Helmet Noninvasive Ventilation using Wall Gases: Sparing Ventilators during the 2020 Coronavirus Pandemic

John Gotchall, MD
April 2, 2020

Contents (sections in ToC linked)

BLUF:

The "bottom-line up front" is that helmet oxygen tents appear to be an effective patient interface which can deliver high FiO_2 and moderate PEEP. This interface may be used with wall gases to spare ventilators during the coronavirus epidemic. Perhaps the best single best-practice resource is this linked 25-minute video by Dr. Bhatki Patel at the University of Chicago.

Author

I am John Gotchall, M.D., a pulmonary and critical care physician who worked with the Oregon State University Fast Respiratory Response Team (OFRR) of non-clinical engineers and scientists, and respiratory therapists at Good Samaritan Regional Medical Center, to assess helmet, non-powered oxygen tents as a means of sparing ventilators. The contents of this folder are an open-source library with in-service materials, available to all clinicians interested in deploying helmet-based noninvasive ventilation (HNIV) to deliver high oxygen concentrations and PEEP during this coronavirus epidemic. I have no conflicts of interest.

Motivation

The immediate goal of this project is to spare ventilators and protect health care workers during the 2020 coronavirus pandemic. The project uses FDA registered equipment to deliver oxygen and PEEP to awake patients.

I am mindful of the quadruple aim in healthcare and believe HNIV supports quadruple aim metrics when used optimally:
(i) Improve individual outcomes and population health;
(ii) Improve patient experience and satisfaction;
(iii) Lower total cost of care; and
(iv) Improve health care worker satisfaction.

Target User Group

The target users are **physicians**, **respiratory therapists** and **nurses** treating patients with acute hypoxemic respiratory failure (AHRF), with or without COVID-19 pneumonia.

Concept: Helmets may spare ventilators

Helmet oxygen tent (also referred to as helmet or hood) interfaces have treated patients with ARDS more effectively than oronasal mask interfaces (JAMA 2016). Brakti Patel and colleagues, at the University of Chicago, showed non-invasive pressure support ventilation with a helmet was superior to face mask NIV in this 2016 study: **Patel B., et al. *Effect of Noninvasive***

Ventilation Delivered by Helmet vs Face Mask on the Rate of Endotracheal Intubation in Patients with Acute Respiratory Distress Syndrome: a randomized clinical trial. **JAMA. June 14, 2016; 315(22):2435-2441, linked here**. The study was stopped early because helmet ventilation was superior for several outcomes, including intubation rate (18% vs 62%), ventilator-free days (28 vs 12.5) and 90-day mortality (34% vs 56%). A higher proportion of HNIV tolerated PEEP > 10 cm (48% vs 23%). Tolerance was similar. This study shows helmets were an effective interface *driven by pressure support ventilators,* before the COVID-19 pandemic.

Helmets driven by wall gases have been widely used in Europe during this coronavirus crisis for patients with mild to moderate AHRF, including many patients with COVID-19 pneumonia but have not been rigorously studied; helmets will likely have utility after this crisis. Dr. Patel's review of the helmet interface, including instructional video materials is linked above.

The Italian model uses helmets without ventilators. The helmet becomes a large mixing chamber, receiving high flow oxygen from wall gases on the inspiratory circuit while attaching a PEEP valve and filter to the expiratory circuit. This system can deliver an FiO_2 of 50-73% and PEEP of 5-20 cm H2O using wall gases rather than a ventilator. By stopping medical gas flow and using only oxygen, the system can deliver 100% oxygen if needed (for example, to hyper-oxygenate a patient with helmet failure prior to intubation). This helmet wall-gas system may benefit 20-25% of patients with AHRF due to coronavirus (observation from Italy).

Beyond this immediate pandemic, helmet oxygen tents may be used to treat patients with AHRF using either wall gases or a ventilator.

