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## RESPIRATION AND THE AIRWAY

# Tracheal tube biofilm removal through a novel closed-suctioning system: an experimental study

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### Abstract

**Background:** Tracheal tube biofilm develops during mechanical ventilation. We compared a novel closed-suctioning system vs standard closed-suctioning system in the prevention of tracheal tube biofilm.

**Methods**: Eighteen pigs, on mechanical ventilation for 76 h, with *P. aeruginosa* pneumonia were randomized to be tracheally suctioned via the KIMVENT\* closed-suctioning system (control group) or a novel closed-suctioning system (treatment group), designed to remove tracheal tube biofilm through saline jets and an inflatable balloon. Upon autopsy, two tracheal tube hemisections were dissected for confocal and scanning electron microscopy. Biofilm area, maximal and minimal thickness were computed. Biofilm stage was assessed.

**Results:** Sixteen animals were included in the final analysis. In the treatment and control group, the mean (SD) pulmonary burden was 3.34 (1.28) and 4.17 (1.09) log cfu gr<sup>-1</sup>, respectively (P=0.18). Tracheal tube P. *aeruginosa* colonization was 5.6 (4.9–6.3) and 6.2 (5.6–6.9) cfu ml<sup>-1</sup> (median and interquartile range) in the treatment and control group, respectively (P=0.23). In the treatment group, median biofilm area was 3.65 (3.22–4.21) log<sub>10</sub>  $\mu$ m<sup>2</sup> compared with 4.49 (4.27–4.52) log<sub>10</sub>  $\mu$ m<sup>2</sup> in the control group (P=0.031). In the treatment and control groups, the maximal biofilm thickness was 48.3 (26.7–71.2)  $\mu$ m (median and interquartile range) and 88.8 (43.8–125.7)  $\mu$ m, respectively. The minimal thickness in the treatment and control group was 0.6 (0–4.0)  $\mu$ m and 23.7 (5.3–27.8)  $\mu$ m (P=0.040) (P=0.017). Earlier stages of biofilm development were found in the treatment group (P<0.001). **Conclusions:** The novel CSS reduces biofilm accumulation within the tracheal tube. A clinical trial is required to confirm these findings and the impact on major outcomes.

Key words: biofilms; catheters; intubation intratracheal; pneumonia

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**Editor's Key Points** 

- During mechanical ventilation, biofilm develops on tracheal tubes
- This may contribute to ventilator associated pneumonia and obstruction of the tube
- In this study a novel device designed to remove biofilm was assessed in pigs
- The device reduced biofilm without clinical complications

Tracheal tube (TT) biofilms are multifaceted microbial communities adherent to the TT plastic surface, and embedded within an exopolysaccharide matrix.<sup>1 2</sup> TT biofilm rapidly develops during the course of mechanical ventilation (MV),<sup>3 4</sup> and it is consistently found at extubation.<sup>5 6</sup> Importantly, retained respiratory secretions often overlay TT biofilm and form a miscellaneous bio-structure within the tube.

Tracheally intubated patients may inhale pathogens dislodged from the TT biofilm,<sup>1</sup> and antibiotics exert marginal bactericidal activity against sessile pathogens.<sup>7</sup> This may lead to the development of ventilator-associated pneumonia (VAP),<sup>6 & 9</sup> especially when biofilm is allowed to mature to its final stages of development.<sup>10</sup> Moreover, retained secretions and biofilm narrow the TT internal lumen,<sup>11</sup> leading to an increase in airflow resistance and the patient's work of breathing.<sup>12</sup>

Thus, a few devices have been developed to hinder TT biofilm formation. TTs coated with silver deter the initial adherence of pathogens on the TT surface. In laboratory<sup>3 4</sup> and clinical trials<sup>13–15</sup> silver-coated TTs have shown delayed biofilm formation. Yet, the efficacy of coated TTs seems to weaken over time,<sup>16</sup> as colonized mucus builds up within the TT. Dedicated apparatus, such as the Mucus Shaver,<sup>17</sup> or similar devices,<sup>18 19</sup> have been used to remove secretions and biofilm from the TT. Nevertheless, all of these devices are used after TT suctioning and require disconnection from the ventilator circuit.

