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ECRI UPDATE

Respiratory Assistance Helmets: A Noninvasive Ventilation Option during COVID-19 … and Beyond?

During the height of the COVID-19 pandemic, respiratory assistance helmets – sometimes called CPAP hoods, ventilatory assistance helmets or noninvasive ventilation helmets – received considerable attention as an alternative to intubation and the use of a ventilator. ECRI tested several helmet models to gauge their effectiveness for this purpose and to identify considerations for safe use. An open question, however, is whether these products will remain an option once the pandemic recedes.

Ismael Cordero likes to immerse himself in his work. As a long-time biomedical engineer and current senior project engineer in ECRI's Device Evaluation Group, Cordero has plenty of experience conducting deep dives into medical technologies to assess their value to patient care.

But his latest project was a little different. Cordero's immersion in the technology he was evaluating, respiratory assistance helmets, was quite literal. With the COVID-19 pandemic limiting both his access to products and his options for finding test subjects, Cordero wore each of the models himself as a way to gauge the patient experience and assess CO_2 retention levels.

Respiratory assistance helmets became a hot topic during the height of the COVID-19 pandemic as a potential alternative to intubating patients and putting them on a ventilator. These helmets consist of a clear, flexible vinyl hood that fits over the patient's head. The hood attaches to (or comes pre-attached to) a neck ring that forms the bottom of the helmet and that seals against the patient's neck to prevent air from escaping. Ports in the hood allow the inflow of oxygen or air and the outflow of expired gas. Underarm straps that attach to the neck ring maintain the position of the helmet (which rises when pressurized). Patients wearing these helmets are conscious and can conduct many normal activities, such as talking, reading, watching TV or drinking.

Respiratory assistance helmets have been used for several decades on patients receiving hyperbaric oxygen therapy. In the last decade or so, their use has been adopted in several countries for providing CPAP and other noninvasive ventilation therapies. This type of use accelerated during the COVID-19 pandemic, since the helmets are less invasive than intubation and can help prevent aerosolized particles from dispersing in the environment.

ECRI published its ratings of four models in May 2021. (A fifth model that ECRI tested was withdrawn before publication.) Most of the tested products performed well in ECRI's testing and should serve the intended purpose, but the organization did identify important considerations for the safe and effective use of these helmets.

CONSIDERATIONS FOR USE

ECRI recommends that the use of respiratory assistance helmets be managed and monitored by trained respiratory care professionals, with the aid of respiratory monitoring devices, to prevent problems such as:

- Overpressurization – Obstructions and restrictions in the gas flow path can cause the helmet to develop dangerous pressures. Built-in or add-on pressure-limiting devices, along with constant pressure monitoring with alarms, can help prevent this hazard.
- CO_2 rebreathing – Obstructions and restrictions in the gas flow path or insufficient flow rates can result in an accumulation of expired CO_2 in the helmet. Constant monitoring of the CO_2 levels at the output of the helmet can help prevent this hazard. The manufacturers should state the minimum flow requirements for the safe use of the helmet.
- Leaks – Tears in the neck collar

ECRI's Ismael Cordero tested respiratory assistance helmets. One of the helmet models that ECRI evaluated is shown on the test mannequin (background) as it would be worn by a patient.

seal, loose connections, uncapped accessory ports and other conditions can result in leaks, which can reduce the therapeutic pressure levels. Leaks can also lead to aerosolized particles contaminating the environment, which is particularly concerning with infectious diseases and pandemics. Constant PEEP pressure monitoring with alarms can help prevent this hazard.

- Asphyxiation – An obstruction of gas flow may lead to asphyxiation. Helmets should either have a built-in anti-asphyxia valve or be fitted with an external anti-asphyxia valve to permit the patient to breathe in gas from outside the helmet.
- Unknown treatment pressure levels – Many commercially available PEEP valves are not designed to function accurately with the relatively high constant flow rates used with the helmets. As a result, the set PEEP value may be lower than the actual value. Constant PEEP pressure monitoring with alarms, and the use of PEEP valves that are not flow dependent, can help prevent this hazard.

Other complications or hazards associated with the use of these helmets include:

- Claustrophobia – The patient may not tolerate being enclosed in the helmet.
- Pressure sores and skin irritation around the neck – The neck collar seal may rub or press too hard on the neck. Correct seal sizing and placement, along with frequent inspection of the skin by caregivers, can help reduce this hazard.
- Hearing damage – The gas flow rates inside the closed helmet can produce hazardous noise levels that can lead to hearing loss. The use of a bacterial/viral filter at the gas input and the use of earplugs can help reduce the noise to safer levels. ECRI's patient experience volunteers all felt the helmets were too noisy when ear plugs weren't worn.

Another key consideration is that the flows needed to operate the helmets for CPAP therapy are relatively high (>40 LPM) compared to other devices. Thus, Cordero cautions that "the widespread use of these helmets in a hospital needs to be considered in the context of the capacity of the hospital's oxygen pipeline."

OUTLOOK

Device approval status will be a relevant consideration affecting the future use of these products. Two of the models that ECRI tested were approved for use during the COVID-19 pandemic through an FDA Emergency Use Authorization (EUA). Two other models have FDA Class 1 approval for the intended use of providing air/oxygen mixes in hyperbaric chambers, but do not have approval for the treatment of respiratory distress or any other respiratory therapy. (The supplier of the fifth model that ECRI tested abandoned its effort to obtain an EUA or other FDA approval.)

Whether U.S. hospitals will adopt the routine use of respiratory assistance helmets in normal times is uncertain. But, as Cordero notes, "facilities certainly have another option in their arsenal for treating respiratory distress during pandemics." Additionally, these products are an option for providing CPAP and other noninvasive respiratory treatments to patients with highly transmissible airborne diseases.

One interesting note from ECRI's testing is that, despite some concerns about the helmets being a little claustrophobic, most of ECRI's patient experience volunteers preferred the helmets to extended use of a CPAP face mask because the helmets allowed them to talk and read with less obstruction. ✲

To Learn More . . .

This article is adapted from ECRI's "Evaluation Background: Respiratory Assistance Helmets" (Device Evaluation 2021 May 12). The complete article—including model-specific test results and product ratings, along with additional guidance for purchasing and using these products—is available to members of ECRI's Capital Guide, Device Evaluation, and associated programs. To learn more about membership, visit www.ecri.org/solutions/evaluation-and-comparison, or contact ECRI by telephone at (610) 825-6000, ext. 5891, or by e-mail at clientservices@ecri.org.