Efficacy and safety of automated antiseptic lavage and suctioning of oral, oropharyngeal, and subglottic secretions (VapCare) among ventilated patients with COVID-19 developing ventilator-associated events during hospitalization: a prospective randomized open blinded end-point study

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Abstract

Background

Globally, invasive mechanical ventilation is one of the many methods relied on by intensivists to treat patients diagnosed with COVID-19. In this population, substandard oral care and secretion management permit the colonization of pathogens in the oral cavity and aspiration of these microbe-laden secretions is the leading cause of ventilator-associated pneumonia (VAP). This study was conducted to analyze the effects of VapCare, an automated and intelligent secretion clearance and oral hygiene management system for VAP prevention, compared to the manual process.

Design

A single-center, prospective, randomized, open-blinded, end-point study was conducted on invasively ventilated patients diagnosed with COVID-19.

Setting

A tertiary care facility that is National Accreditation Board for Hospitals accredited in Bangalore, India.

Participants

Twelve adult patients diagnosed with COVID-19 via RT-PCR, antigen, computed tomography scan, or any other approved method intubated for at least 48 hours were recruited from the medical intensive care unit.

Intervention

Patients were given (n=6) or not given (n=6) the VapCare medical device along with the current standard of care.

Results

Six patients were assigned to the control group (Cx) that received manual suctioning, and six were assigned to the treatment group (Tx) that received VapCare. 3(50%) of the patients in the Cx experienced a ventilator-associated condition (VAC), and 2(33%) of the patients received a confirmed diagnosis of ventilator-associated pneumonia (VAP). There was no incidence of VAC or VAP in the Tx. With an outlier (subject two) excluded, the average cost of antibiotics per patient in the Tx was 32% less at 68,319 INR, while the average cost in the Cx was 100,783 INR. Clearance of secretions was almost 2x in the Tx compared to the Cx. The amount collected from the subglottic region (from where aspirations into the lungs can occur) was lower in the Tx (6.5 ml) when compared to the Cx (7.4 ml), showing that VapCare effectively clears secretions before they reach the subglottic region.

Conclusion

VapCare can reduce VAP incidence in invasively ventilated patients diagnosed with COVID-19. Antibiotic costs were also reduced by 32% in the Tx compared to the Cx. This study also allows us to hypothesize that

automated suctioning can reduce the amount of secretions that can reach the subglottic region and, therefore, potentially reduce the chance of aspiration and, subsequently, VAP.

Trial Registration

Clinical Trials Registry – India, CTRI/2021/08/035429. Registered 5 August 2021. Registered Prospectively.

Introduction And Background

In December 2019, the Wuhan city of Hubei province of China began to experience acute atypical respiratory infections.[11] The pathogen responsible for these atypical infections was a novel coronavirus named the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2).[8] SARS-CoV-2 was found to be highly contagious and has spread far and wide to over 180 countries, wreaking havoc in its path. The disease caused by this virus was termed coronavirus disease-19 or COVID-19. COVID-19 was first declared a public health emergency, and by March 11, 2020, the World Health Organization declared COVID-19 a pandemic.[8] As of May 2022, 515 million infections and more than 6.25 million deaths have been recorded.

Ventilator-associated pneumonia (VAP) is the most common preventable nosocomial infection in the intensive care unit (ICU).[1] VAP, a secondary infection, is associated with significant morbidity and attributable mortality in this population.[9] The primary pathogenesis of VAP is due to the aspiration of microbe-laden oropharyngeal, gastric, or tracheal secretions from around the cuffed endotracheal tube into the lower respiratory tract. Common strategies in eradicating VAP include, but are not limited to, oral care with chlorhexidine lavage and measures to prevent aspiration such as semi-recumbent positioning, periodic suctioning of secretions from the oral cavity, and continuous subglottic suctioning when available. These practices, along with meticulous infection control, have proven time and time again to reduce the occurrence of VAP. Unfortunately, in low-resource settings, due to the lack of skilled staffing and inconsistent adherence to hospital protocols, there is still a preventable occurrence of VAP in ICUs.[4,7] Due to the severe nature of the infection and high mortality rate amongst patients diagnosed with VAP, it is essential that they receive high-quality oral care and secretion management.

VapCare and VapLumen, a first-in-world automated secretion clearance and oral hygiene management system, was designed to prevent VAP. VapCare aids nurses and doctors in reducing microbial colonization in the oral cavity by providing consistent suctioning of secretions from the oral, oropharyngeal, and subglottic regions while also providing an oral lavage of chlorhexidine.

