Review of clinical efficiency results

Automated Suction – Advanced treatment for ventilator-associated pneumonia

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Abstract: Ventilator-associated pneumonia (VAP) is the most common healthcare-associated infection (HAI) in adult critical care units. It is associated with increased intensive care unit (ICU) stay, patient ventilator days, and mortality. VAP is thought to increase the mortality of the underlying disease by ~30%. Currently, the diagnosis of VAP is based on a combination of clinical, radiological, and microbiological criteria. Diagnosing VAP can be challenging because there are several reasons why a patient can have respiratory decompensation while mechanically ventilated. There wide range of clinical conditions that mimic VAP in ventilated patients, include acute respiratory distress syndrome (ARDS), pulmonary oedema, pulmonary contusion, tracheobronchitis, and thromboembolic disease. Some of the clinical features used to define a VAP (e.g. change in tracheal secretions) are subjective and are subject to inter- and intra-observer variation. The most commonly used drugs for clinically treating patients diagnosed with VAP are antibiotics, since the most common cause of ventilator-associated pneumonia is microaspiration of bacteria. Bronchoscopes, endotracheal cuffs, tubes and other contact accessories can all be colonized by VAP-causing pathogens. Since ventilated patients often need suction, in order to clear the airway of saliva, blood or other secretions, the suction procedure itself poses an additional risk of infection for the patient. While the risk of infection can be minimized by using closed suctioning, apparently the quality and frequency of the suction procedure, has a great influence on the effectiveness of VAP treatment and the necessary duration of ventilating the patient.

Keywords: automatic suction; advanced aspiration; VAP treatment; pneumonia; pulmonology; intense care

1. Introduction

With the aging population, the number of patients with acute and chronic respiratory failure has increased steeply, and more and more patients are in need of airway aspiration. Currently, airway absorption is a treatment performed by a person directly next to a patient's bed and is conducted 24 times a day on average. In particular, chronic respiratory failure patients with tracheotomy need 24-hour airway aspiration by their caregiver. In particular, damage to the airway mucous membrane by the catheter occurs frequently, and in some cases hypoxia and cardiac arrest cases are reported. The purpose of the following study is to evaluate the effectiveness of a novel therapeutic device, which can provide automated suction through a closed catheter system, in order to facilitate the patient's faster recovery and early weaning from the ventilator. While closed manual suctioning is a standard procedure, automated suctioning is a new way to support not only VAP recovery, but also to take the burden off the caregivers' shoulders, as the subject device can initiate suction cycles automatically, based on the condition of the ventilated

patient. The most direct use of the device is for patients with E-tube or T-tube, especially for intensive care units with high airway aspiration demands, or for patients in mechanical ventilation with acute or chronic respiratory failure.

2. Methodology

The automated suction system was determined in advance to be suitable for clinical application at the Medical Device Development Research Center of Bundang Seoul National University Hospital before entering the study. This study is based on the trial that was designed as a single institution, single group, forward-looking, exploratory and researcher-led study to evaluate the effectiveness of the newly developed automated closed suction system for patients who are unable to release their own phlegm. The study includes 10 subjects from one domestic institution.

① **Volume of use**
One automated suction device per one patient

② **Method of use**
A. Application of the suction system immediately after patient consent during the screening phase.
B. Turn on the device and connect it with an exclusive suction catheter.
C. Check the number and quantity of manual airway suction identified during the screening process and set the automatic suction frequency and suction time in the suction system accordingly.
D. Recheck the medical device, measure the amount of absorbed sputum, and keep the suction bottle empty every 8 hours when attending caregiver rotates.

③ **Hours of continuous use**
The maximum of 15 days (Returning to conventional manual methods in less severe cases).

④ **Combined modality therapy**
A. Basically, patients with acute and chronic respiratory failure in intensive care have the same best route clinical practice as existing patient care.
B. The administration and treatment of new drugs related to airway absorption before and after application of the automated suction device are recorded in the evidentiary record.
C. Bronchial cleansing through bronchoscopy is performed to remove all remaining secretions in the airways and evaluate the baseline airway mucosa condition.
D. After several days of application, bronchoscopy is performed to re-evaluate airway mucosa conditions.

