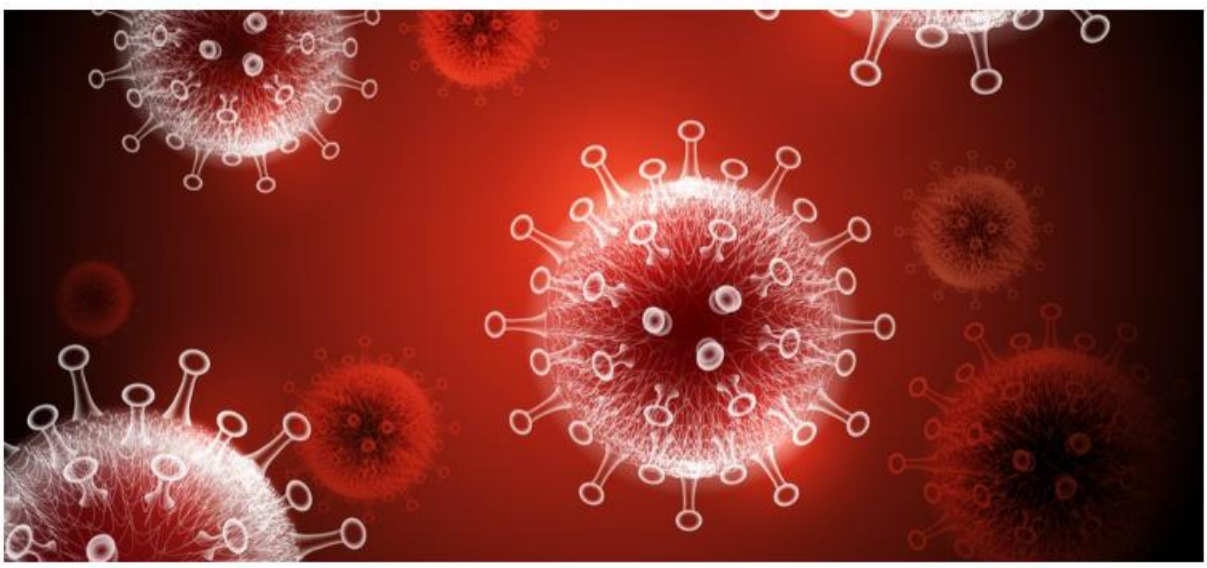
20 July 2020 09:04

How a novel airway system could prevent COVID-19 complications

by Yoav Venkert, Tzipi Yakoby

Yoav Venkert, CEO, and Tzipi Yakoby, VP clinical, Hospitech Respiration, writes about the need to find a solution for ventilation complications, the solutions available, and what Hospitech offers.



The world is currently facing one of its most widespread viral pandemics to date, the COVID-19 pandemic.

Coronaviruses cause respiratory tract infections that can range from mild to lethal. Mild illnesses include some cases of the common cold (which is also caused by other viruses, predominantly rhinoviruses), while more lethal varieties can cause SARS, MERS, and COVID-19.

Since the onset of the COVID-19 pandemic, researches emerged showing superinfections (e.g., ventilator-associated pneumonia [VAP]) to be among the most common complications of Severe Acute Respiratory Syndrome.

Over the years, various studies indicated a worrying trend, where people who have prolonged stays in the intensive care unit (ICU), and more particularly ventilated patients, are likely to develop secondary infections. These patients include COVID-19 patients who at times, remain ventilated for several weeks. Recent researches suggest that around 50% of patients who died from COVID-19 had a secondary bacterial or fungal infection.

These figures are consistent with surveys of past vital pandemics which attribute the high death rate to secondary bacterial infections, including superinfections.

COVID-19 patients and VAP

Preliminary studies and anecdotal evidence from high-burden COVID-19 areas suggest that superinfections are common, and more particularly Ventilator Associated Pneumonia (VAP).

Critically ill patients with COVID-19 who are intubated are at risk for developing VAP and other infections typical for all critically ill and/or intubated patients (e.g. central line or urinary tract infections).