Materials And Method

The VapCare system comes with two major components. **Figure 1** is a schematic diagram of the device setup. The first component is an intelligent electromechanical system that controls suctioning based upon a build-up inflow sensor input. This device also has multiple ports to convert suction pressure from a wall-mounted or portable suction unit into modulated suctioning as required in the oral, oropharyngeal, and subglottic regions. The sensing unit uses flow detection and assessment to regulate the suction duration and when to cease suctioning. This device can also detect port blockages and has been designed to minimize suction duration

and pressure applied to the patient's airway compared to other continuous closed-loop systems. The user can set suction frequency and pressure.

The second component is the disposable VapLumen that slides over the top of an endotracheal tube (ETT) and extends into the oropharynx. The VapLumen has multiple suction ports and a single port for sprinkling an oral lavage solution. The disposable VapLumen must be connected to the first component to perform automated suctioning and oral lavage. The VapLumen is equipped with a bite blocker and a fastener to ensure that the ETT is held in place safely. The VapLumen also has soft-tipped tubes made with biocompatible materials that can be adjusted to each patient's requirements to optimize positioning in the oropharyngeal region.

All respiratory therapists, nurses, and doctors involved in the care of patients were trained on VapCare prior to the start of the study. Prior to being recruited to the study, patients were screened by the physician to ensure that they fit the inclusion and exclusion criteria. Refer to **Table 1** for the inclusion and exclusion criteria.

Table 1: Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria
Patients must be over 18 years of age.	Patient has been intubated for >24 hours before recruitment to study.
Patient must be intubated with above the cuff suction enabled endotracheal tube.	Patient with past history of pulmonary tuberculosis.
Health care worker is able to place the suction lumen appropriately and fix it in position.	Patient with HIV infection.
Patient or a legal representative of the patient must be able to give written consent for the study.	Patient with past history of ventricular fibrillation.
Patient is expected to be on a ventilator for >48 hours.	Patient with history of cardiac arrest.
Patient is COVID positive.	Patient with history of bleeding disorders.
	Patient is pregnant.
	Patient with severe head/neck and facial injuries.
	Patient with tracheostomy on admission.
	Patient enrolled in another study.
	Patient has already participated in the study.

All subjects in this study were followed from the date they were enrolled until they were discharged. This study took place between August 2021 and February 2022. Case report forms were filled out by nurses and doctors involved in the care of these patients. Patients in the Cx received oral care and manual suctioning, which is the current standard of care. Patients in the Tx received VapCare, which provides pressure-controlled automated suctioning and oral lavage.

To assess the safety of VapCare and the VapLumen, the physician performed a laryngoscopy prior to the placement of the lumen, and follow-up laryngoscopies were performed daily to ensure there was no tissue

damage. Visual assessments were also performed by healthcare workers every 2 hours to detect the incidence of any adverse events due to the device.

Twelve patients that met the inclusion criteria were admitted during the study. Six were assigned to the Tx, and six were assigned to the Cx. The Tx received automated suctioning and oral lavage along with daily teeth brushing. The Cx received the current standard of care, including manual suctioning as needed, teeth brushing once a day, and manual oral swabbing with chlorhexidine every four to six hours. The VapCare device was used as intended and according to the manufacturer's instructions. Data regarding the incidence of ventilator-associated condition (VAC), infection-related ventilator-associated complication (iVAC), and possible ventilator-associated pneumonia (pVAP) was collected. Furthermore, data regarding the average cost of antibiotics (ABX) and the amount of secretions collected was tracked for comparison.

AIM

This single-center, prospective, randomized, open blinded end-point (PROBE) study was conducted to assess the performance and safety of the automated device, VapCare, (along with VapLumen) in delivering oral care, secretion clearance, and in reducing the incidence of VAP compared to manual suctioning. The average cost of ABX and the average amount of secretions removed were also collected from the treatment (Tx) and control group (Cx) to analyze if there is a cost reduction and if automated suctioning is superior to the manual process in clearing secretions.

Setting

A tertiary care facility that is National Accreditation Board for Hospitals accredited in Bangalore, India.

Randomization

We randomized patients through a central office using variable permuted block sizes. We randomized patients through interactive voice-based randomization software.

Allocation Ratio and Concealment

We allocated the patients in a 1:1 ratio, and the allocation sequence was concealed at the central office handling the randomization sequence.

Blinding

This was an open label trial and blinding was not applicable to the investigators or the patients.

