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Tapered-cuff versus cylindrical-cuff tracheal tube in preventing fluid leak: An in-vitro experimental study

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ABSTRACT

Background: Ventilator-acquired pneumonia is a common complication in intensive care units. Ensuring optimal tracheal sealing might prevent this complication.
Aim: To compare the effectiveness of polyvinyl chloride taper-shaped versus polyvinyl chloride cylindrical-shaped cuffed tubes in reducing the peri-cuff leak.
Design: Experimental study using a sheep trachea model. The tracheal tubes were inserted into the trachea placed in a vertical position at a fixed height. The cuff of each tube was inflated until reaching a pressure ranging between 25 and 30 cm H_2O. Ten milliliters of methylene blue were poured above the cuff and the volume of fluid leaking around the tube was collected and quantified at 30 min, 60 min and 360 min.
Results: Sixty measurements were performed with cylindrical shaped cuffed tubes and 48 measurements were performed with the taper-shaped cuffed tubes. Repeated measures analysis of variance showed that there was a significant difference in the volume of leakage for both tubes over time ($p = 0.016$). Accordingly, the post hoc analysis revealed a significant decrease of the volume leaking at 30 min versus 360 min. The between subject variables assessment showed a significant decrease of leak volume with the taper-shaped cuffed tracheal tubes ($p = 0.011$).
Conclusion: Our experimental study suggests that polyvinyl chloride taper-shaped cuffed tubes are more effective in ensuring appropriate tracheal sealing and reducing the fluid leak around the cuff of the tracheal tube.

1. Introduction

Ventilator-acquired pneumonia (VAP) is a common healthcare-associated infection in critically-ill patients requiring intubation and mechanical ventilation [1,2]. In fact, its incidence ranges between 10 and 20% [2,3]. Several reports highlighted that VAP is associated with a significant increase in the intensive care unit (ICU) length of stay, duration of mechanical ventilation and mortality [1,3]. Therefore, tremendous efforts have been made to establish guidelines and recommendations aiming to prevent this complication [4]. Most of these recommendations are targeting the main two facilitating mechanisms of VAP: micro aspiration and bacterial biofilm formation inside the tracheal tube (TT) [5]. In this regard, subglottic suction, frequent monitoring of the TT cuff pressure, oral care with chlorhexidine and other interventions have been reported to be effective in preventing VAP onset [6,7]. Improving the tracheal sealing by the tracheal tube cuff might be a seductive intervention to limit the risk of micro aspiration. In fact, experimental studies have shown that tracheal sealing is incomplete with the cuff of the cylindrical high volume low pressure TT and multiple folds have been identified between the tracheal mucosa and the cuff wall [8,9]. On the other hand, taper-shaped cuff tube provides better tracheal sealing as its outer diameter fits closely the internal diameter of the trachea [10]. The aim of our in-vitro experimental study is to compare the effectiveness of polyvinyl chloride taper-shaped cuffed tube versus polyvinyl chloride cylindrical cuffed tube in reducing the fluid leakage around the TT in a sheep trachea model.

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2. Material and methods

2.1. Design

The effectiveness of taper-shaped cuffed tube and cylindrical cuffed tube were assessed *in vitro* using a sheep trachea model. Our study was conducted according to the National Institutes of Health guide for the care and use of laboratory animals. Sheep were not butchered for the sake of the study. Accordingly, no ethical approval was required.

2.2. Material

Two types of TT were compared: (1) TT with cylindrical-shaped cuff in polyvinyl chloride (Portex Endotracheal tube, Smith medical international Ltd), with an outer diameter of 10.9 mm and cuff rest diameter of 30 mm, and (2) TT with taper-shaped cuff in polyvinyl chloride (Mallinckrodt Tapered Guard Evac endotracheal Tube, Covidien), with an outer diameter of 10.8 mm and a cuff rest diameter of 25.4 mm. All the tubes used in the experiment had an inner diameter of 8 mm.

