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Evaluation of a Closed Suction System with Integrated Tube Scraping Technology: A Randomized Controlled Trial

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Abstract

BACKGROUND: Endotracheal tube (ETT) scraping or sweeping refers to mucus removal from an ETT that can increase airway resistance. The study objective was to evaluate the effect of ETT scraping on the duration of mechanical ventilation (MV), time to first successful spontaneous breathing trial (SBT), duration of hospital stay, and occurrence of ventilator-associated events (VAE).

METHODS: This was a single-center, randomized clinical trial of adult subjects intubated between October 2019 and October 2021. Subjects were randomly assigned to either ETT suctioning via a standard in-line suction catheter (control group) or ETT suctioning and scraping via a suction catheter with balloon sweeping technology (experimental group). Airway suctioning was performed as clinically indicated, and ETT was scraped every time a respiratory therapist suctioned the patient. The study outcome was duration of MV, time to first successful SBT, hospital stay, and VAE rate. Intent to treat statistical analysis was performed.

RESULTS: Of 272 randomized subjects, the median age was 63 (IQR 52-73) years, 143 (53%) were males, and 154 (57%) had a primary diagnosis of acute respiratory failure. There were no significant differences between the groups in median duration (hours) of MV [72.2 (37-187) vs 70.6 (37-148); $P = 0.58$]. There was no significant difference between the study groups in median time (hours) to the first successful SBT [46.7 (IQR 30-87) vs 45.7 (IQR 27-95), $P = 0.81$], length of hospital stay ($P = 0.76$), the incidences of ventilator-associated conditions ($P = 0.13$), or infection-related ventilator-associated complications ($P = 0.47$).

CONCLUSION: ETT suctioning plus scraping, compared to ETT suctioning alone, did not significantly improve the duration of mechanical ventilation, time to first successful SBT, length

of hospital stay, and VAE. These study findings do not support the routine use of ETT scraping for mechanically ventilated patients.

Keywords: *Biofilm; VAP (ventilator-associated pneumonia); airway obstruction; mechanical ventilation; secretion clearance; endotracheal tube*

Trial Registration: ClinicalTrials.gov Identifier: NCT03868735

Rush University Medical Center IRB approval: ORA #: 20051302-IRB01

INTRODUCTION

Artificial airway management is essential care for critically ill patients. A component of airway management is the assurance that artificial airways remain clear of secretions and biofilm that can decrease the intraluminal diameter, resulting in an increase in airway resistance or even a total airway occlusion.[1-5] Evidence suggests that standard suctioning devices cannot prevent secretions and biofilm from narrowing artificial airways, such as endotracheal tubes (ETTs); thus, devices specifically designed to clear and maintain the nominal function (by sweeping or scraping) of ETTs have been developed.[3,5,6]

Several studies have demonstrated that these ETT clearance devices are effective at reducing luminal biofilm secretions and the resultant increase in airway resistance (R_{AW}).[4,7-10] Randomized controlled trials by Pinciroli et al[2] and Berra et al[10] have demonstrated that compared to standard suctioning, the devices can reduce mucus accumulation and overall biofilm thickness. However, when evaluated cumulatively, the evidence has yet to confirm that ETT clearance devices improve important clinical outcomes such as prevention of ventilator-associated events (VAE), mechanical ventilation days, and days in the intensive care unit.[1,3]

Since the studies evaluating the impact of ETT clearance devices have been laboratory, observational, or relatively small randomized trials, we designed a large randomized trial to understand better the role of ETT scraping on patient outcomes. The primary aim of this study was to evaluate the effect of ETT scraping on the duration of mechanical ventilation (MV). The secondary aims of this study were to assess ETT scraping on time to first successful SBT, duration of hospital stay, and occurrence of VAE.

METHODS

This was a single-center, prospective, randomized clinical trial conducted at an academic medical center between October 2019 and October 2021. Adult subjects (18 y or older) who were admitted to the medical intensive care unit and received mechanical ventilation via an endotracheal tube (ETT) for at least 24 hours were included in the study. Any subject who was pregnant, received mechanical ventilation via tracheostomy, required extracorporeal membrane oxygenation, or transferred from an outside facility receiving more than 24 hours of mechanical ventilation was excluded. The study protocol was approved by our institutional review board (ORA# 20051302-IRB01) and the study was registered on clinical trials.gov (NCT03868735).