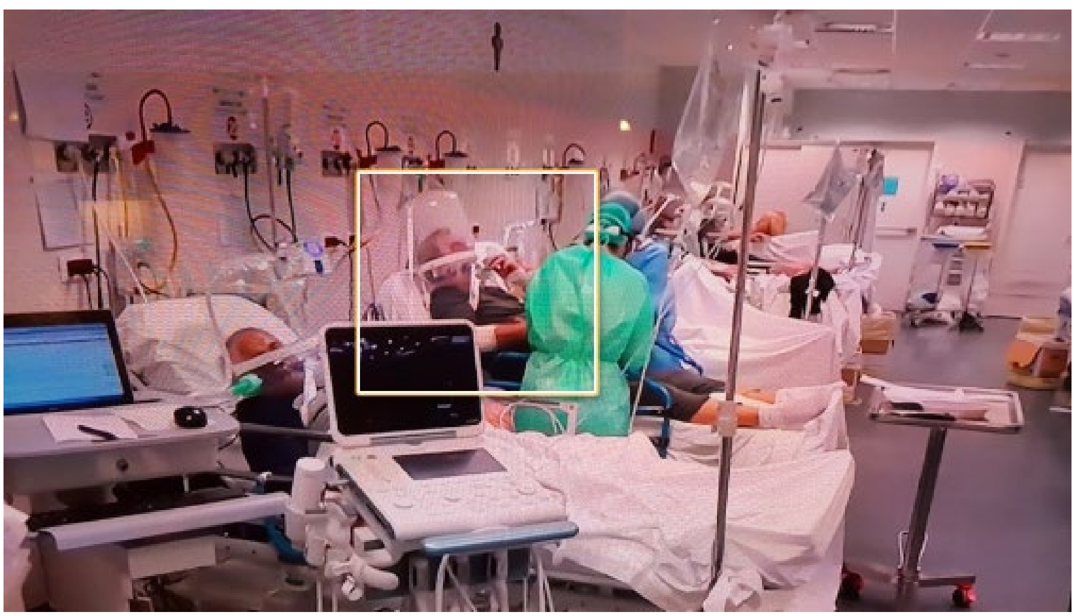

Figure 1: This screenshot from The Today Show on March 21, 2020 shows half of an 8-bed ICU in Italy. All patients appear to be getting helmet ventilation using wall gases.

HNIV driven by wall gases

The helmet interface has been used by Italians and other European physicians to provide PEEP and high FiO_2 to patients with acute hypoxemic respiratory failure, including ARDS related to COVID-19. This methodology provides an exhalation filter, 60-150 LPM flow, 73% FiO_2 and ePEEP 5-20 cm (minus PEEP needed to inflate the helmet). The helmet interface has been shown to be more effective than high flow nasal cannula and face-mask for treating AHRF; optimally fit helmets seem to disperse fewer droplets and particles into the environment. We have given this method a dry run with respiratory therapists, and an engineer who doubled as a normal subject.

I think of the helmet as a big mixing chamber, capable of delivering up to 73% oxygen and 5-20 cm PEEP with controlled dispersion.

The U. Chicago setup starts with two wall sources (flush oxygen and flush air). If additional oxygen or flow is needed, the third wall gas source is added to the existing port.

A detailed explanation of this system set-up is found at 8:49 of the University of Chicago (UC) video, linked here. The expiratory limb contains an adjustable PEEP valve and HEPA filter. The inspiratory limb contains an oxygen analyzer (temporary use), three lines of high flow wall gases and a standard filter. The oxygen analyzer can be removed after titration. A simple manometer can be used to assess PEEP from the expiratory limb for analog end-expiratory measurements. The UC system keeps an EZ PAP PEEP monitor in line.

The UC video explains how to titrate PEEP and FiO_2. High flow is required for higher levels of PEEP and to avoid CO_2 retention.

Figure 2: This photograph shows a wall gas driven a wall gas driven helmet noninvasive ventilation system, modeled by John Selker, Ph.D. In his right hand (center of photo) is the expiratory circuit with an in-line filter followed by an adjustable PEEP valve. In his left hand (right of photo) are three lines of flush wall gases delivering 100-150 LPM to the inspiratory circuit.

Helmet noninvasive ventilation using BiPAP V60 machine.

This system is described in the UC video at 16:23, including a discussion of its limitations.

Helmets

Two helmet non-powered oxygen tents are manufactured in the U.S. and registered with the FDA as Class 1 devices. Europeans use a different helmet, StarMed, not available in the U.S. The StarMed seems to have a better neck-seal and less dispersion than U.S. models. The helmets can be cleaned and reused, as directed by your infection control team. To expedite your order, consider prepayment.

Sea-Long, linked here

Sea-Long received attention after the JAMA 2016 study showing the interface effectively treated patients with mild to moderate ARDS. They are based in Texas and are ramping production. To order, go to their website and call their number: (502) 969-4949. In addition to ordering helmets, consider ordering additional non-latex rubber neck seals to replace soiled, torn or contaminated rubber neck seals. A bill of materials (BoM) is linked here to help you order additional supplies for this application.

