

A FIVE-YEAR STUDY TO EVALUATE Cleaning Endotracheal Tube Prior to Weaning Trials

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INTRODUCTION



An endotracheal tube (ETT) is generally required for the management of critically ill, mechanically ventilated patients in the Intensive Care Unit. Patency of the ETT is commonly maintained by standard of care suctioning with the use of suction catheters. The effectiveness of ETT suctioning alone to maintain airway patency is questionable. ETT suctioning may be associated with short-term physiological complications, such as lung de-recruitment and resultant hypoxemia in patients with lung injury. Biofilm and mucus accumulate on the inner lumen of the ETT with increasing time of intubation and mechanical ventilation. Standard ETT

suctioning and humidification do not prevent this build-up of mucus or biofilm. ETT intra-luminal volume loss due to mucus and biofilm is associated with longer period of time on mechanical ventilation and increased rate of ventilator-associated pneumonia.

PURPOSE

The primary objective of this study was to compare objective outcome measures before and after implementing a daily ETT cleaning protocol with the endOclear® Restore™ device. The daily ETT cleaning protocol was initiated at 0600 and consisted of suctioning of the endotracheal tube following the standard of care protocol followed by cleaning the ETT with the endOclear® Restore™ device. Appropriate documentation was completed following the cleaning.

DEVICE

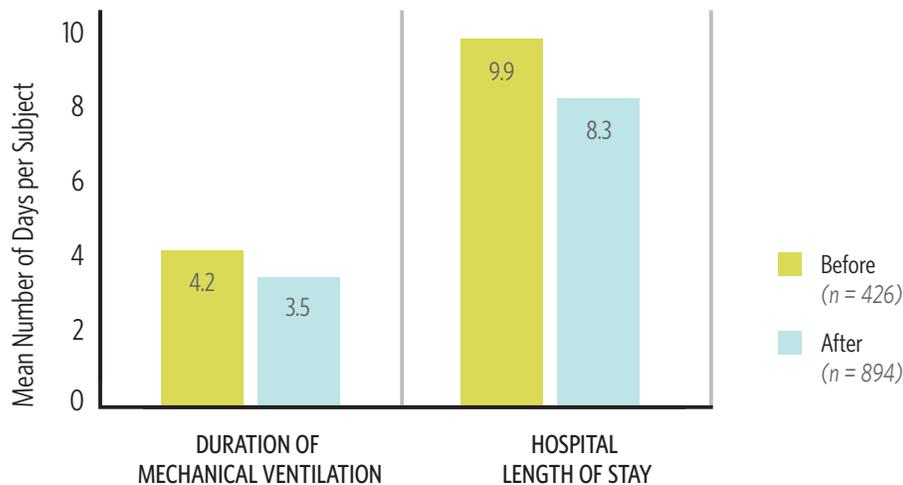
The endOclear® Restore™ device is a sterile, single use, mechanically operated wiper designed to remove adherent ETT secretions and biofilm left behind after standard of care suctioning and restoring the ETT luminal patency. The endOclear® device can be used in a daily protocol to prevent the build-up of mucus and biofilm. The device is listed with the U.S. Food and Drug Administration as a Class 1 device (510(K) exempt.).

METHOD

This is an IRB approved, five-year retrospective, observational, single centered study to evaluate the efficacy of cleaning the ETT daily with the endOclear® Restore™ device prior to the spontaneous breathing trial. The primary endpoints are average duration of mechanical ventilation, average hospital length of stay, and average hospital direct cost per subject.

RESULTS

The results of cleaning the ETT before weaning trials were supported by this five-year, retrospective, observational study of 1,320 subjects on mechanical ventilation greater than 24 hours. Data was collected on 426 subjects prior to using the daily ETT cleaning protocol and 894 subjects after implementing the protocol. This resulted in a decrease in average time on the ventilator from 4.2 to 3.5 days (0.7 ± 0.8 , $p < 0.01$), a decrease in length of stay in the hospital from 9.9 to 8.3 days (1.6 ± 1.9 , $p < 0.01$), and a decrease in direct cost per case from \$13,101 to \$12,024 ($\$1,077 \pm 2,784$, $p < 0.15$), a total of \$926,838 net benefit. Data is presented as mean \pm SD.



CONCLUSION

This study demonstrates the importance of the removal of adherent ETT secretions after 24 hours of mechanical ventilation. Removal of adherent secretions with the endOclear® Restore™ device should be done every day prior to the time of the spontaneous breathing trial. Cleaning the ETT daily can return the ETT to nominal performance and maximum potential for decreased time on the ventilator and shorter length of hospital stay.

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