Randomization

Study eligible subjects were randomly assigned in a 1:1 ratio to either the standard ETT suction catheter or the experimental ETT suction catheter with balloon sweeping technology (CleanSweep™ Closed Suction System, Teleflex Inc.). Randomization was computer-generated, and the generated numbers were placed in a sealed opaque envelope. Each study envelope was opened in sequential order by the study team. Subjects and clinicians involved in the care were not blinded to the study assignment after enrolment.

Experimental Group

In the experimental group, an ETT suction catheter equipped with balloon sweeping technology (**Figure 1a and 1b**) was placed on eligible subjects within 24 hours of intubation. The suction catheter size was estimated by multiplying the ETT's inner diameter by two and using the next smallest size catheter. For example, a subject with 8.0 ETT was given a 14Fr suction catheter. The ETT was cleaned with the balloon sweeping technology every time a respiratory therapist suctioned the patient's airway. Airway suctioning was performed per department policy (catheter

advanced until resistance is met and withdrawn slowly for a duration no longer than 15 seconds while applying negative pressure). The frequency of airway suctioning was determined based on the patient's clinical need. Suction catheters were changed if visibly soiled or every seven days per departmental policy. The clinical team screened each subject daily to undergo a spontaneous awakening trial and a spontaneous breathing trial, conducted using an institutional protocol. A subject was considered to have a successful SBT if they tolerated 30-minute SBT with a rapid shallow breathing index < 105. The extubation was performed based on the medical team's decision.

Control Group

In the standard group, a standard suction ETT catheter was placed on eligible subjects within 24 hours of intubation. Airway suctioning was performed using a regular suction catheter per department policy, and the frequency of suctioning was determined based on the patient's clinical need. Suction catheters were changed if visibly soiled or every seven days per departmental policy. Each subject was screened daily by the clinical team to undergo a spontaneous awakening trial and a spontaneous breathing trial, conducted using an institutional protocol. A subject was considered to have a successful SBT if they tolerated 30-minute SBT with a rapid shallow breathing index < 105. The extubation was performed based on the medical team's decision.

VAE prevention bundle

Both the study groups received a ventilator bundle that consisted of maintaining the head of bed elevation ≥ 30 degrees, ETT cuff pressure > 20 cm H_2O, deep vein thrombosis prevention, daily sedation interruption and SBT, and oral care every 4 hours with chlorhexidine at 12 pm (noon) and 12 am (midnight).

Data Collection

Subject's demographic characteristics, body mass index (BMI), primary diagnosis, sequential organ failure assessment (SOFA) score, reason for intubation, and ETT size were recorded at the enrolment. Data related to lung protective strategy, airway suctioning, VAE prevention bundle, spontaneous awakening trial and SBT was collected for the duration of MV. Ventilator associate condition (VAC) and infection related ventilator associated condition (IVAC) data were obtained from the infection control department. Ventilator duration, need for reintubation, use of non-invasive ventilation post extubation, length of ICU, and hospital stay were recorded. No follow-up data were recorded. Data were collected from subjects' electronic medical record and captured using REDCap, a secure data collection platform.

Outcomes

The primary outcomes was the duration of mechanical ventilation. The secondary outcomes were time to first successful SBT, extubation outcome (defined as need for non-invasive ventilation (NIV) or reintubation within 48 hours of planned extubation), length of intensive care unit (ICU) stay, length of total hospital stay, and occurrence of ventilator-associated events (VAC and IVAC). VAC and IVAC were defined based on the CDC's National Healthcare Safety Network guidelines (https://www.cdc.gov/nhsn/pdfs/pscmanual/10-vae_final.pdf, *Accessed December 1, 2022*)

Statistical Analysis

Based on previous institutional data, the length of mechanical ventilation was noted to be approximately 6.3 days (SD ±3.64). To achieve a clinically significant 20% reduction in the length of mechanical ventilation (6.3 x 0.20 = 1.26 days), 136 subjects were needed in each group with alpha at 0.05 and power of 0.80. The categorical variables are presented as frequency

and were analyzed using Chi-Square or Fisher's exact test. Continuous variables are presented as mean (SD) or median (IQR) based on the normal distribution and analyzed using T-test or Mann-Whitney test. Intent to treat and per-protocol analysis was performed. Intent to treat analysis included all randomized subjects, whereas, per protocol analysis included all randomized subjects who received planned non-terminal extubation. A p-value of < 0.05 was considered significant and data analysis was conducted using SPSS 26.0 for Windows (SPSS, Inc., Chicago, IL, USA).

