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Helmets Save Lives, or At Least Ventilator-Free Days

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Editor's Note: *The Annals of Emergency Medicine Journal Club monthly provides a succinct review of high-impact articles from this and other premier medical journals relevant to emergency medicine. The reviews are followed by questions demonstrating principles by which readers—be they clinicians, academics, residents, or medical students—may critically appraise the literature. We are interested in receiving feedback about this feature. Please e-mail journalclub@acep.org with your comments*

ARTICLE IN REVIEW

Grieco DL, Menga LS, Cesarano M, et al. Effect of helmet noninvasive ventilation vs high-flow nasal oxygen on days free of respiratory support in patients with COVID-19 and moderate to severe hypoxemic respiratory failure: the HENIVOT randomized clinical trial. *JAMA*. 2021;325:1731-1743.

What Question Did This Investigation Aim to Answer?

In patients with moderate to severe hypoxemia due to COVID-19, does early treatment with helmet noninvasive ventilation (HNIV) increase the number of days free of respiratory support compared with heated high-flow nasal cannula (HHFNC) oxygenation alone?

What Study Design Did the Authors Choose?

Design: Randomized controlled trial

Setting: 4 Italian ICUs

Population: 109 patients with moderate to severe hypoxemic respiratory failure from COVID-19

Intervention: Randomization to continuous treatment with HNIV or HHFNC

Primary and Secondary Outcomes: The primary outcome was the number of days free of respiratory support (defined as HHFNC, noninvasive positive pressure ventilation, or invasive ventilation) within 28 days after enrollment. Secondary outcomes included the number of patients requiring endotracheal intubation, number of days free of invasive mechanical ventilation, length of stay, and mortality.

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How Did the Authors Interpret the Results?

A total of 110 patients treated at 4 Italian intensive care units were randomized to receive either continuous HNIV or HHFNC oxygenation, with 109 completing the trial. The median number of days free of respiratory support within 28 days following randomization was 20 days in the HNIV group (interquartile range 0 to 25 days) and 18 days in the HHFNC group (interquartile range 0 to 22 days), a difference found to be statistically insignificant (95% confidence interval −2 to 6 days, P=.26).

Nine secondary outcomes were evaluated, 7 of which showed no significant difference between the HHFNC and HNIV groups. The 2 secondary outcomes showing statistically significant differences between the 2 groups were the rates of endotracheal intubation (30% in the HNIV group versus 51% in the HHFNC group, 95% confidence interval 3% to 38%, P=.03) and the median number of days free of invasive ventilation within 28 days of enrollment (28 days in the HNIV group versus 25 days in the HHFNC group, 95% confidence interval 0 to 7 days, P=.04).

The authors concluded, in this head-to-head study comparing HHFNC with HNIV in patients with COVID-19 and moderate to severe hypoxemia, that there was no significant difference in the number of days free of respiratory support at 28 days.

How Might This Study Impact Your Clinical Practice in the Emergency Department?

HNIV is an unfamiliar form of respiratory support in many American emergency departments. Owing to the COVID-19 pandemic, the role and associated risks of noninvasive positive pressure ventilation in hypoxic respiratory failure have garnered significant attention, resulting in practice-changing recommendations from critical care societies.[1] This study asks us to consider

whether HNIV should be used as an alternative to HHFNC in patients with severe COVID-19. Although the study failed to show a statistically significant difference in the number of days free of respiratory support or mortality benefit, 2 secondary outcomes warrant further study: a decreased rate of endotracheal intubation and a decreased number of days spent on mechanical ventilator support. These findings, in concert with existing work in patients with non-COVID acute respiratory distress syndrome (ARDS), may indicate that additional study is warranted.[2]

DISCUSSION POINTS

1. *Ventilator-free days (VFDs) are a commonly used composite outcome measure in critical care ARDS trials. How are VFDs defined, and what are some possible limitations of using failure-free days to assess risk and benefit of an intervention?*

As detailed in the article titled "Reappraisal of ventilator-free days in critical care research" by Yehya et al,[3] VFDs are one example of many "failure-free day" composite outcome measures used in critical care trials (eg, dialysis-free days, vasopressor-free days) and have been frequently used in ARDS trials to quantify the efficacy of an intervention by combining both survival and duration of ventilation. VFDs are generally viewed as a superior alternative to total ventilator duration, as VFDs numerically "penalize" nonsurvivors allowing for greater power to detect a treatment effect compared with dichotomous measures such as mortality or reintubation.[3]

Generally,

- VFDs = 0 if the subject dies within 28 days of mechanical ventilation.
- VFDs = 28 – x if the subject is successfully liberated from mechanical ventilation x days after initiation.
- VFDs = 0 if the subject is mechanically ventilated for over 28 days.

