Evaluation of a novel endotracheal tube suctioning system incorporating an inflatable sweeper

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Introduction: Accumulation of secretions in an endotracheal tube can increase the resistance to flow resulting in an increased patient work of breathing when the patient is interacting with the ventilator. Retained secretions can also serve as an infection risk. Standard suction catheters are limited in their ability to keep the lumen of the endotracheal tube clear. A novel closed-suction catheter has been introduced that incorporates a balloon at its distal end that, when inflated, physically scrapes secretions out of the endotracheal tube (CleanSweep catheter (CSC), Teleflex, Morrisville NC). We hypothesized that the CSC would be more efficient at removing secretions from inside the endotracheal tube than a standard suction catheter (SSC).

Methods: We performed a bench study examining resistive pressures across different sizes of endotracheal tubes when cleaned by the CSC as compared with an SSC. This study was followed by a prospective crossover study again comparing the CSC with an SSC in intubated intensive care unit patients receiving mechanical ventilation and requiring frequent suctioning.

Results: For the bench study the CSC was significantly better in reducing airway resistive pressures ($P < 0.001$). In the prospective crossover study the CSC over 2 h also removed significantly more secretions than the SSC ($P < 0.05$).

Conclusion: Both our bench and crossover clinical study demonstrated improved clearance of secretions with the CSC vs an SSC. Further research is needed to ascertain the clinical outcome benefits of enhanced secretion removal.

Key Words: *endotracheal tube; secretions; suction catheter; ventilation; peak pressure; plateau pressure*

INTRODUCTION

The endotracheal tube (ETT) is a life-saving device that can help protect the natural airway and that allows delivery of mechanical ventilator support. Unfortunately, these tubes compromise normal glottic function, impede coughing, and impair normal airway secretion clearance. Consequent secretion retention in the lungs and in the tube can serve as a bacterial breeding ground and can produce significant airway obstruction with consequent elevations in a patient's work of breathing when the patient is interacting with the ventilator [1, 2]. These all have the potential to prolong the need for mechanical ventilator support [3, 4].

ETT suctioning devices have been used for decades to facilitate secretion removal during mechanical ventilation [2, 5–8]. While these devices can clearly remove secretions, the impact on clinical outcomes has not been carefully studied [8]. Indeed, these catheters have significant downsides: secretion removal is restricted to only regions near the catheter tip, tracheal stimulation can elicit unfavorable hemodynamic conditions and central nervous system reflexes (e.g., fluctuations in intracranial pressure), the catheter can traumatize the airways (and perhaps even stimulate secretion production), the applied negative pressure can create distal airway collapse and hypoxemia, and the procedure can cause considerable discomfort [2, 9]. Opening the ventilator circuit to insert the suction device can also cause a loss of positive end-expiratory pressure (PEEP) and an increase in pneumonia risk [6]. This latter issue has prompted the development of closed-suction catheters that are integrated into the ventilator circuit [6].

Strategies to make the suctioning process more effective can potentially improve lung function and also reduce the need for recurrent suctioning. Examples of such strategies include novel catheter tip designs and multiple small catheters imbedded in the ETT wall [10–13]. Perhaps the most direct approach is to use mechanical devices to physically extract airway secretions out of the tube. First described using standard Fogarty catheters [14], more modern versions use a variety of catheter designs to physically "scrape" the inside of the ETT [15–19]. These devices generally enhance the efficiency of secretion clearance but, unfortunately, they are usually standalone catheters requiring circuit disruption for use and the need for a separate suction system.

A novel closed-system suctioning device with an integrated inflatable balloon at its tip was recently introduced (CleanSweep Teleflex, Morrisville NC). The balloon is not designed to be inflated with the catheter beyond the distal end of the ETT, and it is only inflated during catheter withdrawal thus "sweeping" the secretions off the interior wall of the ETT (Figure 1). Theoretically this design has appeal in regards to potentially enhancing secretion removal. The question we want to answer is whether the CleanSweep suction catheter is more efficient for secretion removal than the standard suction catheter (SSC; Halyard, Alpharetta, Georgia) that is currently being used at our institution. This study would be performed firstly in a bench model followed by a crossover clinical design in mechanically ventilated patients requiring frequent suctioning.