RESULTS

A total of 417 subjects were assessed for study eligibility, 145 subjects were excluded, and 272 subjects underwent randomization; 136 were assigned to the standard group and 136 to the ETT scraping group (**Figure 2**). The baseline characteristics of the subjects are presented in **Table 1**. Study participants' median age was 63 years, 143 (52.6%) were males, median BMI was 29, median SOFA score was 6, and 108 (39.7%) were African American. The primary diagnosis was hypoxemic respiratory failure among 131 (48.2%), and the main indication for initiating mechanical ventilation was acute respiratory failure in 178 (65.4%) subjects. The median ETT size was 7.5, and a lung protective ventilation strategy was used for 207 (76%) subjects. The subject baseline characteristics did not differ significantly between the two study groups.

Before extubation or tracheostomy, the median number of ETT suctioning performed in the standard group was 13 (IQR 4-39) and 14 (IQR 5-34) in the ETT scraping group. The overall ETT suctioning frequency did not differ significantly between the two groups. However, the ETT suctioning frequency per ventilator day was significantly higher for the ETT scraping group [5 (IQR 3-8) vs. 4 (IQR 3-5); $P = 0.031$]. The median number of endotracheal scrapings was 4

(2-9) in the ETT scraping group, with an average of 1 (IQR 1-2) scrapings per ventilator day. The application of the VAE prevention bundle, including cuff pressure management, and head of bed elevation, was similar between the groups.

Primary Outcomes

In the intent-to-treat analysis that included 136 subjects in each group, no significant difference in the length of mechanical ventilation (hours) was observed between the two study groups; 72.2 (IQR 37-187) in the standard group and 70.6 (37-148) in the ETT scraping group ($P = 0.58$; **Table 2**).

Secondary Outcomes

In the intent-to-treat analysis, there was no significant difference in the pre-defined secondary outcomes between the study groups. For subjects who received standard ETT suctioning, the time to first successful SBT (hours) was 46.7 (IQR 30-87) as compared to 45.7 (IQR 27-95) in the ETT scraping group ($P = 0.81$). A total of 14 (10.3%) subjects required NIV or reintubation in the standard group and 20 (14.7%) in the ETT scraping group ($P = 0.38$). The median days in ICU [standard group 9 (IQR 4-20) vs ETT scraping group 7.8 (IQR 4-18); $P = 0.62$] and hospital [standard group 14.7 (IQR 8-26) vs ETT scraping group 13.9 (IQR 8-25); $P = 0.76$] were not significant between the two groups. A higher number of subjects in the ETT scraping group developed VAC (11.8% vs. 6.6%) and IVAC (8.8% vs. 6.6%) as compared to the standard group, but no significant difference was observed.

Per Protocol Analysis

Per protocol analysis of the primary outcome was consistent with the main analysis, with no significant difference noted in the duration of mechanical ventilation (hours) between the two study groups [Standard group 63 (41-164) vs. ETT scraping group 62 (36-138); $P = 0.61$; **Table**

3]. There were also no significant differences in the time to the first successful SBT, need for NIV or reintubation, ICU and hospital length of stay, and occurrence of VAC or IVAC between the two study groups (**Table 3**).

Additional Analysis

Intent to treat analysis among subjects intubated for more than 48 hours did not show any significant differences in the primary or secondary study outcomes (**Supplementary Table 4**).

DISCUSSION

Our findings suggest that ETT scraping with an ETT suction catheter with balloon sweeping technology, compared to standard ETT suctioning, did not significantly improve patient outcomes. Results were similar between the intent to treat and the per-protocol analysis after excluding patients who did not receive planned extubation. These findings are clinically significant as they provide more insight into when and how ETT cleaning devices should be utilized. Our study suggests that these devices do not need to be used routinely as a part of an airway management regimen. Instead, these devices could be used in select patients with evidence of ETT luminal narrowing as noted by an increase in R_{AW} or the need for prompt removal of an ETT occlusion by secretions.

Similar to a study conducted in 2017 evaluating an ETT tube clearance device on $R_{AW,}$ our findings were that ETT cleaning had no impact on SBT success.[4] In that study, the mean pre-and post-ETT scraping R_{AW} was 15.17 ± 3.83 and 12.05 ± 3.19 cm H_2O/L/s, respectively ($P < .001$). The change in R_{AW} had no impact on subsequent SBT success. Interestingly, while a decrease in approximately 3 cm H_2O/L/s was noted as the mean change in R_{AW}, it was evident in the study data that some subjects had no change in R_{AW} pre- and post-ETT scraping, while others had as

much as a 10 cm H_2O/L/s decrease.[4] The duration of time on the mechanical ventilator had no noticeable impact on the R_{AW} pre- and post-ETT scraping change.[4] This is in alignment with a paper published by Wilson et al that demonstrated that an increase in ETT R_{AW} from secretions is unpredictable regarding the duration of intubation.[11] Our supplementary data among patients intubated for more than 48 hours and potentially at high risk of developing mucus buildup/biofilm also did not demonstrate a significant clinical benefit from the routine ETT scraping.

