Comparison of Prophylactic Effects of Polyurethane Cylindrical or Tapered Cuff and Polyvinyl Chloride Cuff Endotracheal Tubes on Ventilator-Associated Pneumonia

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Received: 7 Sep. 2012 ; Received in revised form: 25 Dec. 2012 ; Accepted: 24 Jan. 2013

Abstract- Because microaspiration of contaminated supraglottic secretions past the endotracheal tube cuff is considered to be central in the pathogenesis of pneumonia, improved design of tracheal tubes with new cuff material and shape have reduced the size and number of folds, which together with the addition of suction ports above the cuff to drain pooled subglottic secretions leads to reduced aspiration of oropharyngeal secretions. So we conducted a study to compare the prophylactic effects of polyurethane-cylindrical or tapered cuff and polyvinyl chloride cuff endotracheal tubes (ETT) on ventilator-associated pneumonia. This randomized clinical trial was carried out in a 12 bed surgical intensive care unit. 96 patients expected to require mechanical ventilation more than 96 hours were randomly allocated to one of three following groups: Polyvinyl chloride cuff (PCV) ETT, Polyurethane (PU) cylindrical Sealguard ETT and PU Taperguard ETT. Cuff pressure monitored every three hours 3 days in all patients. Mean cuff pressure didn't have significant difference between three groups during 72 hours. Pneumonia was seen in 11 patients (34%) in group PVC, 8 (25%) in Sealguard and 7 (21%) in Taperguard group. Changes in mean cuff pressure between Sealguard and PVC tubes and also between Taperguard and PVC tubes did not show any significant difference. There was no significant difference in overinflation between three groups. The use of ETT with PU material results in reducing ventilator-associated pneumonia compared to ETT with PVC cuff. In PU tubes Taperguard has less incidence of ventilator-associated pneumonia compared to Sealguard tubes.

Acta Medica Iranica, 2013; 51(7): 461-466.

Keywords: Endotracheal tube, Polyurethan; Polyvinyl Chloride; Ventilator-associated pneumonia

Introduction

Ventilator-associated pneumonia (VAP) is defined as nosocomial pneumonia occurring in a patient after 48 h of mechanical ventilation. It is commonly classified as either early onset (occurring within 96 h of start of mechanical ventilation) or late onset (occurring more than 96 h after start of mechanical ventilation). VAP occurs in 9–27% of all intubated patients and is one of the most common causes of death in critically ill patients (1). Different risk factors lead to VAP, but endotracheal intubation impedes mucocilliary clearance, increases inflammation and disrupt the cough reflex thus promoting the accumulation of secretions and increasing the risk of VAP, so it is the most common risk factor for VAP (2,3). Interventions like continuous or intermittent suction of subglottic secretions (4-8), selective decontamination of subglottic space (9,10), elimination of endotracheal tubes (ETT) biofilm formation (11,12), decontamination of ETT (13,14), use of specific antiseptic impregnated ETTs (15-17) and synchronized mucus aspiration in distal end of ETT (18,19) lead to deceasing VAP. Blocking the leakage of subglottic secretions is one of the most important interventions for decreasing VAP. ETTs with high volume and low pressure cuff (HVLP) has diameter of 1.5-2 times of the trachea after inflation which leads to formation of folds and channels for aspiration of microsecretions. Control