Amron International, linked here

This company in California also makes helmet oxygen tents. We are in the process of acquiring, testing and building a bill of materials for this device.

Production

Production of these helmets is currently limited and international demand is increasing. As of March 27, production was approximately 200 units per week at the Texas plant and about 200 per week at the California plant. The OFRR is working with the manufacturers and others to increase production; we expect production to increase each week.

Supply Chain Considerations

"Just in time" inventory strategies are deeply problematic during a respiratory pandemic. Adequate supplies of durable respiratory equipment can be ordered in surplus. Orders drive production, so ordering adequate supplies may be helpful for others. We anticipate shortages of helmets, PEEP valves, HEPA filters and other oxygen breathing circuit supplies.

Hoarding respiratory supplies is unethical. Medical systems with a surplus should redistribute excess supplies to systems with acute needs.

Bill of Materials (BoM)

The bill of materials for helmet based non-invasive ventilation using wall gases is linked here.

Helmet Assembly

Neck-Seal Sizing

There is an exception to the manufacturer's instructions herein. **Use a neck circumference 2 sizes smaller than that recommended by the manufacturer to reduce leak.** Patel and colleagues recommend and regularly use this accommodation. Our subject found this fit comfortable and without complications in our dry run. Measure the neck circumference. Mark the rubber neck-seal at the size indicated **minus two (2) sizes.** Cut the neck-seal at that mark.

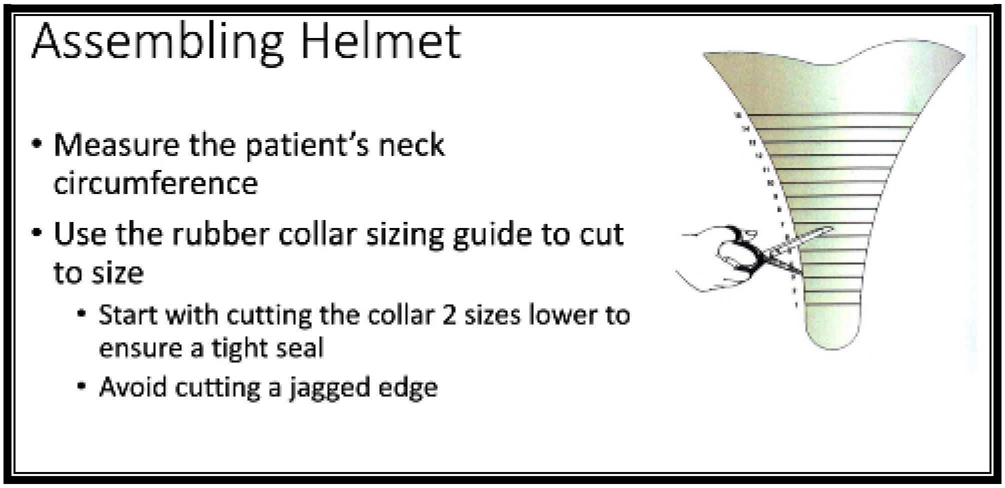

Figure 3: Neck-seal fitting instructions from University of Chicago.

Rubber O-Rings

Greasing the rubber O-rings with oxygen compatible grease may further reduce leaks in the circuit. Compatible greases are noted in the BoM. This step may not be essential if you do not have that grease; grease not rated for high-oxygen content may spontaneously combust.

Donning the Sea-Long helmet

This linked video features Dr. Bhatki Patel explaining helmet non-invasive ventilation (HNIV) use for ARDS. Further details are found in the indexed video under the BLUF section above.

Dr. Bhatki used the following to accommodate patient comfort. Many of these concepts are expanded elsewhere:

(i) The Sea-Long non-latex rubber neck-seal is typically cut two sizes smaller than the manufacturer's recommendation to minimize leaks.

(ii) Felt arm straps were used to secure the helmet beneath the arms. These arm straps may be repurposed from the cushioned arm straps used to position patients during surgery, from you OR stores.

(iii) Consider a rolled-up towel to the back of neck where the helmet tends to rub.

(iv) Two wrist restraints may be used prn to hold the helmet down, clasped together over the top of the helmet and tied to bed rails to limit rise of helmet in order to minimize leak.