Other studies have also sought to evaluate if ETT scraping devices impact bacterial colonization of ETTs and related effects. Pinciroli et al performed microbiological testing on ETTs that were collected from patients that received ETT scraping every 8 h, or standard suctioning per institutional standard. They found that ETT cleaning reduced the amount of ETTs that contained no bacteria when compared to the standard suctioning group.[2] Additionally, ventilator associated penumonia-causing microorganisms were less likely to be found in cleaned ETTs, but not by a statistically significant amount. While promising regarding how this might impact patient outcomes, no differences were found between mean days of mechanical ventilation and days in the ICU between the control and treatment groups.[2] Bardes et al evaluated ETTs treated daily with a tube cleaning device and found no significant differences in tidal volumes, peak pressures, and airway resistance in patients treated with the ETT cleaning devices versus those not. Interestingly, in regards to pneumonia, the device group (n = 11) had almost twice the number of cases of pneumonia as the control group (n = 6), but the difference was not statistically significant (P = .36).[12] Pirrone et al evaluated the impact of ETT cleaning on silver-coated ETTs. Of 36 ETTs (18 control, 18 treatment) and 29 tracheal samples, it was noted that ETT cleaning devices did not reduce bacterial colonization of ETTs (15 vs 9, P = .18), microbial load (1.6 ±

1.2 vs 0.9 ± 1.2 logCFU/mL, *P* = .15), biofilm deposition (439.5 ± 29.0 vs 288.9 ± 157.7 mg, *P* = .09), positive tracheal aspirates (13 vs 10, *P* = .39), or in microbial load of tracheal secretions (4.8 ± 4.0 vs 4.2 ± 3.8 logCFU/mL, *P* = .70). They concluded that when compared to standard suctioning, ETT cleaning did not decrease bacterial colonization of ETTs and did not lower respiratory tract colonization.[13] Differences in VAE between groups in our study did not reach significance, and this study was not powered to detect a difference in VAE. Future clinical trials should be powered to determine if there is a risk associated with routine ETT scraping.

This study has several limitations. First, this was a single-center study with institutional-specific ventilation weaning protocols. Second, the treatment allocation could not be blinded to the clinicians, which might have led to a bias due to clinicians being aware of the experimental device. Third, ETT suctioning and scraping were done at clinicians' discretion based on their clinical patient assessment, as the study protocol did not dictate a specific ETT cleaning time or pattern. However, although noted as a potential limitation, we felt it necessary to leave the decision to suction and subsequently clean the artificial airway suctioning at the discretion of the respiratory therapist based on their assessment of the patient, departmental policy, and reflecting actual clinical practice. Finally, all patients in the experimental group received ETT scaping when suctioned by the respiratory therapist. Future research should focus on ways to identify patients with a clinically significant amount of R_{AW} (> 10 cm H_2O/L/s)[4,14] from secretions and biofilm and the impact of ETT scraping on their clinical outcomes.

CONCLUSION

Our results suggest that the use of ETT suctioning plus scraping, compared to ETT suctioning alone, does not significantly improve the duration of mechanical ventilation, time to first successful SBT, length of hospital stay, or occurrence of VAEs. These study findings do not

support the routine use of ETT scraping for mechanically ventilated patients, and future studies are needed to identify patients who can benefit from ETT cleaning.

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Figure Legends:

Figure 1a: CleanSweep Closed Suctioning System

Figure 1b: Inflated scraping balloon

Figure 2: Study Flow Diagram

Quick Look

Current Knowledge

Endotracheal tube narrowing due to secretion accumulation or biofilm formation can increase airway resistance or even cause total airway occlusion. ETT clearance devices have shown to be effective at reducing luminal biofilm secretions and airway resistance.

What This Paper Contributes To Our Knowledge

This randomized controlled trial compared the use of ETT suctioning plus scraping to ETT suctioning alone among adult subjects receiving mechanical ventilation. ETT suctioning plus scraping reduced the duration of mechanical ventilation, time to first successful SBT, length of hospital stay, or occurrence of VAEs when compared to ETT suctioning along. This study does not support the routine use of ETT scraping devices in mechanically ventilated patients.