3. Results

The technical purpose of the automated suction device is to provide a continuous vacuum source, within the stated operating vacuum range, for the aspiration of fluids and particulate matter in medical procedures. There are two aspects of the evaluation of the clinical results. On one hand, the open suction procedure shall be compared to closed suction. The usefulness of open suctioning relative to closed catheter systems is debated. When comparing open suctioning and traditional closed catheter suctioning in patients with respiratory failure, closed suctioning tend to prevent hypoxaemia more effectively than open suctioning. On the other hand, the consideration shall include the necessary duration length of patient ventilation. The main objective of the automated suction device, is to eliminate the suction pain for the patient and ultimately, to support the early weaning from the ventilator by performing precise, high frequency suction, by the application of the least amount of negative pressure. The automated suction device is operating with short suction cycles, namely 5, 10 or 15 seconds respectively for a single suction phase.

The device applies 2 or 3 phases in one suction cycle, based on the severeness of the condition of the patient. There is a 25 second delay between the individual suction phases, in order for the patient to breath normally through the ventilator, although the positive pressure from the ventilator is providing oxygen to the patient, even during the suction phase. The automated suction device can operate in a wide pressure range up to 300mmHg. However, the aim is to apply the least amount of pressure, namely between 50-80mmHg for most patients. While this setting is in fact a low suction pressure, compared to the pressure usually applied during manual suction, the high frequency of the suction performed by the device, makes it possible to achieve favorable results even with low pressure settings. The automated device can operate in 3 different modes. The operation modes include manual start of each suction cycle by the caregiver, semi-automatic start with a predetermined timing for each suction, and a fully automatic start which is initiated by the device, based on the deteriorating vital functions of the patient. Additionally, besides the achieved clinical results, the pain level of the suction for the patient must also be taken into account. Although most ventilated patients are highly seduced, there are patients who were connected to the automated suction device in a conscious state, where they were able to communicate and indicate the level of pain they felt during the automated suction. It is found that the suction procedure was virtually painless with the automated device. This is due to the fact that the device operates the aspiration catheter in a very precise way, where the catheter suction depth is always optimal and the movement path of the catheter is always the same. As a general result, the automated suction device enables the caregiver to apply suction more frequently, apply the lowest amount of suction pressure, for the least amount of time per individual suction cycle, resulting in a very effective and virtually painless suction procedure for the patient.

3.1. Result Tables and schemes

Table 1. Patient conditions before and after automated suction (each row is an individual patient)

Patient condition before suction	Age/ Sex	Suction depth and Tube type	Evaluation of condition after automated suction treatment
Small amount of blood-mixed sputum. Suction depth was adjusted by 1cm due to suspected COVID-19.	70/M	8cm/E	During the 3 days of treatment, the ventilator has not changed to AC mode, however Fi02 decreased from 66% to 55%~60%. TV increased by more than 50ml.
Intubation due to the burning of the respiratory tract. A black lump was observed during suction. A large amount of secretion.	31/M	10cm/E	During the 9 days of treatment, the device suction was judged to be effective in semi-automatic mode, as the patient had to be aspirated frequently every 15 minutes, due to a large amount of secretions in the bronchial.
Conscious patient with small amount of blood-mixed sputum. Severe mucosal bleeding was observed on bronchoscopy.	32/F	8cm/E	During the 4 days of treatment, the ventilator mode has changed from PC to PS/CPAP. In the