(v) Feeding and suction catheters can be placed beneath the helmet. A third port can be put in the helmet for feeding and suctioning using a rubber stopper through which is placed a tracheostomy inner cannula or other suction/feeding devices. When feeding, avoid splatter by being sure the patient has the feeding tube in mouth before placing the intake portion in the feeding supplement or other liquid.

(vi) Ear plugs are indicated to avoid hearing loss from loud, turbulent airflow.

Strapping Systems and Cushions

Strapping systems may be necessary to limit leak and skin abrasions. Helmets tend to move up and down during tidal breathing, causing skin abrasions. Strapping can be used from the caudal helmet ring, anteriorly and posteriorly, secured under the arms.

Additional strapping has been used over the top of the helmet using standard wrist restraints secured to bed rails.

Cushions may be useful where the helmet ring rubs on the back of the head or neck. A rolled-up cloth tool may be an immediately available and effective cushion.

HNIV Indications

Indications for considering HNIV with wall gases are similar to the indications for high flow nasal cannula:

- Mild to moderate acute hypoxemic respiratory failure which may benefit from PEEP. Consider HNIV as a substitute for high flow nasal cannula for patients with SpO_2 less 90% on 6 lpm oxygen. Patel (JAMA 2016) used HNIV in patients with ARDS and an average APACHE II score of 25.
- Alert or arousable: Patel (JAMA 2016) excluded patients with GCS less than eight (<8) and patients with impaired airway protection or gag reflex.
- Claustrophobia with oronasal mask ventilation
- Patients who prefer HNIV, including those with a Do Not Intubate treatment preference.

Contraindications

Contraindications include:

- Failure to improve with HNIV after 2-hour trial
- GCS less than eight (<8) and patients with impaired airway protection or gag reflex.
- Upper airway obstruction
- Elevated ICP
- Poorly controlled CO_2 retention

Cautions and Limitations

- CO2 rebreathing and dys-synchrony due to large chamber dead-space
- Clinician learning curve
- Lack of RCTs involving helmet wall gas-powered ventilation
- Lack of RCTs for COVID-19 pneumonia (although Italian clinicians estimate HNIV spared 20-25% of patients from intubation).

HNIV Failures

Consider identifying patients with HNIV failure early and proceed to safe intubation. Rather than intubating directly, the HNIV could be used with a ventilator in pressure support mode and FiO_2 100% to pre-oxygenate prior to rapid sequence intubation.

HNIV failure in Patel's study (JAMA 2016) was more often due to neurologic failure (63%) than respiratory failure (38%). Skin ulcers at the device interface occurred in 7% of patients, regardless of helmet or mask interfaces, but the ulcers were on the neck with HNIV rather than the nose. Helmet deflation occurred in 5% of patients and was quickly corrected.

Indications for intubation

- Hypoxemia despite adjusting FiO2 and PEEP.
- RR above 36 bpm.
- Acidosis with pH less 7.20
- Loss of protective airway reflexes
- Cardiac or respiratory arrest
- Patient intolerance, bleeding, vomiting or excessive secretions

Converting HNIV to ETT interface

1. Pre-oxygenate with 100% oxygen. Consider assisted ventilation through the helmet using ventilator in PS mode.
2. Consider an additional set of hands: one person assigned to remove helmet and one to perform (rapid sequence) intubation as a choreographed maneuver.
    a. When ready to intubate, undo helmet straps, place hands under the rubber collar, spread opening and pull helmet off the head.
    b. Keep the helmet and parts in a bag for respiratory therapy to collect and process. The helmet and some components may be cleaned and reused.

Monitoring

Ideally, these devices will be used with standard ICU level monitoring, including telemetry and continuous SpO2 monitoring. Ideally, arterial catheters might be used for rapid assessment of CO_2 retention by ABG. Venous blood gases may be an alternative. End-tidal CO_2 has not seemed to work because of turbulent flow.

Liberating from Helmet

First, reduce PEEP and FiO2 as tolerated. Consider discontinuing HNIV when patient has RR less 30 and adequate oxygen saturation with FiO2 of 50% or less and PEEP 5-8 cm H20.

Particle Dispersion (Leak)

Leak depends on the quality of the interface between the rubber neck-seal and the patient, pressures in the helmet and perhaps other factors. I estimate that leak is, on average, less with HNIV than high flow nasal cannula or oronasal mask interfaces.