Bacterial co-infections such as pneumonia pose a serious threat to high-risk COVID-19 patients, with many factors coming together to create severe, life-threatening and, in some cases, deadly complications that cannot be ignored by the health care community.

The relatively high incidence of severe infections and mortality in COVID-19 patients is attributed in part to secondary infections, alongside the lack of natural immunity and viral replication in the lower respiratory tract, leading to severe lung injury and acute respiratory distress syndrome.

There are several guidelines and bundle strategies for reducing the occurrence of VAP including ones that aim at minimising the aspiration of subglottic secretions into the lower respiratory tract and lungs. One strategy is continuous control of the airway cuff pressure (CCCP). Another preventive strategy is subglottic secretion drainage (SSD).

Among significant troubling residual symptoms reported by mechanically ventilated COVID-19 patients was difficulty in swallowing or speaking. These complications are associated with uncontrolled over-inflation of the airway endo tracheal cuff which apply constant pressure on the tracheal tissue. These findings are consistent with previous studies which demonstrated that many orally intubated ARDS survivors have dysphagia symptoms that persist beyond hospital discharge.

Airway management solutions

Over the years, several airway management systems have been developed, which offer partial solutions. These solutions offered automated cuff pressure controllers and airways with suction lines operating in conjunction with automated, intermittent suction regulators. All these devices performed only one of these functions.

As both functions are essential for proper airway management, the routine practice is to use one of the techniques or a combination of the two. The challenge that arises from using this practice is that these two functions are not synchronised.

In response to this challenge, we at Hospitech Respiration, have developed a new innovative system, the AnapnoGuard system. This system significantly reduces ventilation complications in intubated patients and minimises the exposure of clinical teams to contamination.

The system consists of the AG100s control unit and the AG ETT multi lumen airway.

What sets the AnapnoGuard apart from other solutions is that it is the only device in the market which performs both functions in synchrony and operates in closed loop control. The system performs continuous monitoring of leaks around the cuff based on the carbon dioxide (CO_2) level in the subglottic space and automated adjustment of the airway cuff pressure accordingly, to seal the leak at minimal pressure. Automated rinsing and evacuation of subglottic secretion from above the endotracheal tube's cuff.

The AnapnoGuard is already regulatory approved by FDA/510(k), CE, CFDA (China) and AMAR (Israel).

Studies designed to evaluate the efficacy of the AG100s demonstrated the ability to effectively control the ETT cuff pressure and to significantly reduce ventilation complications such as VAP (ventilator associate pneumonia).

A prospective, single centre, open-label, randomised, controlled feasibility and safety trial demonstrated that patients enrolled in the AG group had a trend to reduced VAP risk of ventilator-associated pneumonia (VAP) (14.8% vs. 40%; $p = 0.06$).

Another study shows that the use of automatic cuff pressure control based on subglottic measurements of CO_2 levels is an effective method for ETT cuff pressure optimisation (reducing the leaks by ten folds). The method is safe and can be easily utilised with any intubated patient.

To this date, more than 600 patients have been successfully treated with the system in hospitals in the Israel, Europe, US and China.

The AnapnoGuard system has been in use in several leading hospitals in China for the last two years, where it was also used to treat ventilated COVID-19 patients at the Tongji University Hospital in China's Hubei Province, the original epicentre of the pandemic.

Since early 2019, the system has also been trialled at Mayo Clinic in Florida, USA. During this trial, patients identified by the medical team as high risk for developing airways complications are considered for treatment with the AnapnoGuard system.

Although ventilator associated pneumonia (VAP) has been a concern that affected the standard of care in ICUs across the globe, the outbreak of COVID-19 has highlighted the need for a tested and approved solution that will significantly reduce ventilation complications and the level of mortality rate among intubated patients.

As healthcare systems across the globe begin testing new and innovative ways to provide better care for their patients amid the current pandemic, a solution to reduce ventilation complications, such as ventilator associated pneumonia (VAP), should be considered as a primary goal.

Hospitech Respiration | COVID-19 | coronavirus | ventilation

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