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Tracheal Mucus Velocity Remains Normal in Healthy Sheep Intubated with a New Endotracheal Tube with a Novel Laryngeal Seal

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Background: Tracheal mucus velocity (TMV), an index of mucociliary clearance, is reduced markedly in patients intubated with standard endotracheal tubes (ETTs) with high-compliance low-pressure (hi-lo) cuffs. The authors developed a new ultra-thin walled ETT in which the inflatable cuff is replaced with a no-pressure seal, positioned at the level of the larynx. The seal consists of 12 to 20 toroidal layers of thin polyurethane film ("gills") at the level of the vocal cords and prevents both air leak and fluid aspiration. The authors hypothesized that ETTs with the new laryngeal seal may impair TMV less than ETTs with inflated hi-lo cuffs do.

Methods: The TMV was measured in seven healthy female sheep by radiographically tracking the motion of small discs of tantalum inserted into the trachea through a bronchoscope. The TMV was measured in spontaneously breathing sheep before intubation (baseline) and after intubation with either a hi-lo ETT (control group) or after intubation with a new ETT with gills (study group). Four to six weeks later, the studies were repeated, but the sheep that were previously in the control group served as the study group, and those in the study group served as controls.

Results: Baseline TMV did not differ in the two groups. In the control group, TMV decreased significantly (by 67%) from baseline. In the study group, TMV did not differ significantly from baseline and remained steady during 3 h of intubation.

Conclusions: The TMV does not change in sheep intubated with new ETTs with gills. The new ETTs may help promote a normal mucociliary clearance in patients who require ventilation. (Key words: Equipment: cuffs; endotracheal tubes; gills. Mechanism: mucociliary clearance; tracheal mucus velocity.)

MUCOCILIARY transport is frequently depressed in intubated patients during mechanical ventilation. 1 Reten-

tion of secretions renders those patients at high risk for contracting atelectasis and pneumonia. Amany factors can decrease mucociliary clearance: drugs, high oxygen concentrations, trauma to the tracheal mucus membrane from repeated suctioning, inadequate humidification of inspired gases, and activation of the inflammatory mediators system.

Endotracheal tubes (ETTs) with inflated cuffs exert significant pressure on the tracheal wall. This can lead to epithelial damage and can decrease tracheal mucus velocity (TMV), an index of mucociliary clearance. The TMV is substantially decreased with cuffed ETTs, whereas uncuffed ETTs (exerting no pressure on the tracheal wall) appear to have little influence on TMV.

We developed a new ultrathin-wall ETT with resistance to air-flow less than that of conventional ETTs. We replaced the tracheal cuff with a no-pressure seal, positioned at the level of the glottis, that is made of 12 - 20 toroidal layers of thin polyurethane film ("gills"). The gills prevented air leaks and fluid aspiration. 12

We hypothesized that the new ETT with the novel laryngeal seal may impair TMV less than conventional ETTs using high-compliance low-pressure (hi-lo) cuffs. In this study in healthy, spontaneously breathing sheep, we used serial radiographs to measure TMV by tracking the motion of small discs of tantalum delivered through a bronchoscope. We measured TMV in spontaneously breathing sheep before intubation and after intubation with either a hi-lo ETT or with a new ETT with gills.

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Materials and Methods

Animal Preparation

All animal studies were approved by the Animal Care and Use Committee of the National Heart, Lung, and Blood Institute of the National Institutes of Health. Seven adult female sheep weighing 28–38 kg were sedated with ketamine chloride (7 mg/kg) infused into

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the right external jugular vein through a 16-gauge catheter. The right femoral artery was cannulated through a 16-gauge catheter for continuous blood pressure monitoring and for blood gas analysis. Sheep were positioned prone with their heads immobilized. Sedation was maintained by continuous infusion of ketamine chloride (1 mg·kg⁻¹·h⁻¹). Sheep tolerated the procedures well and were breathing spontaneously, with blood gases in the normal range (partial pressure of oxygen > 90 mmHg, partial pressure of carbon dioxide < 50 mmHg). Arterial blood gases, electrolytes, and blood glucose were measured hourly (Stat Profile plus 9; Nova Biomedical, Waltham, MA). Arterial blood pressure was recorded continuously using a strain-gauge transducer (Gould Statham P23 ID, Gould, Inc., Cleveland, OH).

Each sheep was studied twice, with an interval of 4-6 weeks between studies. Before each study, the absence of respiratory and systemic infection was demonstrated by the results of physical examination, chest radiographs, and blood counts.