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of cuff pressure and its design could help in decreasing subglottic secretion leakage. Modifications of ETTs aimed at decreasing of VAP showed some good results. Three main modifications of ETTs have been developed: coating with antimicrobials, adding a suction channel for the removal of oropharyngeal secretions, and modifying the design of the cuff. Each of these interventions has been shown to limit bacterial colonization of the distal airways and to decrease the incidence of VAP (20). Tubes with polyurethane (PU) cuff lead to decrease in formation of folds on inflated cuffs and so VAP (21-24). Lorente *et al.* showed that use of ETT with PU cuff and subglottic secretion drainage could decrease VAP (25). Despite numerous studies of various such interventions, there is insufficient evidence upon which to base strong recommendations, and important safety concerns remain regarding the use of some devices. Most importantly, cost-effectiveness data are lacking for modified ETTs designed to prevent VAP. Two commercially available ETTs with PU cuffs are available: Microcuff (Kimberley Clark, San Antonio, Texas) and Sealguard (Mallinckrodt, Covidien-Nellcor, Boulder, Colorado). There are no studies directly comparing these 2 tubes, and insufficient evidence upon which to base conclusions as to their relative efficacy. No safety issues have been raised regarding PU-cuffed ETTs, and there are no known theoretical concerns as to these tubes posing an added safety risk.

However, safety data on the use of PU-cuffed according to these, we decided to compare the effect of different cuff materials and shapes (cylindrical, conical), on prevention of VAP in critically ill patients.

Materials and Methods

After approval of the Ethics Committee of Tabriz University of Medical Sciences 96 patients were enrolled in this prospective observational study. Informed consent was obtained from patients' family. All patients who admitted to Shohada Hospital intensive care unit and expect to be under mechanical ventilation for more than 96 hours were enrolled in this study. Exclusion criteria were previous history of immunosuppression or pneumonia and intubation before admission to intensive care unit. Patients randomly allocated to three 32 persons group. In first group patients were intubated with standard high volume low pressure (Hi-Lo) polyvinylchloride (PVC) tubes (barrel shaped cuff). Patients in second group were intubated by Sealguard tubes (PU, cylindrical/barrel shaped cuff with subglottic secretion suction port) and in third group with Taperguard tubes (PU, cone/tapered shape cuff with subglottic suction port). In all patients cuff pressure and airway pressure monitored and noted every 3 hours till 72 hours. Suction was performed based on airway secretion amount and at least 8 times daily by an open system. In PU group subglottic secretion drainage was performed every one hour. All patients received enteral feeding during study. Stress ulcer prophylaxis was performed with intravenous proton pump inhibitors or H_2 blockers during the study. All patients had 30-40 degree head elevation and received sedation (fentanyl and remifentanil/midazolam) to reach the Richmond agitation sedation score (RASS) +1 to -2. Intubation was performed with size 7-7.5 ID tube in women and 8-8.5 ID cuffed tubes in men. All patients had 5 mmHg PEEP during mechanical ventilation. Cuff pressure monitored every 3 hours by a manometer manually and obtained between 20-30 mmHg with nurse to reduce the risk of aspiration and tracheal mucous damage. Pressure more than 30 mmHg was considered as overinflation of cuff and under 20 mmHg as underinflation. Heat moisture exchanger was used for all patients and was changed every 48 hours. The coefficient of cuff pressure variation was measured based on equation: (maximum pressure-mean pressure) + (mean pressure –minimum pressure)/2 which was monitored every 3 hours till 72 hours. Mean coefficient of cuff pressure variation during the study is defined as mean of cuff pressure variation for all the 1 hour periods for all patients. Pneumonia was defined based on clinical, radiological and laboratory findings based on clinically pulmonary infection score (CPIS). All parameters were recorded till 3 days.

All data were inserted in SPSS version 16. Variables were showed as mean ± standard deviation. Independent t-test, Mann Whitney U-test and Chi-square test were used for statistical analysis. *P*-value less than 0.05 was considered as significant.

Results

96 patients were enrolled in this study in three 32 patients group. Demographic characteristic of patients (Age, sex and co-morbidities) did not have significant differences between three groups (Table 1). Mean cuff pressure didn't have significant difference between three groups during 72 hours. Pneumonia was seen in 11 patients in group PVC, 8 in Sealguard and 7 in Taperguard group. Changes in mean cuff pressure between Sealguard and PVC tubes and also between Taperguard and PVC tubes did not show any significant difference.

Table 1. Patients' characteristic at ICU admission.