2.3. Study protocol

The tracheal tube was inserted into the trachea placed in a vertical position at a fixed height. The distance between the tip of the trachea and the table was kept at 10 cm. The tracheal tube was inserted and the distance between the tip of the tube and the distal tip of the trachea was kept at 2 cm (Fig. 1). Before starting assessing the leakage, the cuff of each tube was inflated until reaching a pressure ranging between 25 and 30 cmH_2O, as recommended in human clinical practice. There was no prior lubrication of the tubes before insertion. Ten milliliters of methylene blue were poured above the cuff and the volume of fluid leaking around the tube was collected via a collector applied at the distal tip of the trachea and quantified at 30 min, 60 min and 360 min. Each trachea was used for only one measurement. In addition to the leak volume, we also recorded the diameter of the trachea and the cuff pressure. The room temperature was kept at 18° Celsius throughout the experiment.

2.4. Statistical analysis

The normal distribution of all the quantitative variables was assessed by the Shapiro-Wilk test and Kolmogorov-Smirnov test. Data were expressed as mean ± standard deviation (SD) or median [quartiles] as appropriate. Two groups were compared: Cylindrical cuffed tubes and tapered-shaped cuffed tubes. The diameters of the tracheas and the cuff pressure were compared between both groups by using *t*-test or Mann-Whitney test as appropriate. Repeated measures analysis of variance (ANOVA) was performed to compare the volume of leakage over time between the two types of TT. Therefore, within-subject variables were assessed according to three levels (leakage at 30 min, 60 min and 360 min) whereas between subject variables were assessed according to two levels (Cylindrical-cuffed TT and taper-shaped cuffed TT). The sphericity

