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Comparison of the intracuff pressures of three different tracheostomy tubes

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Abstract
The purpose of this study was to compare the cuff pressures of three tracheostomy tubes, MERA sofit CLEAR, Blue Line Tracheostomy Tube, and Tracheosoft. Each tracheostomy tube with an internal diameter of 7.0 mm was put into a plastic column. The cuff was then inflated with air to seal the column, and the column was filled with water. The air in the cuff was withdrawn gradually and the cuff pressure at the point of water leakage was measured. Six columns of different size were used. In columns with an internal diameter of 18–21 mm, the water leakage pressure was lower in the following order: MERA sofit CLEAR < Tracheosoft ≤ Blue Line Tracheostomy Tube. A mongrel dog was tracheotomized, and each tracheostomy tube with an internal diameter of 7.5 mm was intubated. The cuff air was increased by 1 ml from 4 ml to 10 ml, and the intracuff pressure was then measured. The intracaff pressure of the Blue Line Tracheostomy Tube was the highest at the same cuff volume, and that of the Tracheosoft was next. Based on these results, the MERA sofit CLEAR was found to maintain most safely the lowest intracuff pressure to seal the trachea among the three tracheostomy tubes tested.

Key words Tracheostomy · Tracheal cuff · Intracuff pressure

Cuffed endotracheal tubes are usually used in adults during general anesthesia or artificial ventilation to prevent aspiration and air leakage. However, when the cuff is overinflated or inflated for a long time, it often causes degeneration and necrosis of the tracheal mucosa [1]. There have been investigations of cuff pressure and tracheal mucosal blood flow during endotracheal intubation [2–7], but no such studies using tracheostomy tubes that may be placed for a longer time than the endotracheal tube have yet been reported. Therefore, the present study was performed to clarify the performance of the cuffs of three commonly used tracheostomy tubes: MERA sofit CLEAR (Senko Medical, Tokyo, Japan), Blue Line Tracheostomy Tube (SIMS Portex, Kent, UK), and Tracheosoft (Mallinckrodt, Athlone, Ireland).

In the first study, each tracheostomy tube with an internal diameter of 7.0 mm was inversely placed in a plastic column with the tracheal side up. The tracheal side was then sealed with a stylet. The cuff was inflated with air to seal the column tightly. The column was filled with water up to a height of 10 cm from the upper edge (tracheal side) of the cuff (Fig. 1). The air in the cuff was withdrawn gradually while continuously monitoring the cuff pressure until water leakage started (water leak pressure). Six columns with internal diameters of 18, 19, 20, 21, 22, and 23 mm were used. Five tracheostomy tubes for each type—MERA sofit CLEAR, Blue Line Tracheostomy Tube, Tracheosoft—were tested. The external diameter of the tube was 9.6 mm for the MERA sofit CLEAR and Tracheosoft and 9.7 mm for the Blue Line Tracheostomy Tube. The properties of each cuff are shown in Table 1.

The water leak pressure in columns with an internal diameter of 18–21 mm was lower in the following order: MERA sofit CLEAR < Tracheosoft ≤ Blue Line Tracheostomy Tube. In the columns with an internal diameter of 22 and 23 mm, the Blue Line Tracheostomy Tube had the lowest water leak pressure (Fig. 2).

In the second study, the relation between the intracuff pressure and cuff air volume was investigated using a dog after approval of the research committee. A 15-kg mongrel dog was anesthetized using intramuscular ketamine 10 mg/kg with atropine 0.5 mg. After inserting the catheter into a vein of the forepaw, vecuronium 10 mg was administered; and an endotracheal tube (Portex, Kent, UK) with an internal diameter of 7.5 mm was orotracheally intubated. Tracheostomy

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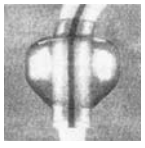
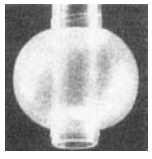
Table 1. Property of the cuffs of three tracheostomy tubes with an internal diameter of 7.0 mm

	Schema	Material	Form	Diameter (mm)	Width (mm)
MERA		Polyvinyl chloride	Barrel-shaped	22.0	22.0
Blue Line		Polyvinyl chloride	Pyriform	22.0	22.0
Tracheosoft		Polyvinyl chloride	Spherical	22.5	22.5