Hui and colleagues (Chest 2015, linked here) have studied dispersion in a human simulator, comparing various oxygen-patient interfaces. Dr. Hui injected smoke particles into the human simulator's lungs during normal breathing, then illuminated the particles with laser light-sheets. The photograph below shows differences in both dispersion distance and intensity between a standard full-face mask (left, the plume reaching 700 jet reaching 700 mm) and helmet (right, plume of about 150 mm) interfaces. Coughing and higher pressures would increase dispersion.

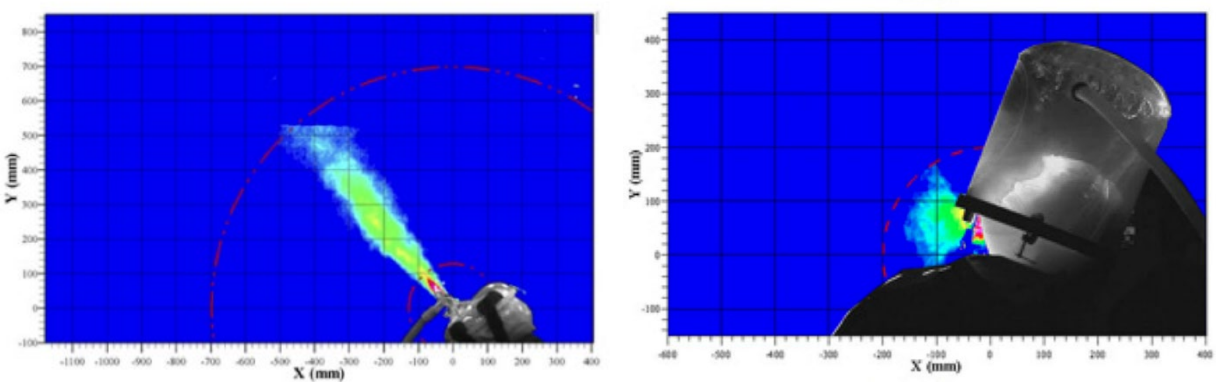

Figure 4: Illustrations of smoke particle dispersion during normal breathing by a human simulator fit with a full-face mask (left) and helmet (right).

Helmets made in the U.S. appear to have more leak than the StarMed helmet made in Europe (and unavailable in the U.S.). In the photograph below, Dr. Hui shows dispersion from the U.S. Sea-Long helmet (left), the European StarMed helmet (middle) and a full-face mask (right).

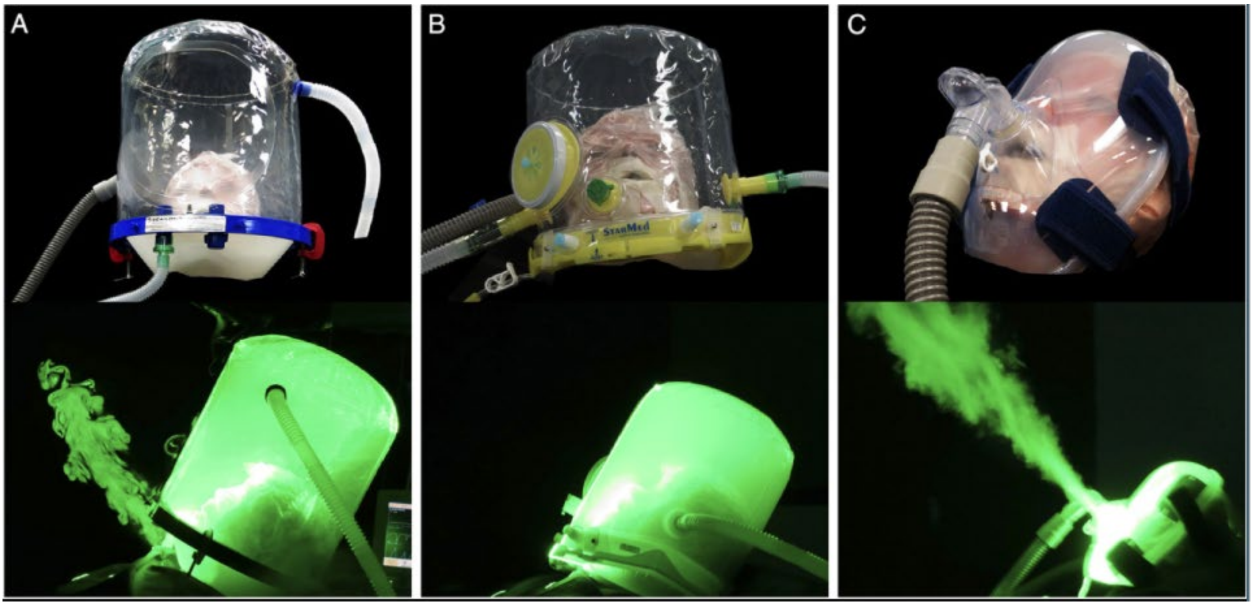

Figure 5: Photographs of dispersion from Sea-Long helmet (left), StarMed Helmet (middle) and full-face mask (right).