METHODS

Bench study

In this bench study, the CleanSweep catheter (CSC) was compared with an SSC. The systems were connected through a standard mechanical ventilator circuit (ISO-Gard, Teleflex, Morrisville, North

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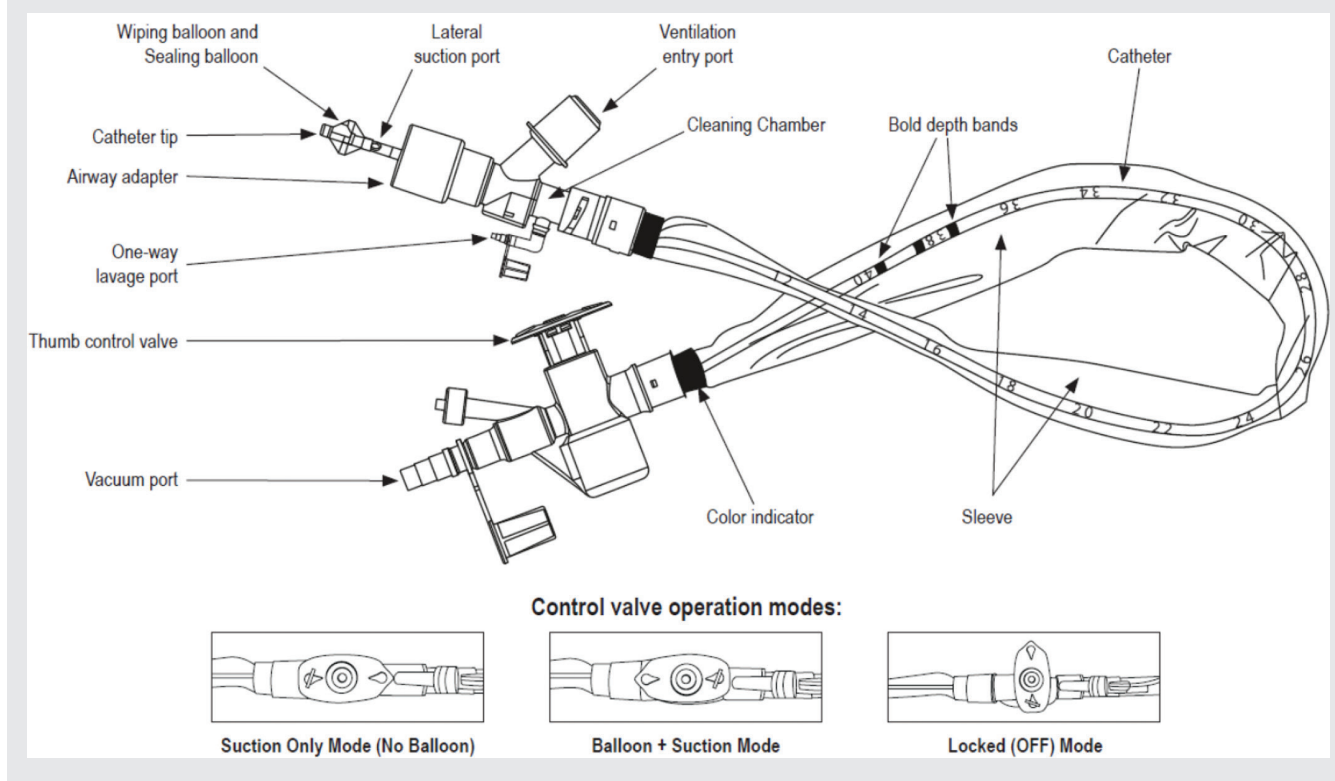
FIGURE 1

CleanSweep suction catheter. Courtesy of teleflex.

Carolina) to a mechanical ventilator (Getinge Servo-i) with the following settings: volume assist control mode, tidal volume (VT) 500 mL, respiratory rate (RR) 12/min, PEEP 5 cm H_2O, inspiratory time (Ti) 0.8 s, Ti rise 0.40 (resulted in a constant flow of 50 L/min). The distal end of the ETT was connected to an Ingmar single chamber test lung with a resistance setting of 5 cm H_2O/L/s. An upper airway model (Biovo Tecnologies, Rosh HaAyin, 4809173, Israel) was used and the head was positioned at approximately 30 degrees (Figure 2). ETTs (Mallinckrodt Covidien, Boulder, Colorado) of three different diameters (7.0, 7.5, and 8.0 mm) were used.