Results

We randomized and enrolled 12 patients (refer to **Figure 2** for flowchart) who were ventilated for more than 48 hours, but subject two was excluded due to being an outlier that skewed the data. Subject two was hospitalized for an extended period because of an acute intraparenchymal hemorrhage secondary to COVID-19. The demographic and relevant information has been provided in **Table 2** and **Table 3**. Of the six patients placed into

the Cx, 3(50%) developed a VAC, and 2(33% of the group) were diagnosed with microbiologically confirmed pVAP. There was no incidence of VAC, iVAC, or pVAP in the Tx that received VapCare.

Table 2: Treatment group demographic and relevant information

Subject No.	Age	Gender	Group	VAC	iVAC	pVAP	Ventilator Days	Ventilator Free Days	Abx Cost	DC Reason
2	54	M	Tx	No	No	No	31	23	519900	Death
4	36	F	Tx	No	No	No	11	9	150000	Home
5	44	M	Tx	No	No	No	2	0	19661	Other
7	32	M	Tx	No	No	No	7	0	19720	Home
9	44	F	Tx	No	No	No	5	0	141863	Home
11	84	M	Tx	No	No	No	8	0	10353	Death

Abx, antibiotics; DC, Discharge; Tx, Treatment

Table 3: Control group demographic and relevant information

Subject No.	Age	Gender	Group	VAC	iVAC	pVAP	Ventilator Days	Ventilator Free Days	Abx Cost	DC Reason
1	65	F	Cx	No	No	No	10	5	173000	Home
3	54	F	Cx	Yes	Yes	Yes	11	0	159200	Other
6	62	M	Cx	Yes	Yes	Yes	14	0	142000	Death
8	54	M	Cx	No	No	No	5	0	120000	Other
10	63	F	Cx	Yes	No	No	8	0	10000	Death
12	79	M	Cx	No	No	No	3	0	500	Home

Abx, antibiotics; DC, Discharge; Cx, Control

The physician in charge conducted a laryngoscopy and documented the findings for a baseline prior to the placements of the VapLumen along with the VapCare system. Daily follow-up laryngoscopies were also conducted, and no tissue damage was documented in the Tx due to VapCare. Four serious adverse events occurred; all were deaths. Two deaths were in the Tx (none related to the study device), and two were in the Cx (one was a confirmed case of pVAP). The two deaths in the Tx were subjects 2 and 11, which were due to acute intraparenchymal hemorrhage and refractory shock, respectively.

Patients in the Cx reported an average length of stay (LOS) of 9.8 days in the ICU, compared to a much longer LOS in the Tx at 16.7 days. However, the Tx average was skewed by one patient (subject 2) who was in the ICU for 55 days. Excluding this outlier, the Tx showed an average LOS of 9.2 days in the ICU.

With the outlier excluded, when we analyzed the daily secretion removal in both groups, we find that the Tx showed a much higher daily average of secretions cleared (29.5 mL) when compared to the Cx (14 mL cleared). It was interesting to see that while the overall secretion clearance is more than 2x in the Tx, the amount collected from the subglottic region (from where aspirations into the lungs can occur) was lower in the Tx (6.5 ml) when compared to the Cx (7.4 ml), showing that VapCare effectively clears secretions before they reach the subglottic region. In other words, only 22% of the secretions collected in the Tx were from the subglottic region, compared to 53% of the secretions in the Cx. More significantly, the total antibiotic spend was 32% less (INR 68,319) in Tx (after removing the outlier case mentioned above) when compared to the Cx (INR 100,783), clearly showing the link between better oral hygiene management and lower antibiotic usage.

Variables

The primary variables were if the patient was diagnosed with VAC, iVAC, or pVAP. The secondary variables were safety, the cost of ABX and the amount of secretions cleared in each group.

Statistical Analysis

The sample size was too small for statistical analysis. Unfortunately, this is a limitation of this study.

Limitations

The findings of this study must be seen in light of some limitations. Due to the sample size, the results are indicative and support a larger statistically powered study. Also, this study was limited to COVID-19 patients, and we were unable to reach our goal of 100 patients because of the inability to recruit patients as COVID-19 cases reduced.

Discussion

In this prospective, randomized, open-blinded trial comparing VapCare against the current manual standard of care to reduce the incidence of micro-aspirations leading to VAP, we established that VapCare can reduce the incidence of VAP in patients diagnosed with COVID-19. This trial also established that there might be a reduction in the cost of ABX due to VAP prevention. We cannot definitively say based on this small sample size that VapCare will significantly reduce the incidence of VAP, although, through this study, we have established a need for a larger trial which is currently underway.