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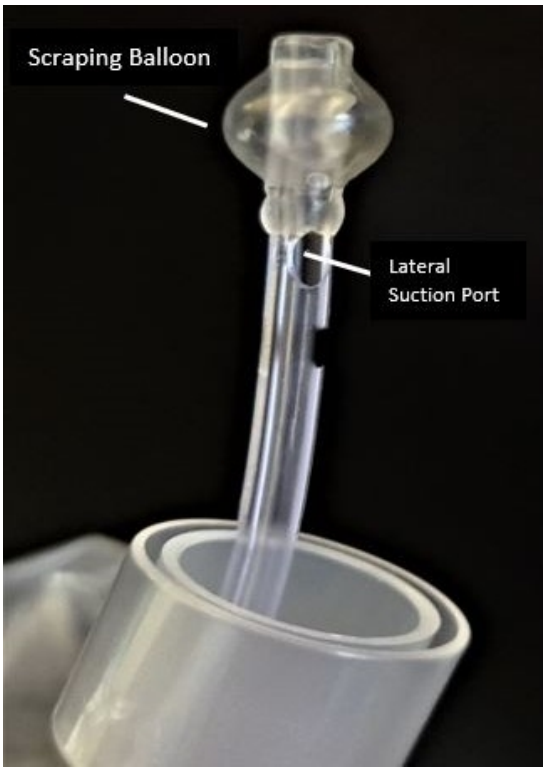

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Figure 2 Study Flow Diagram

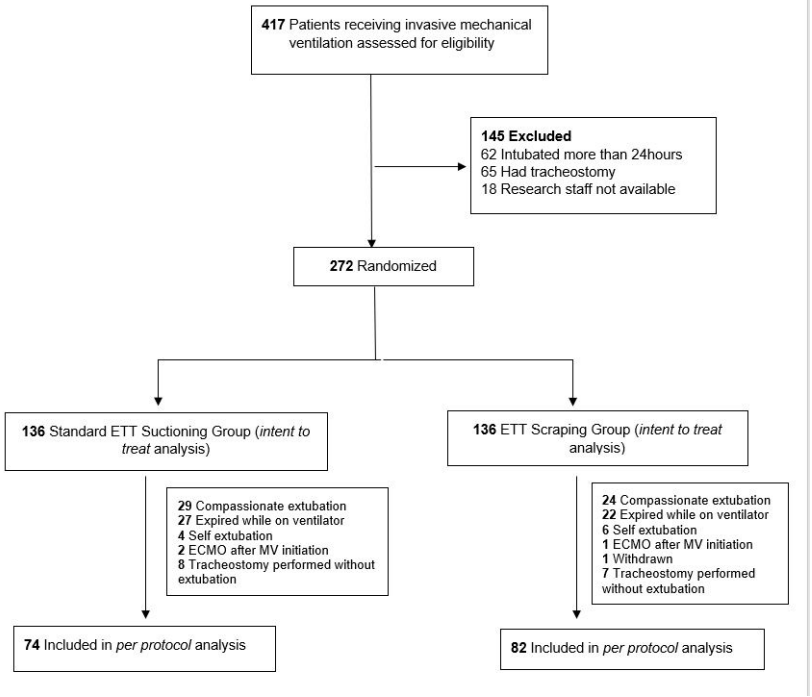

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Table 1. Subject baseline characteristics

Variables	**Standard ETT Suctioning Group (n=136)**	**ETT Scraping Group (n=136)**	**p-value**
Age, y, median (IQR)	63 (52-74)	63 (52-72)	0.67
Male, n (%)	65 (47.8)	78 (57.4)	0.11
BMI, kg/m^2, median (IQR)	29.3 (25-35)	28.8 (24-34)	0.37
SOFA score, median (IQR)	6 (4-8)	6 (4-9)	0.80
Race/Ethnicity, n (%)			0.47
African American	51 (37.5)	57 (41.9)	
Caucasian	30 (22.1)	36 (26.5)	
Hispanic	44 (32.4)	31 (22.8)	
Asian	5 (3.7)	4 (2.9)	
Other	6 (4.4)	8 (5.9)	
Primary diagnosis, n (%)			0.25
Hypoxemic respiratory failure	71 (52.2)	60 (44.1)	
Hypercarbic respiratory failure	8 (5.9)	15 (11)	
Sepsis	10 (7.4)	13 (9.6)	
Cardiac	8 (5.9)	14 (10.3)	
Others (cancer, hepatic, renal etc.)	39 (28.7)	34 (25)	
Reason for intubation, n (%)			0.087
Acute respiratory failure	89 (65.4)	89 (65.4)	
Airway protection	29 (21.3)	26 (19.1)	
Elective	14 (10.3)	8 (5.9)	
Cardiac arrest	4 (2.9)	13 (9.6)	
ETT size, median (IQR)	7.5 (7.5-8)	7.5 (7.5-8)	0.99
Lung protective ventilation, n (%)	109 (80.1)	98 (72.1)	0.12
Number of SBTs performed before extubation/tracheostomy, median (IQR)	1 (0-2)	1 (0-2)	0.77