Artificial mucus was created based on a study published by Rozycki et al. [20] using Polyox water-soluble resin N-750 solution (Dow Chemicals, Woodbury, New Jersey) at a 2.5% concentration. The artificial mucus was made by heating 200 mL of water to 95–97°C and adding 2.5 g of Polyox per 100 mL of water. The solution was placed on a vibrating mixer for 2 h until the solution was homogeneous. The artificial mucus was dyed blue to enhance visualization [18]. Three millilitres of the artificial mucus was inserted into the ETT, and once the peak pressure stabilized (5–10 breaths) airway pressures (peak pressure (Ppeak) and plateau pressure (Pplat)) were recorded. Following mucus insertion, suctioning was performed using both catheters in random order (initial and follow-up suction). The suction catheter (14 French) was inserted past the distal end of the ETT and suction was applied at –120 mm Hg for 5 s while withdrawing the catheter. With the CSC, the balloon was deflated during catheter insertion and inflated once the catheter was in place. After each suctioning airway pressure measurements were repeated.

Five runs on each size ETT using each system as both an initial and follow-up device were carried out. Five additional runs on a 7.0 mm ETT were made alternating between the suction systems with size 12 French catheters. Each individual catheter was cleaned and reused one time.

Mucus volume and airway pressure measurements under each test condition were averaged and differences between the catheter systems were analyzed using two-sided paired *t*-test for each testing condition. Significance was taken at $P < 0.05$.

Prospective crossover study

The prospective crossover study was approved by the Duke Institutional Review Board (Pro00087066). Eight intubated mechanically ventilated patients requiring frequent (<q2h) suctioning were recruited from August 2018 to February 2020. Inclusion criteria required clinical stability (i.e., no intravenous pressors or ionotropes, no neurologic injury, and unchanged ventilator settings in the previous 24 h).

The study was a randomized crossover design with patients serving as their own control. After obtaining informed consent from either the patient (if mental status was deemed appropriate by the principal investigator) or the legal authorized representative, patients received a standard suctioning procedure using our usual SSC system already in place. The initial test catheter was then chosen randomly and put in place. Baseline measurements of Ppeak and peak expiratory flow were obtained from the ventilator monitors. Ventilator settings were not changed during the duration of the study. None of the patients received physiotherapy, and medication administration did not change during the duration of the study. The study was carried out in the 7 am–7 pm time frame during which no procedures or transports were scheduled.

Patients were suctioned q1h using both catheters for separate 2-h periods. To clear the suction catheters (both CSCs and SSCs) 2 cc NS was suctioned after each suctioning procedure to clear the catheters. Measurements of Ppeak, peak expiratory flow, total secretion volume (from sputum trap), and total secretion weight were recorded after each 2-h session. Secretions were weighed using a calibrated scale (Mitutoyo America Corporation FX-3000, Aurora, Il, USA). Comparisons were

FIGURE 2

An upper airway model (Biovo Tecnologies, Rosh HaAyin, 4809173, Israel).

analyzed with paired *t*-tests and a one-sided paired sign test (i.e., based on the bench study, the hypothesis was that the CSC is better than the SSC). A *P* value < 0.05 was considered significant.

In addition, immediately after the crossover from one catheter to the other, an additional suction procedure with the new catheter was performed and measurements were repeated (post-crossover values). In the last four subjects an additional immediate suction procedure was done at the end of the study period and measurements were repeated and treated as additional post-crossover values. Data were analyzed by unpaired *t*-tests. A *P* value < 0.05 was considered significant.

<div align="center">RESULTS</div>

Bench study

Table 1 shows the mean (± SD) cm H_2O peak–plateau pressure changes with each suctioning system as well as the differences (CSC–SSC values). Under all testing conditions, the CSC was significantly (often several fold) better than the SSC in reducing airway resistance (Ppeak–Pplat) pressures (*P* < 0.001).

Prospective crossover study

Table 2 shows patient demographics. All patients tolerated the procedures well and all completed the study. During the 2-h suctioning periods, the average total volume and weight of suctioned secretions were slightly but not significantly higher with the CSC device (Table 3). However, both secretion volume and weight increased with the CSC

TABLE 1

Changes in peak pressure minus plateau pressure (cm H_2O).