It is no surprise that hospitals in low-resource settings worldwide lack enough experienced nurses to handle the patient loads they are required to take on. Understaffing results in more “task-oriented” nursing care, which hinders the quality of care received by the patient.[3] This, in turn, forces nurses to prioritize tasks they believe are essential, and tasks such as oral care and secretion management get put on the back burner. In situations like this, VapCare has proven in a prior study to reduce time spent on oral care and secretion management by 70%.[10] Thus, VapCare is an impactful device for understaffed facilities where VAP is prevalent due to a lack of quality oral care and secretion management. Due to the reduced time spent on oral care and secretion management, interactions between staff and infected secretions are also reduced. This was essential during the COVID-19 pandemic to keep healthcare staff safe because of the highly contagious nature of the virus.

Another critical consideration in VAP prevention is the endogenous flora. Most medical professionals agree that VAP develops because of aspiration of secretions contaminated with pathogenic organisms, which appear to be endogenously acquired.[2] One way to combat endogenous VAP is to provide quality oral care and secretion management. Quality oral care paired with an oral lavage of chlorhexidine that the VapCare system provides ensures that potentially pathogenic microbes (PPMs) do not have the opportunity to colonize. Automated delivery of chlorhexidine hindering the ability of PPMs to colonize is a gamechanger in ICUs where understaffing results in poor quality oral care resulting in VAP. Also, by clearing 75% of the secretions before they reach the subglottic region, VapCare minimizes the likelihood of subsequent aspiration of oral fluids, giving a solid rationale to support the reduction in VAC and VAP with the use of this technology.

Kollef et al., in a large observational hospital database study published in 2012, present a mean cost of VAP of $39,828. [5] The reported increase in mean length of stay was 8.9 days in the ICU and 13.1 days for total hospitalization. [6] Due to the high cost of healthcare, patients diagnosed with VAP are burdened with the cost of stay and the cost of medications to treat this hospital-acquired infection. Also observed in our study was a higher length of stay in the Cx for patients diagnosed with pVAP. We found about a 32% reduction in the cost of ABX for patients in the Tx with VapCare, but further analysis through a larger study is necessary.

Secretion clearance and safety were the final variables compared during this trial. We found that VapCare could clear more secretions efficiently compared to the manual procedure. We also found that fewer secretions could move down to the subglottic region in the Tx. This allows us to hypothesize that VapCare can aid in reducing the incidence of VAP because fewer secretions can be aspirated into the lungs. Regarding safety, none of the deaths in the Tx were related to the trial device. No other serious adverse effects were recorded that were caused by the device.

Conclusion

This study finds that VapCare and VapLumen can reduce the incidence of VAP in invasively ventilated patients diagnosed with COVID-19. ABX costs were also reduced by 32% in the Tx compared to the Cx. This study also allows us to hypothesize that automated suctioning can reduce the amount of secretions that can reach the subglottic region and, therefore, potentially reduce the chance of aspiration and, subsequently, VAP.

Declarations

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Contributors

AM did the analyses and wrote the first draft; all the authors contributed to the interpretation of the data and revision of the manuscript and approved the final version.

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This was an investigator-initiated study. The investigators served as sponsors.

Competing Interests

None declared.

Ethics Approval and Consent to Participate

Family members provided written, informed consent for all patients. The study was conducted in accordance with the principles outlined in the Declaration of Helsinki and was approved by the

The Narayana Health Medical Ethics committee. (A26/2021)

Availability of Data and Materials

Please contact author for data requests.

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Figures

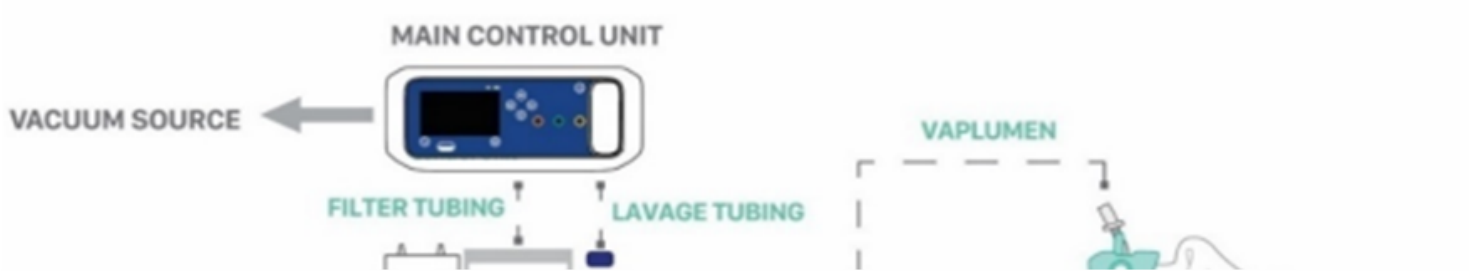

Figure 1

See image above for figure legend.

