THE ENDOCLEAR® LIBERATOR™ CLEANING DEVICE IN Decreasing Airway Resistance

LINDA SCHOFIELD, PhD, RN | Nursing Research Coordinator
McLaren Northern Michigan | Petoskey, Michigan

RATIONALE: Mechanical ventilation is an essential, life savings therapy for patients with critical illness and respiratory failure. Studies have estimated that more than 800,000 patients receive mechanical ventilation in the United States each year. These patients are at high risk for complications and poor outcomes, including death. These complications can lead to longer duration of mechanical ventilation, longer stays in the ICU, increased health care costs, and increased risk of disability and death.

BACKGROUND

An endotracheal tube (ETT) is generally required for the management of critically ill, mechanically ventilated patients in the Intensive Care Unit. Standard of care suctioning with the use of suction catheters maintains the patency of the ETT. The effectiveness of ETT suctioning alone to maintain airway patency is questionable and ETT suctioning may also be associated with short-term physiological complications, such as lung de-recruitment and resultant hypoxemia in patients with lung injury.[1] Biofilm and mucus accumulate on the inner lumen of the ETT resulting in intra-luminal volume loss with increasing time of intubation and mechanical ventilation. Standard ETT suctioning and humidification do not prevent this build-up of mucus or biofilm.[2-5] ETT intra-luminal volume loss due to mucus and biofilm is associated with longer times on mechanical ventilation and increased rate of ventilator-associated pneumonia.[5]

STUDY DEVICE

The endOclear® Restore™ device is designed to clear the ETT of mucus and debris and to restore the luminal patency. The endOclear® Restore™ device can be used in a daily protocol to prevent the build-up of mucus and biofilm or PRN based on clinical indications. Several case studies at Massachusetts General Hospital demonstrates the device is safe; easy to use during an emergent-airway situation; and rapidly removes secretions when there is ETT is obstructed by RN and RT personnel.[7] The new endOclear® Liberator™ hybrid closed suction is a sterile in-line, 72-hour multiple use, combination wiper, and suction catheter in a closed system.

PRIMARY OBJECTIVE

The primary objective of this study was to compare the efficacy of removing adherent endotracheal tube secretions employing the closed, multi-use, inline endOclear® Liberator™ device every six hours with the efficacy of removing adherent endotracheal tube secretions with the standard of care daily, single use endOclear® Restore™ device prior to daily weaning trials.

STUDY DESIGN/STUDY ENDPOINTS

This study is an IRB approved, continuous outcome equivalence, prospective, randomized, controlled, single centered study to evaluate the efficacy of the endOclear® Liberator™ inline multi-use system (test treatment) compared to that of the original endOclear® Restore™ device (control treatment) in decreasing airway resistance. Patients that met eligibility criteria were enrolled in a 1:1 randomized ratio to receive either the test treatment (endOclear® Liberator™) cleaning device, four times per day or the control treatment.