Dr. Hui told me, "As long as we can improve the sealing of the neck … it does not matter which brand we use." In order to reduce leak, the OFRR has tried various sealants between the neck-seal and the patient. Dr. Selker found that "Skin Tac" adhesive applied to the patient-facing portion of the neck-seal allowed use of "Nexcare Soft & Stretch" tape to improve the neck-seal effectiveness. This seal was easy to break when the subject was liberated from the hood.

It is not clear to us that every HNIV using wall gases will require extra strapping under the arms or across the top of the helmet. In part, extra strapping maybe related to how the helmet moves during the breathing cycle.

Patient Comfort & Access Accommodations

Ear Plugs

The helmet is noisy. Ear plugs should be available for all patients and might be indicated to comply with OSHA standards for hearing protection. Noise cancelling earphones might be considered for communication and entertainment.

Neck pain or abrasions

A hand towel or neck pillow can be placed at the posterior neck inside the helmet to improve comfort and reduce abrasions. Duoderm or Mipalex can be placed at the nape of the neck.

Axillary pressure (ulcers and paresthesias)

Try tethering the helmet by placing wrist restraints over the top of the helmet to secure to the bed and limit the helmets vertical piston-like movement with tidal breathing or coughing.

Feeding

Figure 6: Shows blue bite-valve feeding tube.

This high flow ventilation system creates a Venturi effect in the helmet which will pull liquids in, soiling the helmet and patient. To prevent this, always have the patient place their feeding device in their mouth with a tight seal before placing the supply end of the tube in water, supplemental feeds or other liquids. Likewise, remove the supply end before the patient releases their end of the tube.

The OFRR has developed a potentially effective feeding system using a CamelBak-style bite-valve and bladder. This system (Figure 6), and can be run either though the central rubber fitting between the air ports, or run through a side port in the helmet, sealing the port with a 1-hole #2 rubber stopper inserted from the inside of the helmet, so it cannot be pushed out by the air pressure. You may cut the stopper to facilitate insertion of the tube, if necessary. The quick-release connection to the bladder on the CamelBak hose is helpful in simplify the management of the system during installation. Because the patient's head position within the helmet shifts, it is useful to be able to adjust the position of the feeding-liquids tube. The bite-valve can be moved about the helmet because a steel plate is taped to the tube inside the helmet and a magnet is placed on the helmet externally, within reach of the patient or attendant.

Oral and nasogastric tubes or Dobhoff tubes can be threaded through the rubber collar and connected to tube feeds.

Humidity

Humidity is not usually needed and adding humidity tends to fog up the helmet. High flow dry air has been shown to reduce humidity below 30% in the chamber, however; intermittent humidity and oral fluids might be considered prn.

Nebulization

Consider avoiding nebulized treatments to limit aerosolization.

Suctioning

Turn FiO2 up to 100%. Remove rubber stopper and insert Yankauer suction through the port. Or, remove the helmet to perform oral care.

Lines

Central lines and dialysis lines can be threaded under the rubber collar. It may be useful to loop extra tubing around the ear to prevent kinking, then thread under the collar.

Cost Effectiveness

The primary goal of HNIV in the current pandemic is to spare ventilators and improve outcomes.

Hemet ventilation probably reduces the total cost of care, Kress and colleagues (Canadian Resp Journal 2018, linked here) estimated that helmets attached to a ventilator projected cost savings of $2,527 in ICU costs and $3,103 in hospital costs per patient treated for ARDS using a helmet attached to a ventilator delivering pressure support. We do not have data on the use of helmets driven by wall gases for any form of AHRF but clinicians in Europe and Chicago have empirically endorsed its utility in this crisis.

