CADTH COVID-19 PANDEMIC

COVID-19 CADTH HEALTH TECHNOLOGY UPDATE

Non-Invasive Ventilation With Helmets for Acute Respiratory Distress Due to COVID-19

This article was published on September 29, 2020.

To produce this report, CADTH used a modified approach to the selection, appraisal, and synthesis of the evidence to meet decision-making needs during the COVID-19 pandemic. Care has been taken to ensure the information is accurate and complete, but it should be noted that international scientific evidence about COVID-19 is changing and growing rapidly.

Service Line: CADTH Health Technology Update
Version: 1.0
Publication Date: September 2020
Report Length: 10 Pages

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Cite As: Non-Invasive Ventilation With Helmets for Acute Respiratory Distress Due to COVID-19. Ottawa: CADTH; 2020 September.

About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

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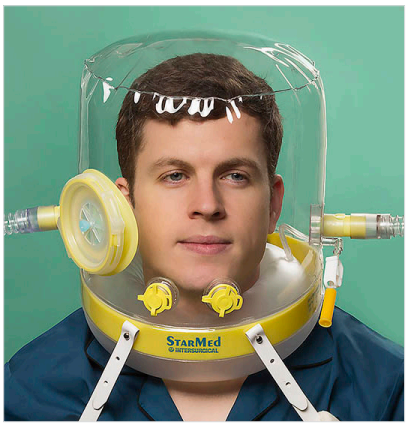

StarMed CaStar R hood non-invasive ventilation. Photo copyright Intersurgical Canada. Reproduced with permission.

Patients who are hospitalized with severe respiratory illness due to COVID-19 may need some form of supplemental oxygen and breathing support.

Patient helmets — also called hoods, "helmet masks," "bubble helmets," or helmet non-invasive ventilation — can filter virus particles exhaled by patients receiving respiratory support, reducing the risk of virus transmission to health care providers and other patients. Helmets may also reduce demands on intensive care unit (ICU) resources and may be more comfortable for patients than facial masks.[1-4]

How It Works

Originally developed for use in hyperbaric medicine, portable respiratory helmets are reusable plastic bubbles that loosely cover a patient's head.[5] They include a rigid neck ring with a soft silicone or latex collar sized to fit the patient to minimize air leakage and are held in place with underarm straps or counterweights.[6-9] Additional ports on the helmet accommodate the respiratory tubing and nasogastric tubes.[6] A monitor controls gas flow and measures carbon dioxide, inhaled oxygen levels, and temperature.[6]

Ventilation helmets allow the provision of non-invasive ventilation while minimizing the exposure of health care providers and others to aerosolized virus particles.[1,2] The helmets contain aerosolized particles more effectively than nasal or facial masks because a high-efficiency particulate filter can be used on the helmet's expiratory port, creating a relatively closed system.[6]

Who Might Benefit?

Many patients who experience critical illness due to COVID-19 will have acute respiratory distress syndrome or respiratory failure with severe hypoxemia (low levels of oxygen in the blood).[10-13] Approximately 10% to 14% of patients with severe or critical COVID-19 illness may need treatment in the ICU;[6] 60% to 70% of these patients will have progressive acute respiratory distress syndrome and 20% to 25% will need endotracheal intubation and mechanical ventilation.[6]

Helmet-based non-invasive ventilation can provide respiratory support for moderately ill patients in earlier stages of COVID-19–related acute respiratory distress.[3,6] A helmet fitted to the patient at this stage can increase inspired oxygen when used with non-invasive ventilation, such as through an adapted continuous positive airway pressure (CPAP) machine.[6] In addition, helmet ventilation may reduce the patient's expiratory effort, potentially mitigating lung injury.[14]

Patients may find the helmets more comfortable than oxygen masks — which may be important when respiratory support is needed for longer periods, as for patients with respiratory distress due to COVID-19.[9,15] This could also improve treatment delivery, with less need for sedation (as is needed for patients who have been intubated).[6,7,13,16,17] The

helmets also allow the patient to wear their glasses, drink, expectorate to clear sputum, and to communicate.[6,17,18] Different sizes of helmets are available to accommodate children and adults, and, unlike face masks, helmets can accommodate all patients, regardless of facial morphology or injuries.[6,17]

Availability in Canada

The Starmed CaStar hood for non-invasive ventilation (Intersurgical Ltd, Burlington, Ontario) has received Health Canada authorization for use during the COVID-19 pandemic.[19] Since June of 2020, the Starmed hood has been distributed to the following Canadian provinces: Newfoundland and Labrador, Nova Scotia, New Brunswick, Quebec, Ontario, Alberta, and British Columbia (Michael Hayden, Intersurgical Ltd, Burlington, ON: personal communication, Aug 19, 2020).

