Smart secretion management to protect nurses from COVID19 and other infectious diseases

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Abstract

Background: COVID-19 has been linked to over 40 million infections and 1.1 million deaths in 210 countries as of October 19, 2020. This highly contagious communicable disease has put not only infected individuals but other patients and frontline workers like nurses at risk in hospitals, especially in Intensive Care units (ICUs).

There is a need for minimizing patient contact, improving hand hygiene practices, and optimizing healthcare provider time, especially nurses. Globally it is estimated that nearly a million health care providers have been infected with COVID-19 as of the end of October 2020.

Methods: This retrospective service evaluation documents the experience of health care providers in a COVID-19 ICU in India that was used to implement new protocols for secretion management and oral hygiene. Patient chart information and staff feedback were utilized.

Intervention: This pilot study captures the practical benefits of using VAPCare, an automated, closed-loop system for oral secretion removal.

Results: Six patients were included in this small-scale study; three patients following the current standard of care for suctioning and oral hygiene and three receiving the new VAPCare and Lumen device protocol. With the new device protocol, the number of infected secretion interactions by a nurse was 50% lower, and nursing time spent on oral hygiene and secretion management 70% less than seen with the current standard of care. The number of disposable gloves used with VAPCare and Lumen was reduced by over 50%. All 10 nurses and six doctors gave positive feedback on device usage. The department recommended updating protocols to prioritize the use of the new secretion management system for patients with COVID19 and other highly contagious conditions. Conclusion: The findings are an early indication that using VAPCare for patients could help protect infected patients, other ICU patients, and health care workers.

KEYWORDS

closed system suctioning, critical care nursing, intensive care nurses, oral hygiene

The work represented in this paper is original with appropriate citations to referenced materials. No material has been used without permission.

INTRODUCTION AND BACKGROUND 1

At the end of 2019 and early 2020, several cases of pneumonia of unknown aetiology were reported in Wuhan, Hubei Province, China.^{1,2} The disease, which is now called COVID-19, is caused by a novel coronavirus and has been linked to over 40 million infections, and 1.1 million deaths in 210 countries as of October 19, 2020.³ In India alone by July 2020, over 1000 health care workers (doctors and nurses) have tested positive for COVID-19.4,5 Data from the United States of America indicate that as of September 2020, over 570 000 health care providers were infected in North America.⁶

Ventilator-Associated Pneumonia (VAP) continues to be a leading cause of morbidity and mortality in intubated patients.⁷ The primary pathogenesis is microaspiration of secretions from oropharynx into the distal bronchi.8-10 Challenges in dealing with ventilated patients include managing the need for heavy sedation to prevent patients biting staff or the Endotracheal tube (ETT), the collection of fomites from use of the same suction line and tube over time, and the generation of infectious aerosols from turbid suctioning in normal pressure environments.^{11,12}

Transmission to other patients and nurses has been a significant feature globally (up to 41% of cases) of both outbreaks of Severe acute respiratory syndrome (SARS), Middle East Respiratory Syndrome (MERS), and now COVID-19.13,14 The highest numbers of nurse and doctor infections (as a proportion of all health care workers) have been recorded in middle- and low-income countries compared with higher-income ones.¹³ However, from the data, nurses and other frontline health care providers are disproportionately affected by infectious diseases when there is a massive outbreak.^{13,14} The long working hours, lack of appropriate Personal Protective Equipment (PPE) availability, high infection contact, and suboptimal cleanliness have been linked to the increased spread of any communicable disease like COVID-19.^{15,16} This risk is further magnified in resourceconstrained settings making cluster care challenging.

Suctioning with adequate oral hygiene protocols remains crucial for intubated patients. Such protocols include secretion management in the oral, oropharyngeal, and subglottic regions of a patient's respiratory tract; along with teeth brushing and antimicrobial rinses.¹⁷

2 AIM

This pilot study considered the performance and safety aspects of an automated device, VAPCare, along with a disposable product (Lumen) in delivering secretion and oral hygiene management. The nursing time spent, patient contact duration, secretion collection, and personal protective equipment (PPE) usage were observed in a small number of patients where the device was used and in patients where manual suction and oral hygiene protocols were followed. The study was completed at a tertiary care ICU of a National Accreditation Board for Hospitals (NABH) accredited Hospital in Mumbai, India. This paper aims to present the initial evaluation of a new medical device to reduce nursing time spent and contact duration with infectious secretions of COVID-19 patients.