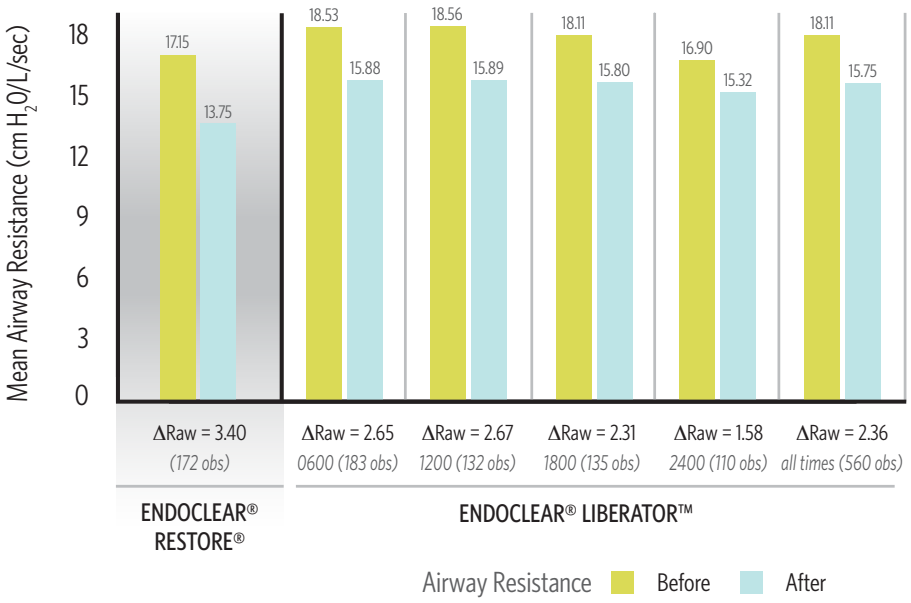
McLaren
NORTHERN MICHIGAN

RESULTS

A randomized controlled study of the endOclear® Liberator™ Closed Suction catheter demonstrated a reduction in airway resistance at all cleanings. The study group consisted of 57 subjects whose ET tube was cleaned four times per day at scheduled times and PRN as clinically indicated with the endOclear® Liberator™ device, resulting in 183 observations. The control group consisted of 57 subjects who received the standard of care using the endOclear® Restore™ device daily and PRN as clinically indicated, resulting in 172 observations. The ΔRaw at 0600 with the endOclear® Liberator™ (study group) was 2.65 $cmH_2O/L/sec$ and 3.40 $cmH_2O/L/sec$. for the endOclear® Restore™ device (control group).

endOclear® Comparison — Effect on Airway Resistance

endOclear® Restore® and endOclear® Liberator™ Device | *57 cases as of 2/25/2017*



Closed Inline endOclear® Liberator™ Device Study

2/25/2017

STATISTICAL RESULTS

	Restore	Liberator	
Mean	3.402907	2.647541	0.0755366 DELTA
Variance	33.50987	27.33976	
Observations	172	183	

COST PER SUBJECT

Subjects	57	57	
Cost	$226.51	$120.51	

The table above demonstrates that the P values are less than .05 for each device singly, indicating that the use of both devices results in a statistically significant lowering of airway resistance and, therefore, patient work of breathing.

The table to the right demonstrates mean outcome compared between two randomized groups. There was no significant difference between the two devices in the ability to decrease resistance in endotracheal tube cleaning treatment ($p<0.01$).

CONCLUSION

The endOclear® Liberator™ and the original endOclear® Restore are effective devices for removing adherent secretions from the ET, resulting in lower ETT resistance and therefore decreased work of breathing for patients after treatment with either device. The benefits of the endOclear® Liberator™ over the ECD is it can be used several times per day up to 72 hours, it is a modular device that can be used with other attachments that can be changed without losing pressures or lung volumes, and it is less costly.

REFERENCES

1. Shah, C. and M.H. Kollef, *Endotracheal tube intraluminal volume loss among mechanically ventilated patients.* Crit Care Med, 2004. 32(1): p. 120-5.
2. *The Use of a Unique Mucus Shaver Clearing Device to Improve Ventilator Weaning,* CHEST Meeting 2013, Poster Session, Schofield, L., Saur, G., Washington, J.
3. Mietto, C., et al., *Removal of Endotracheal Tube Debris Obstruction by a Clearing Secretion Device.* Respir Care, 2013.
4. Chaseling W, B. S.-L., Rose K, Armstrong L, Boyle M, Caldwel, J, Chung C, Girffiths, K, Johnson K, Rolls K and Davidson P. (2014). *Suctioning an Adult ICU Patient with an Artificial Airway: A Clinical Practice Guideline.*
5. Russian, C. J., Gonzales, J. F., & Henry, N. R. (2014). *Suction catheter size: an assessment and comparison of 3 different calculation methods.* Respiratory Care, 59(1), 32-38.
6. Sole, M. L., & Bennett, M. (2014). *Comparison of airway management practices between registered nurses and respiratory care practitioners.* American Journal of Critical Care, 23(3), 191-199; quiz 200.
7. Sole, M. L., Bennett, M., & Ashworth, S. (2015). *Clinical Indicators for Endotracheal Suctioning in Adult Patients Receiving Mechanical Ventilation.* American Journal of Critical Care, 24(4), 318-324; quiz 325.