The most frequently cited criticism of VFDs identifies the limitation common to many composite risk estimates: VFDs are unable to distinguish between the composite risks (ie, individual impacts) of mortality and duration of ventilation. Specifically, death and the duration of ventilation more than 28 days are assigned equal weight, likely underestimating the influence of the numerical mortality burden on the measure. Critics of this metric have pointed out that VFDs can give the ambiguous impression that a particular intervention reduces both death and ventilator duration, when in fact the ventilator duration has primarily driven the effect and there was little effect of the intervention on mortality.[3]

2. *The study demonstrated a decrease in the proportion of patients who were intubated in the HNIV group versus the HHFNC group. What mechanistic differences inherent to HNIV may explain this observation?*

HNIV consists of a transparent hood or helmet covering the entire head of the patient, isolating the patient's head from their environment by way of a seal, with a soft collar around the neck. HNIV machine tubing consists of inspiratory and expiratory limbs connected to the ventilator where flow, fraction of inspired oxygen, volume, and airway pressure are titrated according to the patient's oxygenation and ventilation requirements. The expiratory limb is often connected to an antimicrobial filter. The main advantage of helmet ventilation is decreased contact with the face that leads to both improved tolerability and less air leakage. In face mask noninvasive ventilation, when higher levels of positive end-expiratory pressure (PEEP) are needed to improve oxygenation, significant air leakage can impede effective oxygenation.[2] When air leakage is minimized, as in HNIV, higher levels of PEEP can be delivered, likely leading to decreased work of breathing and respiratory muscle fatigue and improved oxygenation. Air leakage is of particular importance in ARDS when delivering high levels of PEEP necessary to optimize alveolar recruitment while also maintaining spontaneous breathing.[4,5]

Alternatively, the benefits demonstrated with the use of HNIV may simply be due to its ability to provide higher levels of respiratory support than the other forms of noninvasive ventilation. The authors found that HNIV decreased intubation rate but did not decrease the number of respiratory support–free days. This distinction may indicate that some patients who would have failed HHFNC did not improve due to the higher levels of PEEP alone, but rather were receiving positive pressure support similar to what may have been otherwise achieved by invasive mechanical ventilation.

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REFERENCES

1. Alhazzani W, Evans L, Alshamsi F, et al. Surviving sepsis campaign guidelines on the management of adults with coronavirus disease 2019 (COVID-19) in the ICU: first update. *Crit Care Med*. 2021;49:e219-e234.
2. Patel BK, Wolfe KS, Pohlman AS, 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*. 2016;315:2435-2441.
3. Yehya N, Harhay MO, Curley MAQ, et al. Reappraisal of ventilator-free days in critical care research. *Am J Respir Crit Care Med*. 2019;200:828-836.
4. Briel M, Meade M, Mercat A, et al. Higher vs lower positive end-expiratory pressure in patients with acute lung injury and acute respiratory distress syndrome: systematic review and meta-analysis. *JAMA*. 2010;303:865-873.
5. Yoshida T, Fujino Y, Amato MBP, et al. Fifty years of research in ARDS. Spontaneous breathing during mechanical ventilation. Risks, mechanisms, and management. *Am J Respir Crit Care Med*. 2017;195:985-992.

IMAGES IN EMERGENCY MEDICINE

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DIAGNOSIS:

Volar dislocation of the metacarpophalangeal joint of the ring finger. The metacarpophalangeal joint was reduced after partial surgical resection of the interposed volar plate. Twelve months after the surgery, the metacarpophalangeal joint flexed to 80°, and the extension was limited by only 5°. The patient had no pain or disability while carrying out any of his daily activities.

Volar dislocation of the metacarpophalangeal joint is somewhat uncommon, and it is reported to have a high possibility of misdiagnosis at the first visit because pathological findings may not be pronounced on some radiographic views, clinical findings may be subtle, and some range of motion may be preserved.[1,2] The mechanism of injury usually involves hyperextension of the metacarpophalangeal joint or force to the dorsal aspect of the affected finger.[2] Cases often require open reduction due to the interposition of the volar plate, joint capsule, and collateral ligament.[3]

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REFERENCES

1. Pirotte MJ, Saucedo J, McCarthy D. Volar subluxation of the metacarpal-phalangeal joint: a case report. *Am J Emerg Med*. 2012;30:1016.e1-2. https://doi.org/10.1016/j.ajem.2011.04.021.
2. Sumarriva G, Cook B, Godoy G, et al. Pediatric complex metacarpophalangeal joint dislocation of the index finger. *Ochsner J*. 2018;18:398-401. https://doi.org/10.31486/toj.18.0032.
3. Dinh P, Franklin A, Hutchinson B, et al. Metacarpophalangeal joint dislocation. *J Am Acad Orthop Surg*. 2009;17:318-324. https://doi.org/10.5435/00124635-200905000-00006.