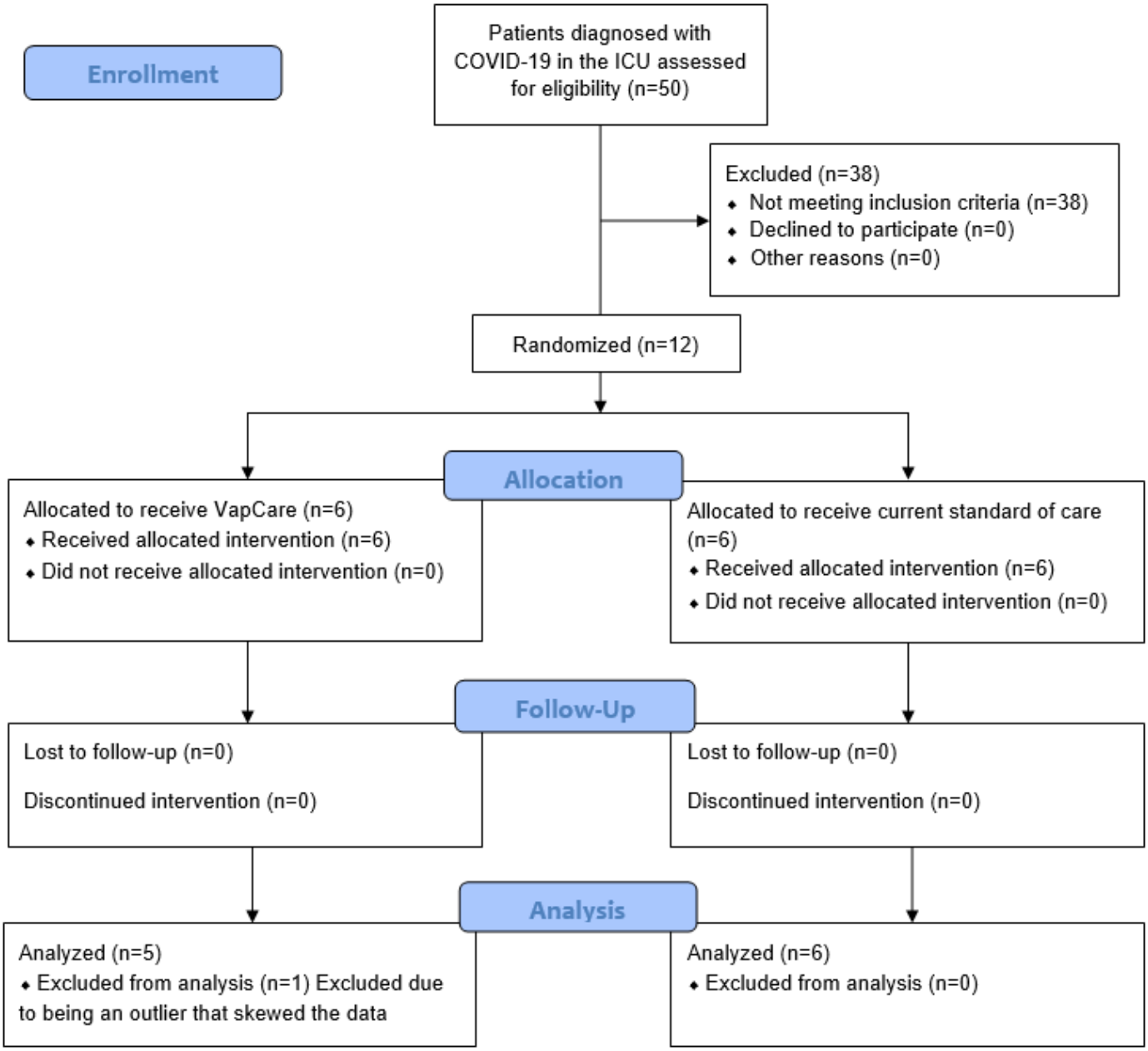

Figure 2

Flowchart of investigated patients in the study.