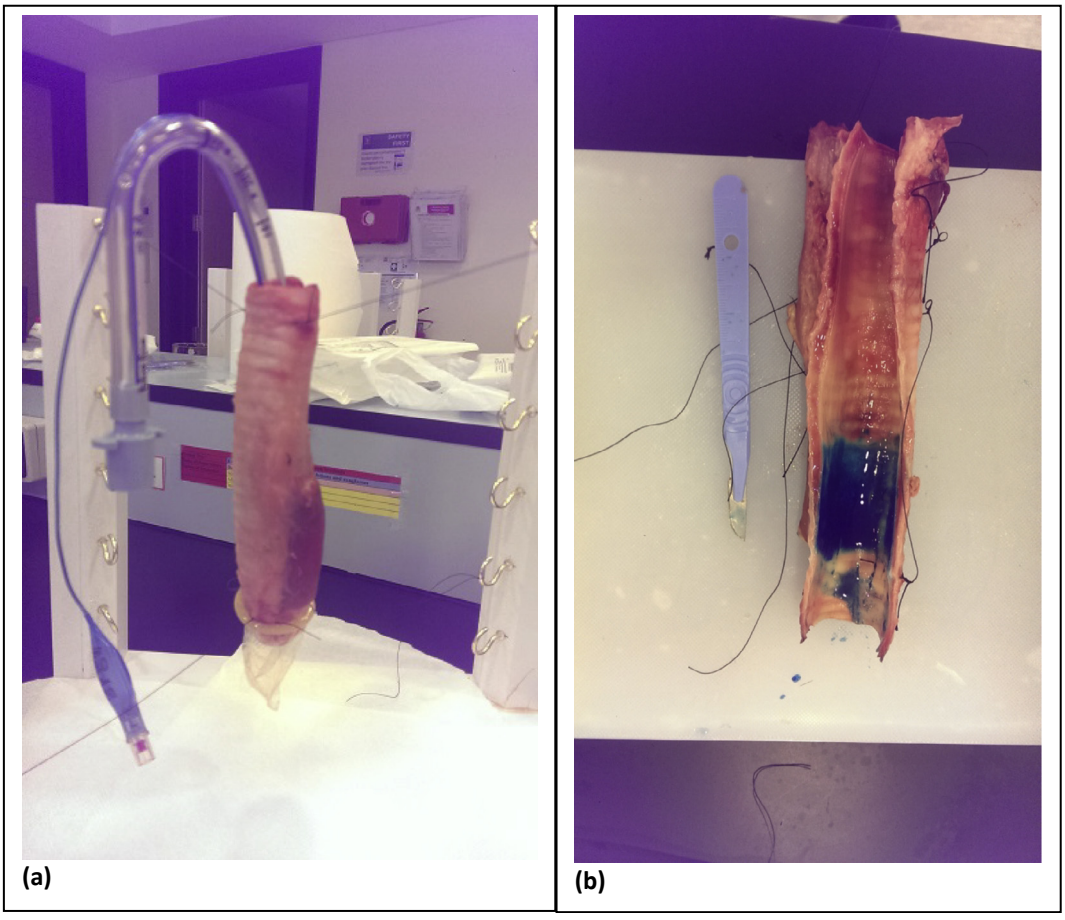

Fig. 1. (a) Sheep trachea intubation and leak collection technique (b)Section of the trachea with the leaking dye.

(homogeneity of sum of variances minus covariance) was assessed by Mauchly's test. Greenhouse Geisser adjustments were considered for analysis that did not meet Mauchly's test of sphericity. A post-hoc analysis was then performed using the Bonferroni test. A two-sided p-value < 0.05 was considered as statistically significant. All the statistical tests were performed by using SPSS (Statistical Package For the Social Science) package version 20.0 (IBM corp, NY, USA).

3. Results

Sixty measurements were performed with cylindrical shaped cuffed tubes and 48 measurements were performed with the taper-shaped cuffed tubes. There was no significant statistical difference between the diameter of the tracheas used in both groups (23.9 ± 4.1 mm for cylindrical shaped cuffed tubes group and 24.8 ± 3.1 mm for taper shaped cuffed tubes group; $p = 0.18$). Similarly, the cuff pressure before starting the leak assessment was comparable between the two studied groups (27.9 ± 1.8 cmH_2O for cylindrical shape cuffed tube group and 28.5 ± 1.6 cmH_2O for taper shaped cuffed tubes group; $p = 0.074$). The volume of leak over time in both groups is summarized in (Table 1). As Sphericity was not met, Greenhouse Geisser adjustment was performed ($p = 0.573$). Thereafter, Repeated measures ANOVA showed a significant difference in the volume of leakage over time ($p = 0.016$). The post-hoc analysis showed that there was a significant difference in both groups regarding the volume of leak at 30 versus 360 min with a lower leak seen in the taper-shaped cuff group (Table 2). The between subject variables assessment showed a significant decrease of leak volume with the taper-shaped cuffed TT ($p = 0.011$) (Fig. 2).