A novel closed suctioning system (CSS) has been developed to dislodge TT biofilm, through high-pressure jets of saline and an inflatable balloon, and to aspirate respiratory secretions and biofilm debris. Here we report the results of a randomized laboratory study, in mechanically ventilated pigs with *Pseudomonas aeruginosa* pneumonia to compare the efficacy and safety of the novel device with standard CSS, in the prevention of TT biofilm formation.

#### **Methods**

The Institutional Ethics Committee approved the protocol. Animals were managed according to the National Institutes of Health guidelines for the use and care of animals.<sup>20</sup> Full methodological details are provided in the online supplement and relevant aspects of the ARRIVE guidelines were adhered to.

#### Animal preparation and handlings

Eighteen Large White–Landrace female pigs (weight, 32.6 (2.9) kg) were induced, intubated with a 7.5 internal diameter (ID) TT (Hi-Lo EVAC, Covidien, Boulder, CO) and connected to a mechanical ventilator (SERVO-I, Maquet, NJ). Sedation and analgesia were maintained as previously reported.<sup>21</sup> Internal TT cuff pressure was maintained through a mechanical device.<sup>22</sup> Pigs were ventilated in volume-control, and PEEP and respiratory rate adjusted to maintain arterial partial pressures of oxygen and carbon dioxide within the physiological range. Inspiratory gases were conditioned through a heated humidifier (Conchatherm III, Hudson RCI, Temecula, CA). Ceftriaxone was administered throughout the study to prevent endogenous colonization. We surgically cannulated the femoral artery for systemic arterial pressure monitoring and collection of blood samples. Additionally, a Foley catheter was introduced into the bladder, through mini-pelvectomy. After surgical preparation, pigs were placed in lateral Trendelenburg  $(-5^{\circ})$  position. Every 6 h, the animal was turned from one lateral side to the other.

#### Randomization

Pigs were randomized as described in the online supplement into the following groups:

- CONTROL GROUP: Tracheal suctioning was performed using a 12-Fr standard CSS (KIMVENT\* Closed Suction Systems, Kimberly Clark, Irving, TX), as clinically recommended.<sup>23</sup>
- TREATMENT GROUP: The novel 12-Fr CSS (Airway Medix Closed Suction System, Biovo Technologies, Israel) was used as illustrated in Fig. 1. Before the beginning of the study, all investigators underwent training to learn how to operate the device.

In both groups, tracheal suctioning was performed every 6 h, or when clinically indicated by visible secretions within the TT;



Fig 1 During operation, the catheter was advanced up to the proximal trachea to aspirate retained secretions. Then, it was pulled back to the tip of the tracheal tube and its distal balloon inflated with saline to adhere against the tracheal tube wall. Finally, it was gently withdrawn, while saline jets and aspiration operated simultaneously to displace biofilm and remove biofilm debris. (A) The Airway Medix Closed Suctioning System; 1, vacuum connection port; 2, aspiration handle; 3, saline infusion connection port; 4, protective plastic sheet; 5, lavage line; 6, hinged valve to isolate catheter tip between applications; 7, Y-piece connector part; 8, tracheal tube connection piece; 9, catheter tip. (B) The distal balloon is inflated with saline instilled at high pressure, through a custom-made syringe pump; thus, fluid jets are generated through minute holes at the proximal portion of the balloon, and projected toward the tracheal tube wall. (c) The balloon is inflated within the tracheal tube to adhere against its wall; then, the catheter is gently pulled back, while saline jets and aspiration operate simultaneously to displace biofilm and continuously aspirate biofilm debris via the suction openings, proximal to the balloon. Of note, the suction holes are located before the inflatable balloon.

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