	PVC	PU Taperguard	PU Sealguard	*P*-value
Age (year)	55.71 ± 19.39	54.00 ± 19.49	57.31 ± 19.77	NS
Male/Female	21/11	22/10	20/12	NS
APACHE	22 (16-30)	23 (17-32)	23 (17-33)	NS
Admission category (S/M)*	26/6	27/5	28/4	NS

* Surgery/ Medical

Cuff pressure was measured 24 for each patient during study which underinflation in PVC group was significantly higher than other two groups. Overinflation between three groups didn't have significant difference during the study (Table 2). ICU length of stay, mortality, number of suctioning, gastric residual volume, sedation scale, usage of prokinetic and paralytic drugs are shown in table 2.

Discussion

A compelling argument can be made that the ETT itself not ventilator increase susceptibility to pneumonia in ICU patients. Microaspiration occurs in almost 100% of Hi-Lo ETT cuffs (26). So interventions that reduce Oropharyngeal colonization or reduce tracheal microaspiration can reduce the incidence of VAP (27,28). Endotracheal tube (ETT) cuff inflation provides a mechanical barrier to the passage of oral contents into the trachea and subsequently reduces the risk of pulmonary aspiration. The integrity of this seal is related to ETT cuff pressure and therefore to the ability of the cuff to reduce aspiration. ETT cuff pressure should be maintained between 20 and 30 cmH_2O to reduce the risks of aspiration and tracheal mucosal damage. Aspiration has been reported at cuff pressures up to 60 cmH_2O (29). Continuous control of tracheal tube cuff inflation using a pneumatic device resulted in severe tracheal wall damage in ventilated piglets. This damage was similar in piglets managed with manual control of cuff inflation. The periodic hyperinflation of the tube cuff may explain these results. This maneuver should be avoided in clinical practice (30). Two recent trials didn't showed a reduction in complication rates continuous regulation compared to manual control of cuff pressure and automated cuff pressure controlling could interfere with self sealing mechanism of high volume low pressure PVC cuffed tracheal tubes and reduced the sealing efficacy (31,32)

Table 2. Patients' characteristic during ICU stay.

	PVC	PU Taperguard	PU Sealguard	*P*-value
Prokinetic drugs	3	2	2	NS
RASS*	-1.0 ± 0.5	-0.7 ± 0.3	-0.65 ± 0.4	NS
NMBD	1	1	2	NS
Residual gastric volume (daily/ml)	145 ± 35	135 ± 31	142 ± 28	NS
Vomiting	2	3	4	NS
Mean airway pressure	16 ± 4	17 ± 3	15 ± 4	NS
PEEP	5 ± 3	5 ± 2	5 ± 2	NS
Number of suctioning per day	12 ± 2	9 ± 1	10 ± 1	NS
Incidence of VAP	11	6	7	NS
Length of ICU stay	12 (8-22)	17 (13-31)	18 (12-33)	NS
ICU mortality	6	5	5	NS
Underinflation	10	4	5	NS
Overinflation	4	3	3	NS
Mean cuff pressure (mmHg)	24.20 ± 0.47	24.10 ± 0.49	24.07 ± 0.48	NS
Coefficient variant	2.45 ± 0.51	2.67 ± 0.50	2.79 ± 0.51	NS