	CSC	SSC	CSC – SSC
14 Fr, 8.0 mm tube, initial	−9.0 (3.1)	−4.0 (1.87)	−5.0
14 Fr, 8.0 mm tube, follow-up	−11.6 (2.1)	−1.6 (1.1)	−10.0
14 Fr, 7.5 mm tube, initial	−19.2 (4.8)	−11.4 (3.0)	−7.8
14 Fr, 7.5 mm tube, follow-up	−15.2 (2.6)	−4.0 (0.7)	−11.2
14 Fr, 7.0 mm tube, initial	−34.6 (7.0)	−14.6 (9.5)	−20.0
14 Fr, 7.0 mm tube, follow-up	−24.6 (5.5)	−3.6 (1.5)	−21.0
12 Fr, 7.0 mm tube, initial	−33.2 (12.1)	−18.4 (6.0)	−14.8
12 Fr, 7.0 mm tube, follow-up	−19.8 (3.3)	−4.2 (2.2)	−15.6

Note: All data are presented as mean (SD). All differences were P < 0.001.
CSC = CleanSweep catheter, SSC = Standard suction catheter, Fr = French.

device in 7 of the 8 patients and these differences reached statistical significance (Table 3). Changes in airway pressures and expiratory flow were not significantly different after 2-h intervals of suctioning with the two devices (Table 3).

At the end of a 2-h session and immediately after the crossover to the alternate device, suctioning with the CSC device after a previous SSC suctioning period resulted in a significantly larger increase in secretion volume and secretion weight than with the SSC system immediately following the 2-h period with the CSC device (crossover data, Table 4). Maximal expiratory flows were slightly (but not significantly)

TABLE 2

Patient demographics

Subject number	Age (years)	Gender	Weight (kg)	ETT/TT size	Days on mechanical ventilation prior to study
1	48	M	61.3	8.0 TT	58
2	49	M	170.1	8.0 TT	30
3	54	M	93.4	8.0 TT	16
4	62	M	72.4	8.0 ETT	15
5	65	M	89.4	8.0 ETT	4
6	41	M	109.9	7.5 ETT	4
7	62	M	93.5	8.0 TT	6
8	45	M	113.9	8.0 TT	12
Mean	53		101		18

Note: ETT = endotracheal tube, TT = tracheal tube.

TABLE 3

Differences after 2 h of suctioning

	CSC	SSC	P
Delta peak airway pressure (cm H_2O)	−0.5 (1.6)	−0.5 (1.06)	NS
Delta peak expiratory flow (L/min)	−1.25 (7.4)	1.56 (5.5)	NS
Sputum volume (mL)	4.5 (2.3)	3.1 (1.9)	NS*
Sputum weight (g)	5.3 (2.1)	4.6 (4.0)	NS*

Note: Data are presented as mean (SD). CSC = CleanSweep catheter, SSC = Standard suction catheter. NS = Not significant.

*Seven of 8 patients had increased sputum volume and weight with CSC compared with SSC (P < 0.05).

TABLE 4

Measurements immediately after crossover to alternate catheter

	CSC after SSC	SSC after CSC	P
Peak pressure (cm H_2O)	−1.0 (0.8)	−0.2 (1.3)	NS
Peak expiratory flow (L/sec)	3.0 (4.3)	−0.2 (2.7)	NS
Sputum volume (mL)	3.1 (1.0)	0.8 (1.1)	<0.01
Sputum weight (g)	4.3 (1.6)	1.4 (1.1)	<0.01

Note: Data are presented at Mean (SD). CSC = CleanSweep catheter, SSC = Standard suction catheter, NS = Not significant.

higher after immediate crossover CSC suctioning, but peak pressures were similar with both devices.