SETTING, MATERIALS AND METHODS 3

The pilot study hospital is an accredited tertiary care centre that follows established best practices for patient hygiene, secretion

What is known about this topic

- · Minimising direct patient contact for nurses caring for infectious disease patients helps reduce infection spread.
- Typical oral hygiene and secretion management cause the generation of aerosols multiple times a day increasing transmission risk from droplets.
- Personal protective equipment and nursing time are often scarce during an outbreak.
- Nurses becoming infected puts vulnerable populations at further risk and harms the health care system.

What this paper adds

- This paper leads to an updated secretion management and oral hygiene protocol to reduce viral load exposure.
- A new medical device, VAPCare with Lumen, might help in reducing the risk of infectious diseases transmission (like COVID-19).
- This new device may also help in reducing the workload of the nurses and minimize consumption of PPE.

management, personal protective equipment (PPE) usage, and additional COVID-19 precautions. These precautions added demands of time and effort to the already strained nursing staff and was causing a shortage of some PPE and extension of shift times. Evaluating VAPCare as a time-saving device that would help keep patients and nurses safe was the motivation for this study.

The recently purchased VAPCare device with disposable Lumen minimizes patient contact and needs for manual secretion management. The department hypothesized that minimizing contact with infected COVID-19 patients would help keep nurses safe. It was decided to assess the use of VAPCare to see if suctioning protocols should be updated for COVID-19 patients to prioritize the use of VAPCare here rather than a first come first served bases across ICUs. Figure 1 is a schematic diagram of the device set up. The VAPCare system has two major components.

The first component is a disposable lumen/sheath that fits on an ETT (ideally one with a subglottic port) and extends till the oropharynx. The Lumen has ports for suctioning and oral lavage. This disposable Lumen must be connected to the second component to perform "smart suctioning and oral lavage." It has a bite blocker and fastener component to protect the ETT and hold it in place. It also has soft tip tubes that can be adjusted in length according to the patient's airway to optimize positioning.

The second component is an electromechanical machine (VAPCare) which controls the suctioning based upon a build-up inflow sensor input. This device has multiple ports to convert suction from the wall unit or suction machine into a modulated suctioning as required by location (oral, oropharyngeal and subglottic). The sensor unit uses flow detection and assessment to regulate the suction time, BACN Nursing in Critical Care / WILEY

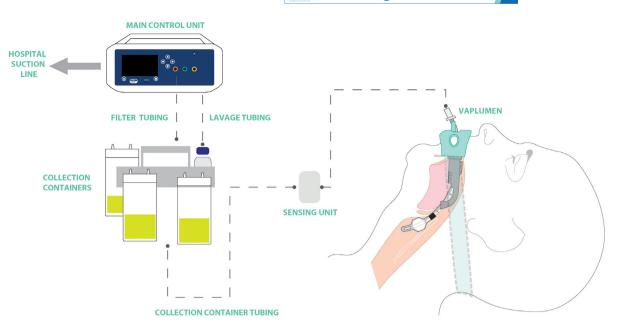


FIGURE 1 Schematic representation of VAPCare device set up. This image belongs to Innaccel Technologies Pvt Ltd. And has been used with permission to represent the product

pressure, and stopping. It can clear out port blockage from thicker secretions or particles and has been designed to minimize suctioning duration and pressure applied to the patient's airway as compared with other continuous closed-loop systems available. Further details can be seen in Figures S1 and S2.

This pilot study is a retrospective chart review that serves as a new service evaluation pilot study. The primary aim of this study was to assess performance to update hospital protocols. The ongoing pandemic made time the driving factor for completion; thus, a smaller sample size was used. The chart review was performed between the first of April 2020 and the 28th of April 2020, on adult, mechanically ventilated COVID-19 patients who did not have any other communicable disease.