Library

Patel et al (JAMA 2016): HNIV vs facemask in ARDS

Patel B, et al. *Effect of Noninvasive Ventilation Delivered by Helmet vs Face Mask on the Rate of Endotracheal Intubation in Patients with Acute Respiratory Distress Syndrome: a randomized clinical trial.* JAMA. June 14, 2016; 315(22):2435-2441, linked here. This group includes Krysta Wolfe, Anne Pohlman, Jesse Hall and John Kress. You may recall their sentinel work showing the benefits of early mobility in the ICU. Solid team. Good article. This study suggests HNIV has utility outside the current crisis. If you order helmets, you'll probably use them sooner or later.

Grieco et al (AJRCCM 2020): HNIV vs Oxygen for HFNC.

Grieco DL, et al. *Physiological comparison of high-flow nasal cannula and helmet noninvasive ventilation in acute hypoxemic respiratory failure*. AJRCCM. Feb 1, 2020; 201(3):303. This study from Italy assess physiological differences between HFNC and HNIV in adult patients with acute hypoxemic respiratory failure in 2017-2018 using a randomized 60-minute cross-over study involving only 15 patients. Ventilation was supplied with a ventilator in NIV mode using PS 8-10 cm for peak inspiratory flows of 100-150 LPM and PEEP 10-12 cm H_2O vs high flow nasal cannula oxygen . The PF ratio was significantly higher with HNIV (mean + 86 mmHg) and there were no differences in pCO_2. Dyspnea, inspiratory effort, respiratory rate improved with HNIV.

Luo et al (Yonsei Med J 2016): HNIV vs oxygen for HARF, a meta-analysis.

Luo Y, et al. Helmet CPAP versus Oxygen Therapy in Hypoxemic Acute Respiratory Failure: A meta-analysis of randomized controlled trials. Yonsei Medical Journal. Jul. 1, 2016; 57(4): 936-41, linked here. Meta-analysis of 4 studies with 377 patients showing improved PF ratio, decreased CO_2, decreased intubation and decreased mortality compared to standard oxygen. Downside: clinical and statistical heterogeneity. Did not include Patel et al (JAMA 2016).

Clinical Rationale COVID-10: Dr. Farkas summarized on EMCrit.org

Farkas, Josh. *PulmCrit Wee – Could the best mode of noninvasive support for COVID19 be … CPAP*??. Emcrit.org/pulmcrit/cpap-covid/. March 17, 2020. This contemporaneous article describes COVID19 pneumonia as PEEP responsive and requiring low driving pressure.

Dispersion/Leak: Dr. Hui's dispersion study with human simulator

Hui D, et al. Exhaled air dispersion during high-flow nasal cannula therapy versus CPAP via different masks. Eur Respir J. Jan. 2019; 53:1802339, linked here. From the Chinese University of Hong Kong, this study examined exhaled air dispersion using a human patent simulator (HPS) in an isolation room. The model used different severities of lung injury and different ventilation strategies: (i) CPAP 5-20 cmH2O via nasal pillows or (ii) an oronasal mask delivering 10-60 LPM. Leakage was negligible with a well fitted oronasal mask, increased with increasing PEEP and was higher with HFNC.

Humidity w/ CPAP delivered by HNIV

Chiumello D, et al. *Effect of a heated humidifier during continuous positive airway pressure delivered by helmet.* Critical Care 2008; 12(R55) from ccforum.com/content/12/2/R55, linked here. Describes the helmet interface as a mixing chamber for delivery of positive pressure ventilation. The patient's expired alveolar gases mix with the dry medical gases, providing humidity inside the chamber. N = 9 patients with acute respiratory failure, delivering CPAP at 40 LPM or 80 LPM, measurements only 2 hrs duration. Without a humidifier, the absolute humidity was higher with ventilator CPAP than continuous low-flow or high-flow CPAP. Comfort was similar for all three modes without added humidity. The relative humidity was 61% with vent-HNIV, 40% with low flow CPAP and 25% with high flow CPAP. Consider starting without humidity, but may need humidity for high flow CPAP with its attendant low humidity.

Other useful web resources

Helmetbasedventilation.com is a website run by Aurika Savickaite, RN and her spouse. They built the website on Mar. 19 in response to social distancing requirements and a desire to do something constructive. Ms. Savicaite worked with John Kress' team at U. Chicago Med. School and has experience with helmet ventilation (HNIV). Our program director John Selker has spoken with her by phone. Our interests seem aligned. Of particular interest may be references to HNIV in Europe.