DISCUSSION AND CONCLUSION

Secretion clearance is a mainstay of respiratory care of the mechanically ventilated patient. Secretions in the artificial airway and proximal bronchi increase airway resistance thereby increasing patient work of breathing when interacting with the ventilator. This increased resistance will also increase airway pressure in volume targeted mechanical ventilation or it may decrease tidal volume in pressure targeted mechanical ventilation. Secretion retention also means a reduced ability to expel harmful material (e.g., infectious agents, inflammatory products, foreign debris) from the lungs. The American Association for Respiratory Care (AARC) Clinical Practice Guidelines emphasize these points and offer recommendations regarding indications and proper procedures for performing endotracheal suctioning [6]. Specifically, the AARC recommends that suctioning should only be done when secretions are clinically evident, that suctioning be limited to the artificial airway and proximal bronchi, that the catheter should be less than 50% of artificial airway diameter, and that closed systems are preferable [6]. Unfortunately, evidence suggests that the use of standard suction

systems is not efficient at preserving the ETT luminal diameter [21]. This can lead to a partial ETT obstruction that can interfere with mechanical ventilation and lead to respiratory compromise [3, 22]. The CSC system does exceed the 50% threshold briefly while the balloon is inflated during withdrawal. Although the benefit may outweigh the risk, this has yet to be evaluated.

Both our bench and crossover clinical study demonstrated improved clearance of secretions with the CSC vs an SSC. In the bench study the CSC was significantly better than the SSC in reducing airway resistive pressures ($P < 0.001$). In the crossover study, despite a single outlier with an isolated large secretion bolus during one SSC suctioning event, the CSC device after a previous SSC suctioning period resulted in a significantly larger increase in secretion volume and secretion weight than with the SSC system. These are similar to results using other mechanical endotracheal tube cleaners [15–19]. Unlike these other systems, however, the CSC system is an integrated closed-suction system that does not require circuit disruption that could result in potential alveolar derecruitment and clinician exposure to pathogens.

In theory, devices that offer improved secretion clearance should provide several clinical benefits. Benefits include reduced patient work, potentially lower infection rates, and shorter duration for the need of mechanical ventilation [2]. Moreover, improved secretion clearance should reduce the need for more frequent suctioning and thus lower the risks associated with suctioning such as atelectasis, hypoxemia, and bronchospasm [6]. However, neither our study nor other studies on mechanical ETT cleaners have been designed to be long enough nor large enough to demonstrate improved clinical outcomes linked to improved secretion removal. To do this will require large expensive randomized controlled trials following many patients over long periods assessing such outcomes as hospital length of stay and even mortality.

There are some limitations to both the bench and crossover studies. For the bench study the airway model used is a reasonable representation of human anatomy but cannot mimic all of the details and variations that exist in intubated patients. Similarly, the simulated sputum is also only a representation of human sputum. It cannot mimic all of the variations in sputum characteristics seen in intubated patients. For the crossover study the low number of enrolled subjects is the primary limitation. We were, in fact, somewhat surprised with the difficulty we encountered recruiting patients. We believe there were at least two reasons for this. First, patients requiring sustained frequent suctioning (i.e., more frequent than q2h) for a prolonged period (> 7 days) were less common than we anticipated. Second, physicians (and sometimes families) were quite reluctant to allow circuit disruptions for catheter placement. This latter point underscores the importance of using closed-system suctioning systems whenever possible. Further exacerbating this recruitment issue was the onset of the COVID-19 pandemic. When this occurred, all nonessential clinical studies involving human intervention were suspended at our institution.

At the end of the day, we are left with a decision to use enhanced mechanical suctioning systems, such as the one we described, based on clinical judgment. Patients with copious secretions, prolonged ventilator requirements, and excessive work of breathing would certainly seem the most likely patients to consider as candidates as we await further studies.

DISCLOSURES

Competing interests
Mr. Davies discloses that he is a clinical consultant for Teleflex Medical. Dr. Huang discloses a financial relationship with Windtree Therapeutics. Dr. MacIntyre discloses financial relationships with Inspirx, Ventec Life Systems, and Hillrom. All authors have completed the ICMJE uniform disclosure form.

Ethical approval

The prospective, crossover study was approved by the Duke Institutional Review Board (Pro00087066). The bench study did not involve human research so Duke Institutional Review Board approval was not needed.

Contributors

All authors were responsible for (*i*) substantial contributions to the conception and design of the work and the acquisition, analysis, and interpretation of data for the work; (*ii*) drafting the work and revising it critically for important intellectual content; (*iii*) final approval of the version to be published; and (*iv*) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All authors read and approved the final version of the manuscript.

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