All nursing and medical staff had been trained on VAPCare during installation by the manufacturer between February and March 2020. Patients included in this study were intubated following standard protocols using an ETT with a subglottic port in the hospital. Transfer patients with trauma or who were already intubated were not included in this study.

Only the first 24 hours on the device or manual suctioning was considered for analysis. These data were gathered by reviewing physician and nursing notes in the charts with regards to periodic checking and implementation of suctioning and oral hygiene protocol. (This approach was chosen because maximum contact with patients occurs during the first 24 hours, and there was no change in management time and protocol in the following days). Thus, the worst-case scenario approach was chosen for head to head comparison. All patients who had manual suctioning stayed on that protocol, and patients on the VAPCare protocol stayed on the device throughout intubation.

Soft tissue injury and tube integrity were assessed through the use of an endoscope post-insertion by the treating physician. Also, visual assessments of the oral region for lacerations and the suction line for blood during every nurse check was performed, which was at least once per hour.

The total time spent, the number of unique instances of patient contact for oral hygiene or secretion management, the volume of secretions documented, and the number of gloves consumed (the only PPE mandated to be changed after each interaction under current protocols) were tabulated for each patient. It was noted that the cap, gown, face shield, surgical mask, and N-95 masks were not disposed after each interaction and only wiped down. The number of wipes used and amount of disinfectant and sanitizer consumed was not documented quantitatively.

Six patients were admitted during this period that met the inclusion criteria, and all were included. Three patients had the use of the VAPCare device, and three patients had traditional manual suction and oral hygiene protocol. The VAPCare device was used as intended according to the manufacturer instructions. This pilot study presents descriptive statistics for the variables, in cumulative form where appropriate. The treatment staff were asked for their subjective opinion about the usability and utility of the device.

The key outcomes that were considered were nursing time, the number of patient secretion interactions, and user feedback on the device suitability. Patient secretion interaction was defined as instances when the medical staff came into contact with the patient's mouth or nose with their gloved hands to perform suctioning and oral hygiene activities. User feedback was also elicited in the form of a freeform discussion with each health care provider in a one on one interview. Their feedback was noted down. The only prompt given was "Please share your thoughts on VapCare and Lumen and in what scenarios you think it should be used, if at all." Device-related adjectives and phrases were analysed with respect to the safety, utility, and usability of the product VAPCare with Lumen for all 16 responses.

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TABLE 1	Pilot study summary results
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Parameter	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Gender	Female	Male	Male	Female	Female	Male
Age	61	59	36	74	78	49
Protocol	Standard	Standard	Standard	VAPCare	VAPCare	VAPCare
Total time spent in suction + oral hygiene in 24 h	116 min	65 min	64 min	24 min	30 min	30 min
Number of interactions with infected secretions of patient	19	13	11	6	7	7
Number of items of gloves consumed	40	26	22	10	10	14
The volume of secretions collected in 24 h	71 mL	17.5 mL	14 mL	100 mL ^a	115 mL ^a	90 mL ^a
Status of the patient (May 31, 2020)	Died	Discharged	Discharged	Discharged	Discharged	Died

^aVapCare secretion volume includes volume from oral hygiene which was not monitored under the standard protocol. Other PPE was not changed in either case between patients because of current shortages.

4 | ETHICAL AND RESEARCH APPROVALS

No ethical approval was sought for this study. During COVID-19, the Ethics committee did not meet. The hospital decided to allow any empanelled doctor to perform any retrospective, observation, case series, and non-investigational intervention studies without individual review. All good clinical practice and research guidelines were followed under hospital and international standards for human subject research. No consent was sought as this was a retrospective study with no direct study-related patient interaction or change in treatment.

5 | RESULTS

Table 1 below summarizes the results of the chart review based on the variables collected. No intubated patients were excluded for reasons of facial trauma or hospital transfer. There were no paediatric patients admitted to this ward, and thus no age-based exclusions were necessary.

The number of different people came into contact with the patient was also not separately documented in this study. While PPE checklists were followed for each shift, a change in the number of gloves used was noticed and thus represented in the results.

As of April 30, 2020, no hospital staff related to the care of COVID patients tested positive for COVID-19. The death of patient 1 and patient 6 (shown in Table 1) was because of acute cardiac events. There were no device-related adverse events or technical issues with the product. The VAPCAre and Lumens were used as intended by following the manufacturer-provided user manual.

