

2015 OPEN FORUM

Presented by

RESPIRATORY CARE

Supported by an unrestricted educational grant
from



Monday, November 9; 10:00 am to 1:30 pm (Inside the Exhibit Hall)

2273051

COMPARISON OF TWO ENDOTRACHEAL TUBE CLEANING DEVICES IN REDUCING AIRWAY RESISTANCE FOR THE MECHANICALLY VENTILATED PATIENT.

Linda C. Schofield, Densie E. Burkhart, Jeffery B. Washington; McLaren Northern Michigan, Petoskey, MI

Background: Endotracheal tube (ETT) intra-luminal volume loss due to mucus and biofilm is associated with longer periods of time on mechanical ventilation and increased imposed work of breathing. Previous studies conducted at McLaren Northern Michigan hospital have demonstrated that daily cleaning of the ETT decreased the median airway resistance from 27 cmH₂O/L/sec to 15 cmH₂O/L/sec, ($p < 0.01$). This result was associated with a decrease in average time on the ventilator by 1.09 ± 4.70 days, and a decrease in the length of stay in the ICU and hospital by 1.50 ± 5.51 , and 1.72 ± 7.44 days respectively. **Purpose:** The primary objective of this study was to determine the non-inferiority of the new Mucus Shaver (MS) device in daily removal of adherent ETT secretions prior to weaning trials compared to the endOclear (ECD) device. The MS is a flexible, sterile, single use, concentric inflatable catheter and the ECD device is a rigid, sterile single use, mechanically operated wiper. **Method:** This study is an IRB approved, non-inferiority, prospective, randomized, controlled, single centered study to evaluate the efficacy of the MS device (test treatment) compared to the ECD device (control treatment). The primary endpoint of this study is the detection of a difference in airway resistance reduction (ΔR_{aw}) before and after the cleaning maneuver no greater than 3 cmH₂O/L/sec between the two treatment groups. Based on our previous study, a ΔR_{aw} of 3 cmH₂O/L/sec or less between the two groups can be considered not clinically relevant. A sample size of 170 subjects was calculated for power of 0.90 with a two-sided alpha of 0.05. Data presented as mean \pm SD.

Results: The ΔR_{aw} with the original ECD device was 1.6 ± 4.9 cmH₂O/L/sec and the ΔR_{aw} with the MS device was 1.9 ± 4.8 cmH₂O/L/sec. Non-inferiority was established after enrollment of 101 subjects (N=188/192 ECD/MS cleaning maneuvers) and the study was ended. The results of the difference between MS device and the ECD device were significantly smaller than the established non-inferiority margin of 3 cmH₂O/L/sec ($p < 0.01$).

Conclusion: The MS device is as effective as the ECD device at removing adherent secretions from the ETT prior to weaning trials, resulting in lower ETT resistance and therefore decreased work of breathing for patients after treatment with either device.

endOclear(R) and Mucus Shaver(TM) data before and after cleaning ETT

	Airway Resistance (mean cmH ₂ O/L/sec)			Peak Inspiratory Pressure (mean cmH ₂ O)			Tidal Volumes (mean ml)		SpO ₂ (mean %)	
	Before	After	ΔR_{aw}	Before	After	ΔPIP	Before	After	Before	After
endOclear®	16.93	15.29	1.6 \pm 4.9	24.40	23.43	1.0 \pm 3.2	576	580	97.95	98.38
Mucus Shaver™	16.56	14.68	1.9 \pm 4.8	24.57	23.63	0.9 \pm 3.8	623	629	98.58	98.95

Sponsored Research - We currently purchase the original endOclear device and use it daily on patients vented greater than 24 hours. The endOclear(R) Mucus Shaver (TM) was provided by endOclear LLC.