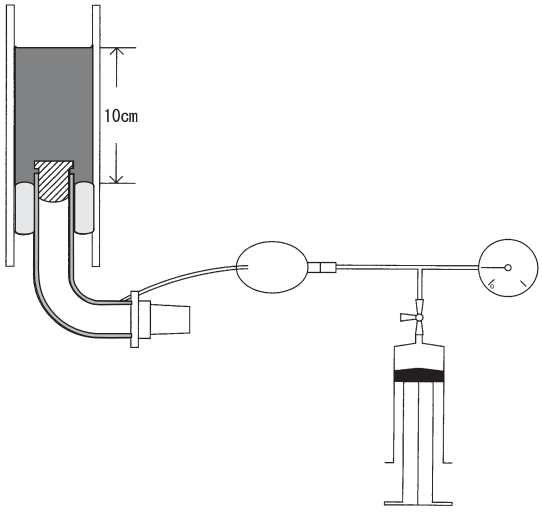


Fig. 1. First experiment. A tracheostomy tube was inserted inversely into a plastic column. The cuff was inflated to inhibit water leakage. Water was filled up to 10 cm high from the upper edge (tracheal side) of the cuff. The water leakage pressure was measured by gradually withdrawing the air in the cuff

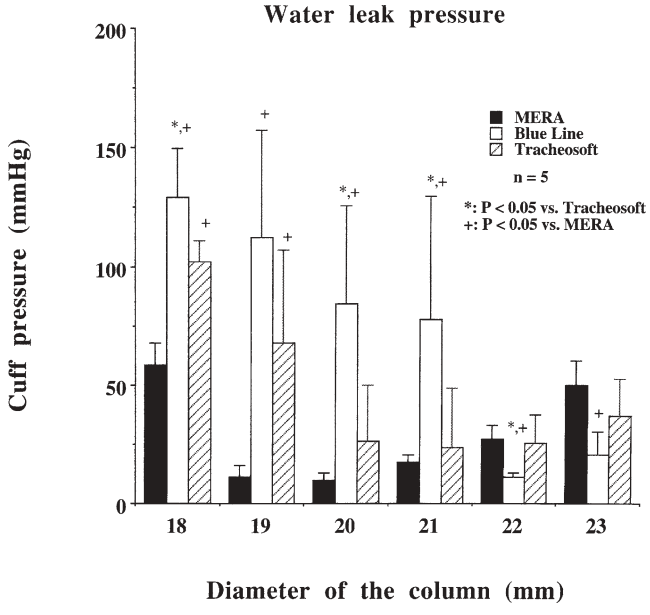


Fig. 2. Water leak pressure. The columns show the means, and the bars show the standard deviation

was then performed. A tracheostomy tube, MERA sofit CLEAR, Blue Line Tracheostomy Tube, or Tracheosoft, with an internal diameter of 7.5 mm was intubated. The external diameter of the tube was 10.3 mm for the MERA sofit CLEAR and Tracheosoft and 10.4 mm for the Blue Line Tracheostomy Tube. The cuff air was increased by 1 ml from 4 ml to 8 ml (Blue Line Tracheostomy Tube), to 9 ml (Tracheosoft), or to 10 ml (MERA sofit CLEAR), and the intracuff pressure was measured. Ventilation was maintained to keep the maximum inspiratory pressure at 20 cm H_2O with 100% oxygen. Anesthesia was maintained with propofol 10 $mg \cdot kg^{-1} \cdot h^{-1}$. Statistical analysis was performed with the Kruskal-Wallis test and the Mann-Whitney U-test. $P < 0.05$ was considered statistically significant. The Blue Line Tracheostomy Tube had the highest intracuff pressure at the same cuff volume, and the MERA sofit CLEAR had the lowest intracuff pressure (Fig. 3).

