffed ETTs and PV-cuffed ETTs was considered unethical and potentially harmful to patients. Therefore, this avenue was not pursued further. One of the collection parameters as part of the study protocol was evaluation of tracheal damage as a matter of interest; however, we found limited data and inconsistent documentation in the medical records. It was, therefore, not included in our analysis. Because this study was a before-and-after design, it is limited by confounding factors related to changes in environmental variables, such as changes in clinical management or quality improvement. However, a bundle approach and clinical protocol had been implemented prior to the initial year standardizing patient care and VAP prevention in both before and after groups resulting in the ETT being the only changed variable between the groups. It is possible that there was an *Acinetobacter/Pseudomonas* outbreak in our center prior to the change in ETT type (Table 2). There is also the possibility that increased awareness of the problem of VAP could have led to improved medical practice (Hawthorne effect).

Despite the noted limitations, our data revealed a statistically and clinically significant reduction in the incidence of VAP in adult ICUs following the implementation of HVLP PU-cuffed ETTs. We conclude that there is evidence of a relationship between the use of these ETTs and lower occurrences of VAP.

Table 2: Ventilation characteristics and incidence of microbiologically confirmed ventilator-associated pneumonia (VAP) before and after PUC-ETT.

Characteristic	Before	After	*P* value
Hospital days	43	49	0.33
ICU days	34	38.5	0.61
Mortality	19 (27.9)	10 (31.3)	0.48
Patients with VAP [*n* (%)]	68 (24.7)	32 (16.3)	**0.028**[*]
Total ventilator days (median)	29	26	0.865
Hospital admission days until VAP (median)	13	17	0.709
Primary microorganism[a]			
Methicillin-resistant *S. aureus*	15	11	
Pseudomonas aeruginosa	10	4	
Escherichia coli	1	2	
Candida albicans	2	2	
Acinetobacter calcoaceticus/baumannii complex	23	4	
Klebsiella pneumoniae	2	2	
Other[b]	9	6	

All patients are represented as VAP patients before and after introduction of the HVLP PU-cuffed ETT.

[*] Statistically significant *P* value. [a] Polymicrobial infections: in the group that received the MICROCUFF tube, 8 patients had 2 microorganisms, 5 patients had 3 microorganisms, and 2 patients had 4 microorganisms. In the group that received the Mallinckrodt tube, 13 patients had 2 microorganisms, 9 patients had 3 microorganisms, and 3 patients had 4 microorganisms.

[b] Other microorganisms in the group that received the MICROCUFF tube were *Enterobacter cloacae*, *Citrobacter freundii*, *Burkholderia cepacia*, *Klebsiella oxytoca* ESBL, *Alcaligenes faecalis*, and *Candida glabrata*. Other microorganisms in the group that received the Mallinckrodt ET tube were BETA STREPTOCOCCUS GRP C, *Stenotrophomonas maltophilia*, *Achromobacter xylosoxidans* MDR, *Candida krusei*, *Alcaligenes xylosoxidans*, *Saccharomyces cerevisiae*, and *Serratia marcescens*.

Table 3: Ventilator-associated pneumonia per intensive care unit before and after PUC-ETT.

ICU (beds)	July 2006–June 2007 PVC-ETT			July 2007–June 2008 PUC-ETT		
	No. of VAPs	No. of vent days	VAP rate (per 1000 ventilator days)[*]	No. of VAPs	No. of vent days	VAP rate (per 1000 ventilator days)[*]
Surgical (18)	11	3166	3.47	5	3328	1.5
Neurosurgical (25)	24	2742	8.75	13	3878	3.35
Burn (6)	13	1178	11.04	4	908	4.41
Cardiothoracic (20)	9	2835	3.17	8	2960	2.7
Coronary care (18)	7	1762	3.97	1	1480	0.68
Medical (10)	4	1556	2.57	1	1565	0.64
Total	68	13239	**5.14**	32	14119	**2.27**

∗: (number of VAPs/number of ventilator days) × 1000.
VAP: ventilator-associated pneumonia.
PVC-ETT: polyvinyl-cuffed endotracheal tube.
PUC-ETT: polyurethane-cuffed endotracheal tube.

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