4. Discussion

Our in-vitro study shows that the use of polyvinyl chloride taper-shaped cuffed tracheal tubes was associated with significant decrease of the leak around the TT cuff. These findings in a sheep trachea model are interesting as the diameter of the used tracheas was close to the adult human trachea [11]. Intubation and mechanical ventilation can be required either for surgical intervention or for any other organ dysfunction leading to inefficient airway protection, acute respiratory failure or poor tissue oxygenation [12]. Therefore, adequate sealing of the trachea is required to ensure appropriate ventilation and to prevent micro aspiration. Polyvinyl chloride cylindrical high-volume low-pressure cuffed tubes are widely used all over the world. However, several *in vivo and in vitro* experimental studies have reported that leak around the cuff may occur even when the internal pressure is kept at 30 cmH_2O [8,13,14]. The underlying mechanism is the presence of folds and redundancy channels between the cuff wall and the tracheal mucosa [8,15]. Therefore, it has been suggested that reducing the risk of micro aspiration might be achieved by improving the tube cuff material or by modifying the shape of the cuff itself [15]. In this regard, *Dave* et al. [10] reported in an experimental *in vitro* study that the volume of fluid leak across the cuff was significantly decreased with polyurethane tapered-shaped cuffed tubes in comparison with cylindrical-cuffed tubes. Similarly, *Shiotsuka* et al. [16], reported a significant reduction in the volume of fluid leak with polyvinyl chloride taper-shaped cuffed tube in comparison to 4 different tubes with cylindrical cuff. Hence, the beneficial effect of the taper-shaped cuffed tube over the cylindrical cuffed tubes is probably independent of the tube material. Our results corroborate these findings as the volume of fluid leaking across the tube was significantly decreased over the time. Interestingly, the post-hoc analysis showed that the difference was mainly between 30 min and 360 min whereas the performances of both tubes were comparable from 30 to 60 min. This may suggest that using taper-shaped cuffed tubes might be helpful to prevent post-operative respiratory complications such as aspiration and atelectasis in patients with prolonged surgery and in critically ill patients requiring intubation and mechanical ventilation. The clinical relevance of such a finding is still a question of debate. In fact, *Bowton* et al. [17] reported in a 2-period prospective observational study that the routine use of taper-shaped cuffed TT in critically ill patients instead of cylindrical cuffed TT did not result in a significant decrease in the incidence of ventilator-acquired pneumonia. However, the authors reported that the rate of adherence to general bundles for VAP prevention was less during the taper-shaped cuffed tubes period. The clinical relevance is also questionable in patients requiring intubation for surgical intervention. In fact, *Choi* et al. [18] reported in a prospective observational study that head rotation during middle ear surgery was associated with significantly higher increase of the internal cuff pressure and greater degree of TT displacement with the taper-shaped cuffed TT in comparison with the other tubes.

Even though our study is one of the rare experimental studies comparing the efficiency of taper-shaped cuffed TT versus cylindrical cuffed TT in reducing the leak across the TT cuff, several

Table 1
Volume of leak over time in both groups.

	30 min	60 min	360 min
Leak in Cylindrical-cuff tracheal tube group (ml)	3.3 ± 3.3	3.4 ± 3.4	3.5 ± 3.4
Leak in Taper-cuffed tracheal tube (ml)	2 ± 1.1	2 ± 1	2.4 ± 1.7

Table 2
Post-hoc analysis comparing the leak between the two groups over time.

Time (I)	Time (J)	Leak volume Difference (I-J)	Standard Error	p	95% CI for difference	
					Min	Max
30 min	60 min	−0.05	0.03	0.319	−0.12	0.02
	360 min	**−0.23**	**0.09**	**0.038**	**−0.46**	**−0.1**
60 min	30 min	0.05	0.03	0.319	−0.02	0.11
	360 min	−0.19	0.09	0.092	−0.40	0.02
360 min	30 min	**0.23**	**0.09**	**0.038**	**0.01**	**0.46**
	60 min	0.19	0.09	0.09	−0.21	0.40

Footnotes: CI: Confidence interval.
Bold : Estmated marginal means of leak.