The Alberta COVID CPAP Hood, (Gemma Plastic Products Inc.) has also received Health Canada authorization for use in Canada during the COVID-19 pandemic.[19,20]

Ventilation helmets manufactured in the US include:

- COVID-19 Helmet Kits (Sea-Long Medical Systems, LLC.); the company confirmed it can ship to Canada (Melissa Nogic, Sea-Long Medical Systems, Inc., Waxahachie, TX: personal communication, Jul 24, 2020)
- NIV Hood (Amron International)
- Subsalve Oxygen Treatment Hood (Subsalve USA)
- Non-invasive ventilator helmet (Extol, Inc.)
- Aerospace Valley Positive Pressure Helmet (NASA)
- Vyatil One non-powered oxygen tent (LMD Power of Light Corp.).[21,22]

What Does It Cost?

Examples of ventilation helmets and helmet kits costs are as follows:

- Sea-Long Medical Systems' COVID-19 Helmet Kit A (PN 5401) costs US$162.70 and the COVID-19 Helmet Kit C (PN 5404) costs US$279.92.[23]
- The Alberta COVID CPAP Hood will cost approximately CA$225 (including all fittings) (Tom Vermeeren, Gemma Plastic Products, Inc., Edmonton, AB: personal communication, Aug 18, 2020).[24]
- A helmet-based, non-invasive ventilator system, developed in the US and being tested in Bangladesh, and intended for use in medium- to low-resource settings, is estimated to cost from US$200 to US$400 to build (including the cost of the helmet and ventilator).[3,25]

Current Practice

Patients with COVID-19 who require supplemental oxygen may receive low-flow oxygen through a nasal cannula or oxygen pendant.[26,27] If the patient requires more respiratory support, this may be provided with high-flow nasal oxygen delivered via a nasal cannula or through non-invasive positive-pressure ventilation.[7] However, non-invasive ventilation methods may leak, increasing the exposure of health care providers and other patients to aerosolized virus particles.[7]

Non-Invasive Positive-Pressure Ventilation

Non-invasive positive-pressure ventilation (NIPPV) may be used to treat some patients with moderate respiratory distress due to COVID-19 or other illness.[28] The use of these technologies for patients with respiratory distress usually requires a ventilator, but simplified non-ventilator versions may be an option when ventilators are in short supply.[28]

Technologies that deliver NIPPV include:

- **CPAP** — Commonly used in the home to treat obstructive sleep apnea, the CPAP machine delivers a constant air pressure into the airway, usually via a mask.
- **Bilevel positive airway pressure (BPAP)** — A type of ventilator used to administer oxygen via a mask or nasal cannula, BPAP provides airway pressure to assist breathing during both inhalation (with a higher level of pressure) and expiration (with a lower level).[29]

However, as oxygen flow increases, so does leakage and the potential for aerosolization of virus particles.[6-8,27,30] High-flow nasal oxygen, positive pressure ventilation (CPAP and BPAP), and endotracheal intubation and extubation are all considered aerosol-generating procedures. These pose a risk for droplet dispersion, necessitating the need for appropriate personal protective equipment for health care providers in these situations.[6,27,28,31-33]

Invasive Mechanical Ventilation

Invasive mechanical ventilation involves the insertion of an artificial airway (endotracheal intubation or tracheostomy tube).[7,26,27] It is intended to help critically ill patients who cannot breathe without assistance by delivering oxygen and removing carbon dioxide, allowing their lungs time to recover. Because invasive ventilation usually involves a closed system, it may pose less risk for transmitting viruses via aerosols.[34] In patients with severe respiratory distress due to an infectious disease, physicians may decide to use invasive mechanical ventilation earlier, rather than later, to try to stop progression of the illness and to minimize aerosolization and possible transmission of the virus.[28] However, a recent German position paper cautions that, with appropriate staff personal protective equipment in place, infection risk should not be a reason to intubate.[35] Health care providers try to balance the needs of and risks for the patient with the risks for health care staff and the resources available.[27,36]

What Is the Evidence?

The Surviving Sepsis Campaign guidelines on the treatment of critically ill patients with COVID-19 rated evidence to support most interventions for ventilation as weak, and the authors "… were not able to make a recommendation regarding the use of helmet NIPPV compared with mask NIPPV. It is an option, but we are not certain about its safety or efficacy in COVID-19."[10]

COVID-19–Specific Studies

One retrospective observational study reported the results of a chart review of patients with suspected COVID-19 assessed over the course of a 10-day period in the emergency department of a large regional hospital in Italy.[4] Of those admitted to the hospital, 85 patients with confirmed COVID-19 needed immediate respiratory support.[4] Seventy-one patients were started on helmet CPAP, seven patients received NIPPV with BPAP, and seven patients were intubated for invasive mechanical ventilation.[4] The authors concluded that helmet CPAP or non-invasive positive pressure ventilation could be an alternative to early invasive mechanical ventilation when intensive care resources are lacking. However, further evidence from a

randomized controlled trial is needed to confirm this and to clarify which patients would be most likely to benefit from non-invasive ventilation.[4]

Regarding patient ventilation strategies and the risk of transmitting COVID-19 to health care providers, a 2020 living systematic review concluded that, based on limited evidence, helmets may reduce the risk of disease transmission.[34]