Tracheal Mucus Velocity

We used a modification of the methods described by Friedman et al. 13 Ten tantalum discs, 1 mm in diameter, 0.12 mm thick, and weighing 1.8 mg, were insufflated into the trachea with compressed air through the operating channel of a 6-mm flexible bronchoscope (model BF 5B2; Olympus Corp., Columbia, MD). We took great care not to touch the tracheal mucosa with the bronchoscope. We measured the movement of the tantalum discs during a 1-h period from serial radiographs taken in the lateral plane at 2-min intervals during expiration, as previously described. 14 A collar containing radiopaque markers of known length was applied to the neck of the sheep, as references to correct for the magnification error inherent in the radiographs. We tracked discs within the distal trachea moving toward the glottis over a distance of 14-16 cm, starting from the level of the right upper lobe bronchus.

After obtaining baseline data for TMV, sheep were randomly intubated with an 8-mm Mallinckrodt Hi-Lo ETT (Mallinckrodt Critical Care, Argyle, NY) (control group), or with a new ultrathin-wall ETT of the same outside diameter (study group). The hi-lo ETT was positioned with the proximal end of the cuff approximately 2 cm below the glottis. The position of the ETT was checked radiographically. The cuff was inflated to a pressure of 15–20 cm H₂0. The new ETT was positioned with several gills visible above the glottis. The ETTs were secured with a bite-block and connected to

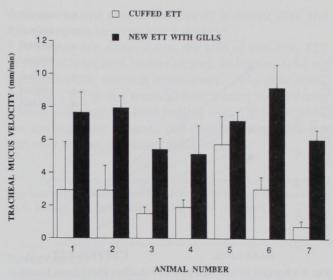


Fig. 1. Tracheal mucus velocity (TMV, expressed as millimeters per minute \pm SD) for each sheep after 3 h of intubation with a standard high-compliance low-pressure endotracheal tube (ETT) with inflated cuff (control group, white bars), or intubated with a new ETT with laryngeal seal ("gills"; study group, black bars). The TMV in the control group was significantly lower than that in the study group (P < 0.001, by analysis of variance for repeated measurements).

a Siemens Servo 900C ventilator (Siemens Elema, Solna, Sweden) in the continuous positive pressure mode, with positive end-expiratory pressure at 4 cm $\rm H_20$. The inspiratory gas was fully humidified and warmed to 38° C with a Conchatherm III humidifier (Hudson Respiratory Care, Tennecula, CA). After 2 h of intubation, we introduced a second set of tantalum discs through the bronchoscope and determined TMV as before.

We averaged the linear velocity of five discrete discs that could be tracked readily. Measurements were taken by two independent observers, and measurements that differed by more than 10% were rejected. Four to six weeks later all sheep underwent a repeated study. After establishing baseline values of TMV, sheep that had served as controls were intubated with a new ETT, and those that had been in the study group were intubated with a hi-lo ETT.

Statistical Methods

The baseline values of TMV for the hi-lo ETTs, and the new ETTs with gills, as well as the changes from baseline TMV after intubation with a cuffed hi-lo ETT and after intubation with a new ETT with gills, were analyzed using analysis of variance for repeated mea-

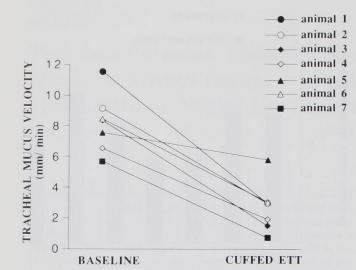


Fig. 2. Changes in tracheal mucus velocity (TMV) from baseline after 3 h of intubation with a standard high-compliance low-pressure endotracheal tube with inflated cuff for each sheep. The TMV after intubation was significantly lower than baseline (P < 0.001, by analysis of variance for repeated measurements).

surements. A probability value of 0.05 or less was considered significant.

Results

The baseline TMV (before intubation) for the cuffed hi-lo ETT was 8.2 ± 1.9 (SD) mm/min, and 7.9 ± 1.5 mm/min for the new ETT with gills (P = 0.801). Figure 1 shows the TMV after intubation with a cuffed ETT and a new ETT with gills. The TMV after intubation with a cuffed ETT was significantly lower than that after intubation with a new ETT with gills $(2.7 \pm 1.6 \text{ mm/})$ min, vs. 7 mm \pm 1.8 mm/min; P < 0.001). Figures 2 and 3 show the changes in TMV from baseline for the cuffed ETTs and for the new ETTs with gills for each individual study. There was a significant decrease in TMV from baseline after intubation with a cuffed ETT $(2.7 \pm 1.6 \text{ mm/min } vs. \ 8.2 \pm 1.9 \text{ mm/min } vs. \ 7.9 \pm 2.6$ mm/min; P < 0.001). For the study group, TMV was not significantly different from baseline (7.0 \pm 1.5 mm/ min vs. 7.9 ± 2.6 mm/min; P = 0.243). As seen on radiographs, the tantalum discs traveled well beyond the tip of the new ETT. After extubation, several tantalum discs were seen within the folds of the gills in the tracheal portion of the ETT in three sheep.

