

Performance Evaluation of Airway Medix Closed Suction System compared With a Standard Closed Suction System

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Introduction: The lower respiratory tract of healthy humans is normally kept sterile by natural defense mechanisms. Endotracheal intubation and mechanical ventilation, which are life sustaining procedures in patients with respiratory insufficiency, profoundly impaired these defense mechanisms, increasing the risk of bacterial colonization and ventilator-associated pneumonia (VAP). Retained mucus in the lower airways must therefore be removed by endotracheal suctioning to prevent accumulation and consequent complications. The purpose of performing suction is to clear secretions from the oropharynx or trachea in patients who are unable to do so independently. The Airway Medix Closed Suction System is a novel device used to aspirate liquids or semisolids from a patient's upper airway while intubated with an endotracheal or tracheostomy tube.

Objectives: To compare the performance, safety, and ease of use (usability) between two closed suction systems, the Airway Medix Closed Suction System and Kimberly Kim-Vent Closed Suction System

Method: The study was a prospective, double arm, randomized, single center, open label and controlled. 28 post cardiac surgical patients requiring mechanical ventilation for more than 6 hours were eligible for this study. Baseline parameters were taken and recorded from all patients about 2 hours after arrival to the intensive care unit (ICU). The date, reason and number of suction episodes were recorded for each patient. All the patients were monitored hemodynamically and respiratory before, during and 3 minutes after each suction episode. During suction the following parameters were monitored: Patient discomfort, cough, Desaturation, Hypotension, Hypertension, Cardiac Arrhythmia. Patients were followed until either ICU discharge or extubation.

Results: 28 patients were divided into two groups - 13 patients were randomized to the Airway Medix Closed Suction System, and the other 14 patients were randomized to the Kimberly Kim Vent Closed Suction System. One randomized patient did not receive study treatment due to investigator decision. All 27 patients underwent at least one suction treatment during their stay in the ICU. The following parameters were analyzed: PaCO₂ (mmHg), PaO₂ (mmHg), saturation, Blood pressure (mmHg) and Heart Rate (bpm). There

were no significant differences between the groups at baseline of any of the parameters. No significant difference was obtained between pre and post suction at both groups. In addition, mean change and SE obtained from pre suction to post suction using the Airway Medix vs. the Kim Vent was calculated. The change between the groups was not significant for all parameters. Mean changes in Heart Rate from pre suction to post suction was smaller in the Airway Medix group in comparison to the Kim Vent group (1 ± 2.1 and 3.2 ± 1.7 respectively). This may be attributed to the fact that shallow suction was performed with the Airway Medix device while deep suction was performed with the KimVent device as common practice. No respiratory and hemodynamic complications related to tracheal suctioning were observed.

Conclusions: Airway Medix Closed Suction System is not inferior Kimberly KimVent Closed Suction System in respect to respiratory and/or hemodynamic complications related to tracheal suctioning.