Experience in Italy

In Italy, the large number of COVID-19 patients and the shortage of ventilators and ICU beds resulted in the widespread use of helmet-based CPAP.[13] Some Italian clinicians suggest that, in selected COVID-19 patients, combining helmet-based CPAP with prone positioning (with the patient lying face down) may improve oxygenation.[13,37] Italian clinicians have also advised that using the helmet with counterweights (rather than the underarm straps), ensuring adequate humidification of the helmet, and using a filter to reduce noise (the "helmet bundle") will make the helmet more comfortable for patients.[8] Italian physicians have also published a protocol for helmet-based CPAP in patients with acute hypoxemic respiratory distress due to COVID-19.[9]

Recent Non-COVID-19 Studies of Non-Invasive Helmet Ventilation in Patients With Acute Respiratory Distress

A Canadian systematic review and network meta-analysis of non-invasive oxygen treatments in adults with acute respiratory failure, published in June 2020, provides further evidence.[16] Although the level of evidence was considered low, helmet-based non-invasive ventilation was associated with a reduced risk for endotracheal intubation compared to either high-flow nasal oxygen or face mask ventilation. Helmet-based ventilation was also associated with a lower risk of all-cause mortality compared with conventional oxygen therapy.[16] The findings of the Canadian review were consistent with those of an earlier (2016) systematic review that compared non-invasive helmet ventilation to mask ventilation for people with acute respiratory failure.[17]

Safety

Ventilation helmets require monitoring and alarm systems to continuously safeguard critically ill patients — in particular, to ensure adequate air flow and clearance of carbon dioxide to prevent asphyxiation.[1,9] Commercial monitoring systems are available, but these may be in short supply during a pandemic.[1] Researchers at Princeton University have designed an inexpensive, multi-patient respiratory monitoring system (the Princeton Open Ventilation Monitor), which consists of a bedside interface unit with a digital display for each patient, and a central, remote monitoring station (networked computer). Instructions and software for building the system are freely available.[1] Although the Princeton system is designed for use with the Sea-Long Medical Systems COVID-19 Helmet Kits, it can also be used with other helmet systems.[1]

Adverse events noted with the use of ventilation helmets include discomfort and skin ulceration from the neck collar and underarm straps.[6,8] The noise level inside the hood may also be bothersome, but this can be reduced with the use of a filter.[8] Other potential disadvantages include the risk of rebreathing (carbon dioxide inside the hood), and lack of synchrony with the patient and the positive-pressure ventilation system.[13,26]

Patients with respiratory distress syndrome due to COVID-19 may also have an increased risk for deep vein thrombosis.[38] Case reports suggest that the underarm straps used to hold ventilator hoods in place may increase the risk for upper limb thrombosis.[38] Alternatives to

underarm straps, such as weights, may be preferable, but could be more time-consuming for staff to position and in short supply.[39]

Although alternatives to invasive mechanical ventilation systems can be beneficial when appropriate, delaying their use in patients who need them may result in the progression of disease, lung injury, or death.[13,28]

Issues to Consider

Unlike a face mask or nasal cannula supplying oxygen, ventilation helmets may be more comfortable for patients, as they don't touch the face, and the clear hood allows the patient to talk, watch television, or read.[13,40] However, UK guidance notes that both helmet and mask CPAP may be distressing for some patients and that low doses of drugs to reduce discomfort may be needed.[41]

In centres where non-invasive ventilation is not routinely used, additional nursing and respiratory staff training and time may be needed initially, particularly to ensure the careful monitoring of patients for the early identification of treatment failure and the need for intubation.[7,9,13,42]

The helmets may also reduce the need for patients with COVID-19 receiving non-invasive ventilation to be treated in negative-pressure rooms and allow some patients to be treated and monitored in hospital wards rather than in the ICU.[2-4,8,13] The costs of endotracheal intubation and mechanical ventilation are also avoided, as are the costs of treating adverse events from these procedures.[7,26]

Related Developments

An aerosol-reducing ventilation mask for use with CPAP and BPAP machines (Glia Inc., London, Ontario), has received Health Canada Interim Order authorization for use during the COVID-19 pandemic.[43] A clinical trial of the technology is in progress and the device is expected to cost approximately US$700 to produce.[43]

In Israel, a clear, canopy-style bed shield has been developed and is in use in at least one COVID-19 treatment unit (Lady Davis Carmel Medical Center, Haifa, Israel).[44] The canopy includes a filtration unit to reduce health care staff exposure to aerosolized virus particles, while allowing the use of non-invasive ventilation therapies for patients.[44] Similar bed hood barriers to minimize staff exposure have also been developed in-house in other centres.[36,45-48] Portable negative-pressure tents are also intended to minimize the transmission of COVID-19 and further protect health care providers.[49]

Looking Ahead

Most studies examining the use of portable ventilation hoods for the management of patients with COVID-19 have concluded that further evidence is needed from randomized controlled trials and trials with a larger number of participants.[14,17] Nevertheless, the evidence to date suggests that, for some patients with hypoxemic respiratory failure due to COVID-19, an initial trial of non-invasive helmet ventilation may reduce the number of patients who need endotracheal intubation. The full extent of the impact on patient outcomes and ICU resources is not yet known.

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