Discussion

Our studies show that TMV in sheep intubated with a new thin-wall ETT fitted with a new laryngeal seal (study group) showed little, if any, decline in TMV velocity during 3 h of intubation, whereas the TMV during intubation with a conventional hi-lo ETT decreased significantly.

Inhaled particles are transported cephalad by the mucociliary escalator, frequently in a helical pattern. ¹⁵ Measuring and averaging the linear velocity of several individual insufflated markers over several minutes provides adequate information about TMV and the immediate response to diverse stimuli. ¹⁶ Several investigators have tracked insufflated Teflon discs by bronchoscopy^{7,17} or have visualized radiopaque Teflon discs by fluoroscopy^{10,17,18} or serial radiographs. ¹⁴ We used discs made of tantalum because they are biologically inert and have a history of use in bronchography. ¹⁹ They are easily manufactured and the tantalum discs were similar to the radiopaque Teflon discs in diameter and weight but were markedly thinner and provided good contrast on radiographs.

Our baseline TMV correlated well with studies using radiopaque Teflon discs as markers. Sackner $et~al.^{10}$ reported a mean TMV of 9 mm/min in nonintubated, anesthetized dog. Landa $et~al.^4$ reported a mean TMV of 17.3 ± 6.2 mm/min in awake, nonintubated sheep and 11.1 ± 3.6 mm/min in anesthetized, nonintubated sheep; and Allegra $et~al.^{20}$ reported TMVs of 10.0–11.4

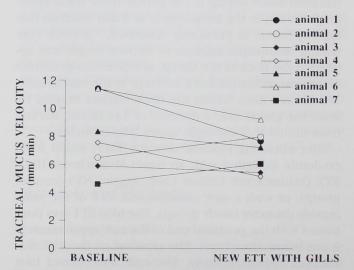


Fig. 3. Changes in tracheal mucus velocity from baseline after 3 h of intubation with the new endotracheal tube with gills. Changes from baseline were not significant (P = 0.243, by analysis of variance for repeated measurements).

mm/min in awake nonintubated sheep. Thus the slightly lower TMV values in our study probably can be attributed to the effects of anesthesia. In animals intubated with uncuffed tracheal tubes, Sackner *et al.*¹⁰ (dogs, anesthetized) and Sabater *et al.*¹⁸ (sheep, awake) found TMVs ranging from 8.3 to 9.3 mm/min and 6.1 to 11.5 mm/min, respectively. These values correlate well with the TMV in this study using the new ETT with gills.

Our results correspond well with those of Sackner *et al.*, ¹⁰ who found a significant decrease of TMV after inflation of the tracheal cuff (inflation pressures not specified; 37% after 1 h; 52% after 4 h of intubation). The TMV was significantly reduced when tracheal cuffs were inflated to pressures commonly encountered in patients in intensive care units who require mechanical ventilation and was commonly 0 mm/min in patients with nosocomial pneumonia. Although we kept the inflation pressures of the cuffs low, we found a significant decline in TMV. However, the mean TMVs in sheep intubated with the new ETT with gills (study group) were not significantly different from baseline values; that is, TMV did not decrease during the 3 h of intubation.

The mechanism by which TMV is suppressed after the cuffs of standard ETTs are inflated is not clear. Damming of mucus by the inflated cuff is unlikely to explain it, because measurements were made in the distal trachea, whereas the cuff was inflated in the proximal trachea. Other proposed mechanism are a critical increase in the thickness of the mucus layer proceeding as a propagated wave, a neurogenic reflex secondary to mechanical distension of the trachea that affects mucus secretions, or decreased ciliary activity.

It is unlikely that mucus was effectively dammed by the gills, because TMV did not decline during the study. We also saw discs moving cephalad, alongside the endotracheal tube. On extubation we found tantalum discs trapped within the gills in some sheep. The design of our tracheal tube imparted no pressure on the tracheal wall, and thus tracheal injury was reduced, or eliminated, and mucociliary transport was preserved.

Some hospital practices require low cuff inflation pressures and deflation of the cuff every hour, or that the cuffs be deflated during every expiration.²¹ There are no data that show whether those measures affect TMV. It has been found that tracheal injury could be prevented only when there was an audible leak during inspiration.²² It follows that continuous protection from fluid aspiration, using a standard inflatable hi-lo tracheal

cuff, is achieved only at the cost of impaired TMV and the risk of tracheal epithelial damage.

Previously we showed that the gills of this new ETT provide an excellent barrier against aspiration, with no damage to the tracheal epithelium.¹² We now show that the TMV in this tracheal tube design also remains normal. Although we used healthy sheep in our studies, our findings may enhance our understanding of issues that may lead to improved patient care.

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