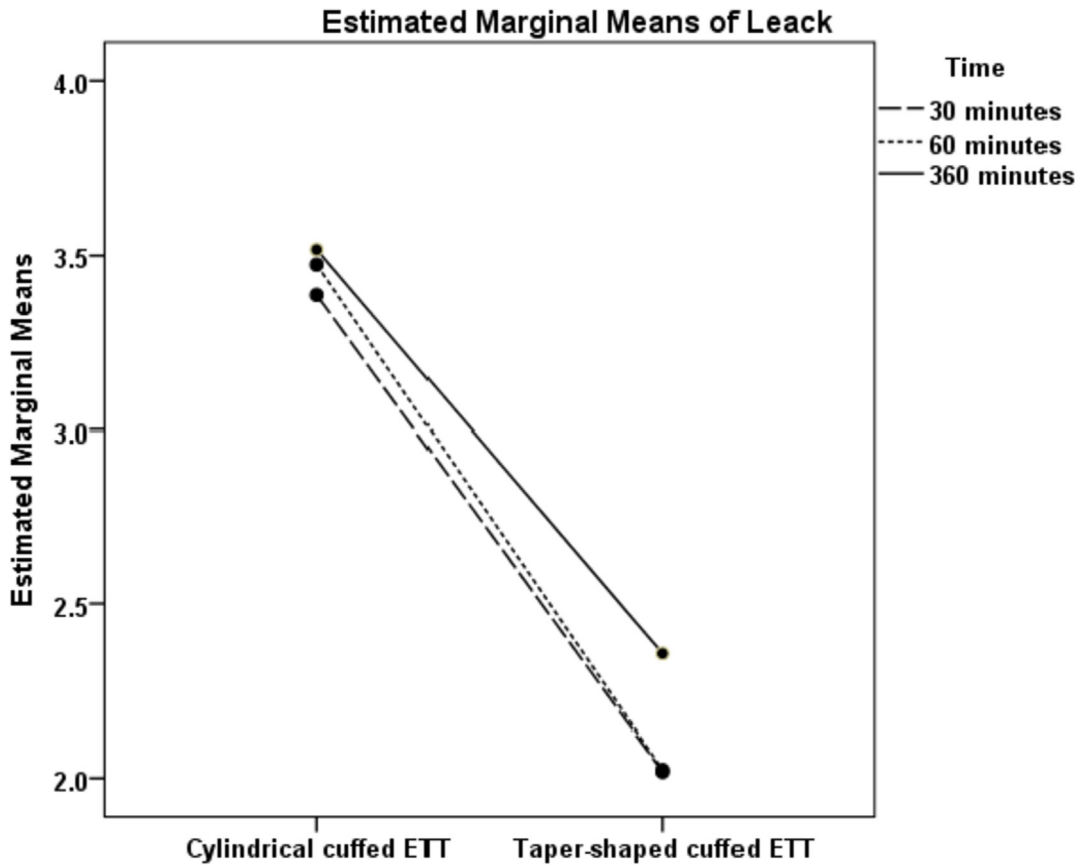

Fig. 2. Estimated marginal means of leak across the groups.

limitations should be highlighted. First, it was an *in-vitro* study with several differences from the in-vivo model, including the viability of the tracheal endothelium and the viscosity of the secretion reaching the subglottic area. Second, previous studies have shown that the settings of mechanical ventilation significantly affect the volume of fluid leak across the cuff. In fact, a positive correlation has been reported between the increase of the positive end expiratory level and the decrease of the fluid leak [9,19]. Therefore, the design of our study does not enable confirmation of the benefit of using a taper-shaped cuffed TT once mechanical ventilation is initiated. Third, the experiment was performed on isolated trachea which exclude the effect of the thoraco-pulmonary system compliance on the amount of leak. Fourth, we only tested tracheal tubes in polyvinyl chloride. Different results could have been found with other materials. In fact, Madjdpour et al. [20] reported in an experimental study that the taper-shaped cuff tube was associated with a significant decrease in the leak volume with polyvinyl chloride tubes but not with polyurethane ones as polyurethane affords better sealing of the trachea. Finally, there was no continuous monitoring of the cuff pressure during the experiment. Although clinical studies suggest that such an intervention is effective in reducing the risk of aspiration [21], other experimental studies showed controversial results. In fact, Carter et al. [22] reported a significant increase in the volume of leakage around the cuff with continuous cuff pressure monitoring when compared with standard monitoring.

5. Conclusion

In-vitro, polyvinyl chloride taper-cuff tracheal tube is more effective than polyvinyl chloride cylindrical-cuff tracheal tube in reducing fluid leak. Whether such a finding is clinically relevant needs to be further investigated.

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None.

Conflicts of interest

None.

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