Device performance was assessed in person by nursing staff (10) and treating doctors (6). The investigators performed a subjective one on one feedback-gathering exercise with the ICU medical team. All the staff had been part of both manual and VAPCare protocols at some point during the study. All 16 health care providers used the term "useful" and "safer" in their feedback and either "easy" or "userfriendly" as well with regards to VAPCare.

6 | DISCUSSION

All doctors and nurses had interactions at some point with patients in the standard group and VAPCare group. It was concluded that the device performs as intended based on the user manual claims and training received. Staff surveyed unanimously felt that VAPCare was both usable and useful for long-term intubated patients. This sentiment was especially true for patients with highly communicable diseases. This assessment was based on the ease of use of the device. no adverse events related to the device as well as the performance before this study and during this study in maintaining good oral hygiene and preventing secretion collection. The time saved, especially by the nurses in heavy-demand centres like the current hospital, made all the ICU staff recommend the use of VAPCare where possible. There was no injury to soft tissues of oral and pharyngeal cavities. Presence of injuries and their severity was assessed endoscopically, post-insertion and by monitoring of the suction line and oral area for lacerations and bleeding. There was no injury to staff and no compromise of the airway from patient biting in any of the six cases. The treating physician notes observed that the patients on VAPCare could be kept on lower sedation because of the bite blocker and easy, automated secretion management.

As seen in Table 1, patients on VAPCare had fewer high-risk health care worker interactions, consumed at least 50% fewer gloves and saved nursing time compared with standard manual suctioning. The number of encounters with a patient's oral and nasal region as well as infected secretions is at least 50% less while using VAPCare and the nursing time can be cut down from 1 to 2 hours to under half an hour in a day, which is a 70% reduction in time spent with infected secretions.

7 | LIMITATIONS

There are limitations to this small study. There was no separation of staff between the two groups, so it is difficult to make firm conclusions on the additional safety of the product. The highly contagious nature of the virus itself along with the multiple patient contact points would make it impossible to link any staff testing positive for COVID- BACN Nursing in Critical Care _______

19 to a particular patient or suctioning method. There were also rotating nursing and doctor staff in the COVID-19 ICU, so the variance in documentation and accuracy, especially in the case of manual secretion management, could be an issue. This study makes no claims on the efficacy of the product to prevent ventilator-associated pneumonia (VAP). This study does not claim superiority in terms of safety and efficacy with regards to patient outcomes with VAPCare and Lumen compared with manual care protocols.

8 | IMPLICATIONS AND RECOMMENDATIONS FOR PRACTICE

This pilot study is only a service evaluation that led to a protocol change in secretion management and oral hygiene of intubated patients. The new protocol in the hospital was that for COVID-19 patients who needed intubation, and the VAPCare device was to be used if available as the first choice over the manual suctioning protocol. Thus, the urgent need to make a change and limited time available to investigators made the study period short, which led to a small sample size. The new protocols have been implemented, and once further data are gathered, there may be broader implications. The use of VAPCare and Lumen has been recommended for use for all intubated patients with highly infectious diseases like COVID-19 at the current hospital.

9 | CONCLUSION

In the opinion of the authors, VAPCare is a product that could help keep health care workers and patients safe from the spread of communicable respiratory diseases like COVID-19. It saves nursing time, minimizes generation of infectious aerosols through intermittent suctioning enclosed within oral and oropharyngeal cavity and reduces the number of PPE consumed. VAPCare can be recommended to be used on all long-term intubated patients, especially for any patient with a communicable respiratory disease. Further studies are required to draw definitive conclusions on the overall time-saving and life-saving impact of VAPCare.

CONFLICT OF INTEREST

None of the investigators/authors has any financial interest in the company or personal relationships with the organization that could bias the study. This paper is a self-published study and has received no financial support from any external organization. There was no external funding for the research presented.

ETHICAL CONSIDERATIONS

The study was conducted per the Helsinki Declaration. This study was a retrospective case study for a service evaluation, no formal IERB approval or registration was required. No animals were used in the study.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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