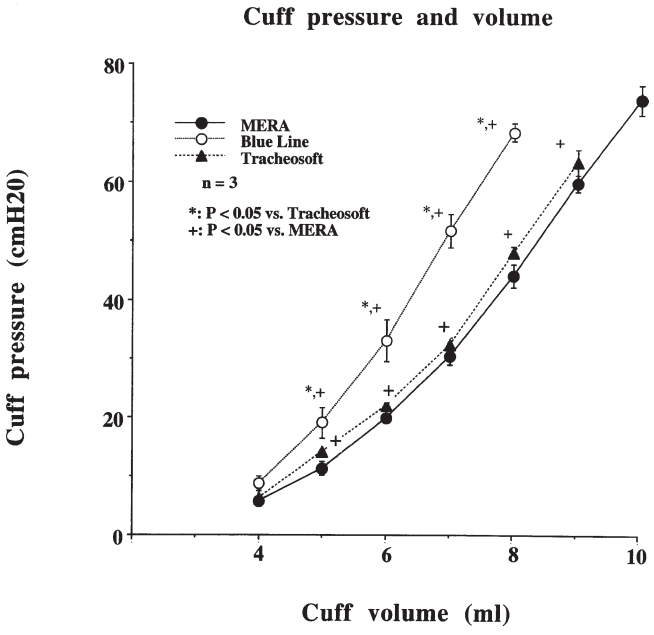


Fig. 3. Intracuff pressure and cuff volume. Means ± SD are shown

Large-volume, low-pressure endotracheal tube cuffs have been reported to have less deleterious effects on the tracheal mucosa than high-pressure, low-volume cuffs. Nevertheless, these cuffs may easily become overinflated, generating excessive lateral wall pressure [8]. When endotracheal tube cuffs are overpressurized, they impair mucosal blood flow. High lateral wall pressure of the trachea induces low tracheal mucosal blood flow [3]. In one study, when the lateral wall pressure reached 50 cm H_2O (37 mmHg), the tracheal mucosal blood flow was completely occluded in humans [3]. In a dog study, a critical wall pressure for decreasing the tracheal mucosal blood flow was around 30 mmHg when the intracuff pressure was 51 mmHg [4]. Joh et al. reported that tracheal mucosal blood flow was significantly impaired by a tracheal wall pressure of more than 30 mmHg [5]. Therefore, during prolonged intubation it is recommended that the tracheal wall pressure be kept at or below 20 mmHg [5]. A tracheal wall pressure of 20 mmHg corresponds to an intracuff pressure of approximately 43 mmHg [5]. The tracheal wall pressure at which the trachea was just sealed was approximately 10 mmHg, which corresponds to an intracuff pressure of 28 mmHg using the Mallinckrodt Hi-Lo endotracheal tube with an internal diameter of 7.0–8.0 mm [5]. Seegobin and van Hasselt reported that a cuff inflation pressure of 30 cm H_2O (22 mmHg) should not be exceeded in a study using various kinds of the endotracheal tubes with large-volume, low-pressure cuffs [3]. In a study using a rabbit model and a specially designed cuffed plastic tube, it was demonstrated that the cuff pressure had to be kept below 20 mmHg to maintain tracheal mucosal blood flow [2]. Based on these studies, a widely cited limit for cuff pressure is 25–30 cm H_2O (18–22 mmHg).

Based on the findings of the present study, the MERA sofit CLEAR maintained a water seal with an intracuff pressure of less than 22 mmHg in the widest range of the column diameters. This suggests that the MERA sofit CLEAR is the safest available tracheostomy tube that comes in the widest range of the sizes. Its ultra-thin membrane prevents longitudinal folding and channel formation when the cuff is inflated, which is known to be the primary source of fluid leakage [9]. Therefore, the MERA sofit CLEAR may have the thinnest membrane while the thickness of the membrane is not known. The most unique property of the cuffs is their shape (Table 1). The barrel-shaped cuff may be the best for decreasing intracuff pressure to seal the trachea. Based on our second study, cuff air can be added to 7 ml in the MERA sofit CLEAR, 6 ml in the Tracheosoft, and 5 ml in the Blue Line tracheostomy tube to maintain the intracuff pressure less than 30 cm H_2O. The data also suggest that the MERA sofit CLEAR has the largest safety range of the intracuff air volume.

In conclusion, among three tracheostomy tubes tested, the MERA sofit CLEAR was found to maintain safely the lowest intracuff pressure to seal the trachea.

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