			process of weaning, the Fi02 value had decreased and the TV had increased.
Patient with large amount of sputum. Initial suction depth was 2.5cm and later it has been increased to 3cm. The caregiver adjusted the suction depth based on the X-ray and the amount of sample sputum.	30/M	2.5cm/T	During the 7 days of treatment, the patient's TV rose and the ventilator was removed while reducing the Fi02. A Nasal High Flow system was connected for the weaning process. After disconnecting the suction device, the patient's condition deteriorated, so the device was connected again and the condition has increased.
Suction device has been connected after bronchoscopy examination. The conscious patient was in severe pain, so the suction time has been reduced to a maximum of 5 seconds.	63/M	10cm/T	During the 3 days of treatment, the patient had been getting better in condition, although the main achievement was to be able to perform the automated suction, as the patient could not handle the pain associated with manual suction previously.
Unconscious patient with a small amount of sputum and severe pneumonia.	85/F	9cm/E	During the 3 days of treatment, manual suction had not been performed. The automated suction device was in semi-automatic operation mode. Ventilator mode has changed from AC to Spont.
Conscious, but isolated patient. The initial suction depth was set to 8cm. Later the suction depth has been increased to 10cm, considering the small amount of sputum. Suction interval time was 40 minutes.	65/F	10cm/E	During the 4 days of treatment, it was judged that the patient's condition was significantly improved, as the Fi02 setting value had decreased and TV had increased.
A small amount of sputum without blood but unstable patient condition. The initial manual suction depth was 7cm, however the automated suction depth has been increased due to the level of sputum.	68/M	9.5cm/E	During the 4 days of treatment, the patient's condition returned stable, so the dosage of sedation was decreased and patient regained consciousness. PC mode has been maintained during the treatment and Fi02 decreased from 55 to 50.
Unconscious patient. As a result of bronchoscopy examination before starting the treatment, there was a lot of mucosal damage and redness. The overall condition was very unfavorable. The suction depth was adjusted reflecting blood-mixed	69/F	10cm/E	During the 15 days of treatment, the ventilator mode was changed from PC to PS/CPAP. The patient has regained consciousness and as a result of bronchoscopy examination, the membrane condition improved significantly.

secretion (10-> 9cm). In the result of the intermediate bronchoscopy during the clinical study, the mucous membrane condition was degrading.			
A small amount of sputum with no bleeding in the mucous membrane.	49/M	9cm/E	During the 4 days of treatment, the ventilator maintained PC mode, however Fi02 and RR indicators have been significantly improved.

4. Discussion and conclusions

Ventilator-associated pneumonia develops in almost every patient with more than 48 hours in ventilation. Effective suction is necessary to clear secretions and to maintain airway patency, and to therefore optimize oxygenation and ventilation. Recent recommendations for endotracheal suctioning advocate several key points to the procedure, including: to advance the suction catheter until resistance is met; to not apply suctioning routinely, but only as needed; to preferably use a closed suction catheter; to not apply suction pressure for more than 15 seconds. However, this clinical guidance seems not to be followed in clinical practice. There are several reason why it is hard for the caregiver to follow these guidelines. One of the obvious reasons is the huge workload of ICU caregivers. The number of caregivers with suction expertise in any given point of care, predetermines how much time is available for suction per patient. Some patients may require suction every 15 minutes. In such severe cases there may not be enough trained caregivers, to carry out so many suction cycles on a single patient. As a general result due to the lack of time, the caregiver may apply a higher suction pressure and perform the suction for a longer period of time, then what is necessary or ideal for the patient. This is to extend the idle time between suction cycles for an individual patient. Applying automated suction to the patient, enable the caregiver to disregard the idle times, and perform suction as frequently as necessary, while minimizing the application time and suction pressure. While the suction is performed automatically, the caregiver can focus on indicator ventilator parameters such as Peak Inspiratory Pressure, Tidal Volume and FiO2. The caregiver is also able to reduce the risk of complications, since each suction attempt will not last any longer than 15 seconds. It is recommended that adult and pediatric patients receive 100% oxygen over their baseline FiO2 for 30-60 seconds prior to suctioning, however the automated suction device allows the ventilator to oxygenate the patient moderately even during the suction cycle. Automated suctioning with the right settings, shall result in decreased secretions, decreased peak inspiratory pressure, increased tidal volume and improved oxygen saturation, with virtually no patient pain during the suction procedure.

5. Patents

Lmeca Co. Ltd. has more than 50 registered patents for the technical developments in medical suction. The following patents are the most basic advancements of the automated suction.

1. Automated Suction Device with Artificial Intelligence (No. P147187-EP)
2. Catheter Guide Structure (No. P167213-EP)
3. Medical Suction Device with Installed Catheter Structure (No. P217088-PCT)

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