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Interim results of an Evaluation of a new Closed Suction System in terms of Biofilm formation and Clinical Pulmonary Infection Score (CPIS).

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Introduction

Within the first 24 hours following tracheal intubation the Endotracheal tube (ETT) begins to be colonized with oral bacteria and respiratory pathogens that adhere to its inner surface in well-organized antibiotic-resistant structures. The use of Airway Medix Closed Suction System (AMCSS) could effectively reduce the bacterial burden, biofilm development and the Clinical Pulmonary Infection Score (CPIS). The goal of this study was to evaluate the efficiency of the AMCSS.

Methods

35 critically ill patients were randomized into two groups. A control group of 20 patients were suctioned using the KIMVENT* Closed Suction System (Kimberly Clark, USA), 15 patients were suctioned using the novel catheter (Airway Medix Closed Suction System, Biovo Technologies, Israel). CPIS calculations were performed daily for all 35 intubated patients. After extubation, the ETTs were cut open longitudinally. Two 1 cm-long hemi-sections of the distal part of the ETT were dissected for qualitative and quantitative analysis of representative biofilm accumulations through scanning electron microscopy (SEM). The mean stage ± SD and range was presented per group (tubes using Airway Medix vs. Kim Vent). During the analysis, investigators were blind to treatment allocation.

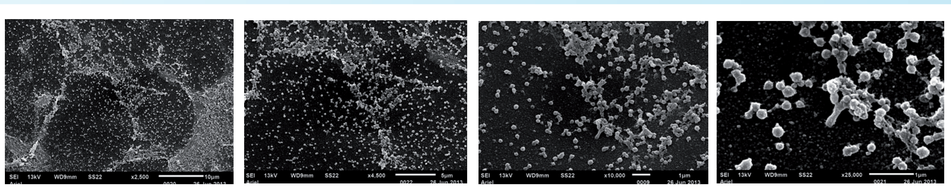
Results

Biofilm stage was lower in the study group compared to the Control—1.2 vs. 2.0 for the biofilm stage. Proportion results of subjects with stages III and IV was greater in the Control group compared to the study—30% vs. 13.3% for the average biofilm stage and 65% vs. 86.7% for the early biofilm stages I and II. These results show a trend to significant. CPIS score was found to be on average lower in the study group compared to the Control group (4.9 vs. 5.9). The proportion of subjects with CPIS above 6 was found to be lower in the study arm (6.7%) compared to the Control (35%). The proportion of subjects with CPIS above 7 was lower in the study arm (0%) compared to the Control (30%). This difference was significant (P=0.027).

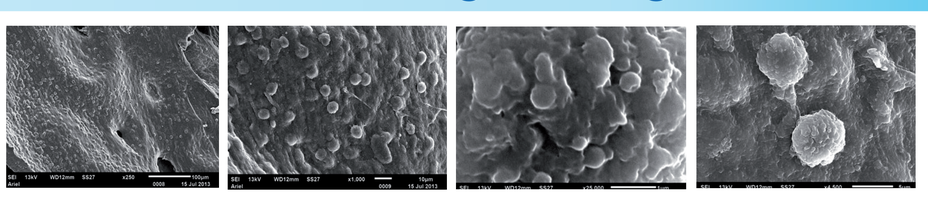
Conclusions

These interim results suggest that the use of AMCSS might reduce the ETT biofilm formation and can be effective in limiting the Biofilm development to the early stages. Moreover we believe that this unique device has the potential to reduce the CPIS and limiting the use of empiric antibiotic. Further results will be needed to confirm these interim results.

SEM of blofilm within ETT: Stages 1-2=lower blofilm stage



SEM of blofilm within ETT: Stages 3-4=higher blofilm stage



Airway Medix Closed Suction Sysytem

IRRIGATES

WIPES

REMOVES

CPIS Results

Device	Mean CPIS	Number of patients	Percentage of patients with CPIS>6	Percentage of patients with CPIS>7
Control (KimVent)	5.8	26	26.9%	23.1%
Treatment (Airway Medix)	4.8	19	10.5%	0%

Number of patients with CPIS>7 was on average significantly lower in the Treatment group compared to the Control group (23.1% vs. 0%), based on a two independent samples t-test (P-Value = 0.032).

Joint Commission International Quality Approval