Number of ETT suctioning/scraping prior to first successful SBT, median (IQR)	7 (2-18)	10 (3-19)	0.27
Number of ETT suctioning/scraping prior to extubation/tracheostomy, median (IQR)	13 (4-39)	14 (5-34)	0.77
Number of ETT scraping before extubation/tracheostomy, median (IQR)	0	4 (2-9)	n/a
Number of times ETT cuff pressure documented > 20cmH_2O, median (IQR)	7 (4-18)	7 (4-15)	0.46
Number of times HOB documented ≥30 degrees, median (IQR)	29 (14-77)	27 (13-66)	0.74
Number of times oral care documented, median (IQR)	14 (5-34)	13 (6-30)	0.73
Number of times oral brushing (chlorhexidine) documented during MV, median (IQR)	4 (1-11)	4 (1-9)	0.75
Number of days DVT prophylaxis used during MV, median (IQR)	4 (2-8)	4 (2-7)	0.83
Number of days with stress ulcer prevention during MV, median (IQR)	3 (2-8)	3 (1-6)	0.39

Abbreviations: ETT, endotracheal tube; IQR, interquartile range; BMI, body mass index; SOFA, sequential organ failure assessment; SBT, spontaneous breathing trial; HOB, head of bed; MV, mechanical ventilation; DVT, deep vein thrombosis

Table 2. ***Intent to Treat*** **Analysis**

	Standard ETT Suctioning Group (n=136)	**ETT Scraping Group (n=136)**	**p-value**
Primary Outcomes			
Length of MV, hrs, median (IQR)	72.2 (37-187)	70.6 (37-148)	0.58
Secondary Outcomes			
Time to first successful SBT, hrs, median (IQR)	46.7 (30-87)	45.7 (27-95)	0.81
Required NIV or reintubation within 48hrs, n (%)	14 (10.3)	20 (14.7)	0.38
Length of ICU stay, d, median (IQR)	9 (4-20)	7.8 (4-18)	0.62
Length of hospital stay, d, median (IQR)	14.7 (8-26)	13.9 (8-25)	0.76
VAC, n (%)	9 (6.6)	16 (11.8)	0.13
IVAC, n (%)	9 (6.6)	12 (8.8)	0.47

Abbreviations: ETT, endotracheal tube; MV, mechanical ventilation; IQR, interquartile range; SBT, spontaneous breathing trial; NIV, noninvasive ventilation; ICU, intensive care unit; VAC, ventilator associated condition; IVAC, infection related ventilator associated complication

Table 3. ***Per Protocol*** **Analysis**

	Standard ETT Suctioning Group (n=74)	**ETT Scraping Group (n=82)**	**p-value**
Primary Outcomes			
Length of MV, hrs, median (IQR)	63 (41-164)	62 (36-138)	0.61
Secondary Outcomes			
Time to first successful SBT, hrs, median (IQR)	46.6 (28-93)	45.7 (26-91)	0.73
Required NIV or reintubation within 48hrs, n (%)	12 (16.2)	17 (20.7)	0.43
Length of ICU stay, d, median (IQR)	10.4 (5-21)	8.5 (4-21)	0.59
Length of hospital stay, d, median (IQR)	17.9 (10-26)	18.6 (10-29)	0.80
VAC, n (%)	5 (6.8)	7 (8.5)	0.68
IVAC, n (%)	5 (6.8)	4 (4.9)	0.74

Abbreviations: ETT, endotracheal tube; MV, mechanical ventilation; IQR, interquartile range; SBT, spontaneous breathing trial; NIV, noninvasive ventilation; ICU, intensive care unit; VAC, ventilator associated condition; IVAC, infection related ventilator associated complication