*Richmond Agitation Sedation Scale

Several studies showed that PU cuffed ETT in comparison with PVC cuffs prevent leakage of cuff with prevention of channel formation within the inflated cuff and so microaspiration (29,33). But it is unclear if the benefit seen was related to the tube cuff, subglottic suctioning, or a joint effect of both ETT modifications. Neither of the above randomized trials detected a difference in duration of mechanical ventilation, ICU stay, or mortality between the groups. Cost-effectiveness data for these devices have not been reported. Thus, further evidence is needed before PU-cuffed ETTs can be recommended as a widespread VAP prevention measure. In a study by Dullenkopf *et al.* (34), 50 patients were randomized to receive endotracheal intubation with a conventional HVLP cuff of PVC from different manufacturers versus an HVLP cuff of ultrathin PU membrane. The HVLP ultrathin PU cuff required significantly lower sealing pressures (9.5 [8–12] cmH_2O) than the other brands (19.1 [8–42] cmH_2O). In the study by Poelaert *et al*. (24), 134 patients undergoing cardiac surgery were randomized to receive an endotracheal tube with either an ultrathin PU cuff or a conventional PVC cuff. The group with the ultrathin cuff presented a lower incidence of early postoperative pneumonia. However, Poelaert and colleagues' study was performed in a small population of patients undergoing cardiac surgery who may not be representative of other types of patients at risk for VAP

HVLP endotracheal tubes with a PU cuff have been introduced, with an ultrathin cuff membrane (thickness, 7 mm) compared with the cuff membrane of conventional HVLP endotracheal tubes (thickness, >50 mm), designed to prevent the formation of folds within the cuff and thus to prevent fluid and air leakage (24,26); nevertheless, there are no data on the prevention VAP.

The tapered shape of ETT has two characteristic: higher coefficient variation of cuff pressure which might increase microaspiration theoretically and always having a sealing zone which result in decreasing microaspiration. Our study showed that VAP occurrence is less in Taperguard compared to Sealguard and PVC tubes which is similar to previous studies (29,35). As the mentioned study showed that PEEP could decrease the incidence of VAP we used 5 cmH_2O PEEP routinely in our patients. In our study cuff pressure variation based on table 2 could not explain the decrease in VAP incidence in Taperguard and Sealguard tubes compared to PVC tubes. The main mechanism may be the creation of smaller channels and passages for aspiration which result in reducing microaspiration in intubated patients. We showed that PU tubes does not have any significant effect on cuff pressure variation and VAP incidence is less frequent in Taperguard PU tubes compared to Sealguard PU tubes and PVC tube which is similar to Nseir *et al.* (36) So we could not depend on absolute cuff pressure value to prevent aspiration and cuff design may be a better way to decrease microaspiration. We could focus more on cuff design because PEEP loss frequently occurs in clinical practice.

The main reason for aspiration is development of folds and passage for microaspirations when these fold are generated, secretions can pass through them based on gravity to the lower airway. This movement could be reduced by PEEP, cuff inflation and peak airway pressure (37). One mechanism to avoid the progression of subglottic secretions into the lower respiratory tract is to prevent channel formation within the folds of the endotracheal cuff (38). Endotracheal tubes with dorsal lumen for subglottic secretion drainage. The dorsal lumen opens above the endotracheal cuff. In the current version this hole is closer to the cuff and the lumen is bigger. Thus, the use of an ETT with subglottic secretion drainage can be defined as ''recommended,'' whereas the incorporation of an ultrathin membrane cuff and tapered-shape cuff could be defined as ''worth considering'' (39). The benefit of tapered-shape cuff is that, at least on one place in the trachea, the inflated cuff fits the trachea perfectly; at this site, there are no folds, and so leakage and microaspiration may be reduced.

As the control of cuff pressure is difficult and continuous pressure monitoring could damage the mucosa and intermittent monitoring could be associated with under inflation of cuff pressure and result in more pneumonia and PEEP lonely does not guarantee the sealing and prevention of pneumonia. We conclude that cuff material and design should be the most important factor associated with VAP. But, it is still uncertain whether the PU cuff or the tapered shape, or both, are responsible for the favorable results. Future multi center studies with large sample size are needed to show the beneficial effect of these type tubes and their cost effectiveness on prevention of VAP.

Limitation of study: Our study had small sample size and performed in a single center.

Acknowledgment

We would like to thank Mr Shahrokh Teshnedel, Qorbanali Tarinezhad and ICU staff of Shohada Hospital for their cooperation in this study.

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