

Noninvasive Ventilation by Helmet vs Face Mask in COVID-19 Pneumonia: Emerging Evidence and Need of the Hour

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Coronavirus disease-2019 (COVID-2019) pandemic has resulted in unprecedented requirement of critical care resources including manpower and equipment. Acute hypoxemic respiratory failure (AHRF) is the most frequent organ failure among patients with COVID-19 leading to admission to the intensive care unit (ICU).

According to a global literature survey, among hospitalized COVID-19 patients, approximately 33% develop acute respiratory distress syndrome (ARDS), 26% require ICU transfer, 16% receive invasive mechanical ventilation, and 16% die. The mortality rate of COVID-19 patients admitted in ICU is 40%, whereas the mortality rate is 59% for patients who received invasive mechanical ventilation.¹

There is a lot of uncertainty regarding optimal initial respiratory support for AHRF due to COVID-19. Liberal use of endotracheal intubation and invasive mechanical ventilation may lead to various infectious, neurologic, respiratory, musculoskeletal, and other long-standing complications.^{2,3}

Alternative respiratory support strategies like noninvasive ventilation (NIV) such as continuous positive airway pressure (CPAP) or high-flow nasal oxygen (HFNO) may obviate the need for intubation and associated risks. However, the role of NIV is also debated as NIV use is associated with high treatment failure rates along with the risk of delayed intubation.^{4,5} NIV in COVID-19 patients with more compliant lungs has the potential for large tidal volume breathing to cause patients' self-induced lung injury.

This uncertainty in safety and effectiveness has resulted in marked variation in international practice. A survey was conducted among 1,132 participants across 85 countries; choice of initial oxygen strategy included HFNO (47%), CPAP or NIV (26%), and immediate tracheal intubation (7%), with remaining respondents opting to optimize conventional oxygen therapy.⁶

Patel and colleagues have conducted the randomized clinical trial (RCT) on effect of NIV delivered by helmet vs face mask on the rate of endotracheal intubation in patients with ARDS.⁷ The intubation rate was 61.5% ($n = 24$) for the face mask group and 18.2% ($n = 8$) for the helmet group (absolute difference -43.3% ; 95% confidence interval (CI) -62.4% to -24.3% ; $p < 0.001$). The number of ventilator-free days was significantly higher in the helmet group (28 vs 12.5; $p < 0.001$).

A recent meta-analysis including 3,800 patients compared all noninvasive modalities and concluded that helmet NIV, face mask NIV, and HFNO were associated with lower risk of intubation compared with conventional oxygen therapy (helmet NIV: risk

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ratio [RR], 0.26 [95% credible interval (CrI), 0.14–0.46]; face mask NIV: RR, 0.76 [95% CrI, 0.62–0.90]; HFNO: RR, 0.76 [95% CrI, 0.55–0.99].⁸

Evidence for HFNO, CPAP, and NIV as effective treatments for AHRF is drawn from AHRF patients without COVID-19. COVID-19 is a novel disease, and extrapolating data from other causes of AHRF is not justifiable.

There is a lack of high-quality data for NIV strategies in COVID-19. Most of the consensus on the application of NIV in patients with COVID-19-related AHRF is based on previous experiences in the treatment of viral pneumonia. According to the European consensus document, helmet CPAP should be the first therapeutic choice for AHRF caused by COVID-19 pneumonia, mainly for minimizing aerosol generation.⁹ As per the current Surviving Sepsis Campaign recommendations, consensus could not be reached on its safety or efficacy in COVID-19.¹⁰

There is an urgent need to evaluate the effectiveness of NIV strategies in patients with COVID-19. At present, clinical practice is mainly based on personal preference, prior experience, and the local availability of resources.

The HENIVOT Randomized Clinical Trial was conducted in 2020 to study the effect of helmet NIV vs HFNO on days free of respiratory support in patients with COVID-19 and moderate to severe hypoxemic respiratory failure.¹¹ There was no significant difference in the number of days free of respiratory support within 28 days in both the groups.

In this issue of the *Indian Journal of Critical Care Medicine* (IJCCM), Saxena and colleagues¹² report results from a single-center clinical trial conducted in 60 patients with COVID-19 who were randomized to receive NIV by either helmet or face

mask. This is the first randomized trial comparing helmet and face mask NIV in patients with hypoxemic respiratory failure due to COVID-19. NIV was delivered in both the groups via a ventilator with a double-limbed circuit in bilevel pressure support mode. Group I patients received NIV via helmet mask that was transparent with an appropriate neck seal. Group II patients received NIV via appropriate size nonvented face masks. Patients in both the groups received the same NIV titration technique. The ratio of NIV and high-flow nasal cannula (HFNC) was set at 4:1-hour duration. The patients deteriorating on NIV were considered for intubation, and the intubation criteria were similar in both the groups. The patients' comfort was gauged using a visual analog scale (VAS).

The endotracheal intubation rate was significantly lower in the helmet mask group (10%) compared to the face mask group (43%) (10% vs 43.3% $p = 0.004$). There was also a significant reduction in hospital mortality with the use of helmet mask NIV (13.3% vs 40% $p = 0.020$). Patients in the helmet mask group had a shorter duration of NIV (4.53 ± 0.776 vs 7.60 ± 1.354 $p = 0.00$) and spent lesser days in ICU as compared to the patients in the face mask group (6.37 ± 0.556 vs 11.57 ± 2.161 $p = 0.00$). The risk of facial and nasal bridge skin lesions was also lesser in the helmet mask group.

With these results, authors have concluded that helmet mask could be a reliable interface for delivery of NIV in COVID-19 and results in a lower rate of endotracheal intubation, better oxygenation with greater patients' comfort, and shorter ICU stay as compared to face mask used for NIV.

There may be several explanations to support the findings of the study. Higher levels of positive end-expiratory pressure (PEEP) are commonly needed to improve oxygenation with the face mask NIV. The face mask NIV is associated with the patients' intolerance and air leak.^{13,14} Air leak and intermittent mask removal can lead to respiratory muscle fatigue and ventilator desynchrony and may necessitate intubation.

Helmet interface has several advantages over the face mask. Helmet NIV can deliver high PEEP levels for prolonged treatments with good tolerability that improves oxygenation. Helmet NIV also results in less air leak due to the helmet's lack of contact with the face and better seal integrity at the neck. Inspiratory effort relief and improvement of hypoxemia are associated with avoidance of intubation during noninvasive support.^{15,16}

But there are some precautions that one should consider while using helmet NIV. Helmet NIV can lead to CO₂ rebreathing due to the large internal volume of the helmet and its high compliance. Some patients may experience claustrophobia and patient-ventilator desynchrony.¹⁷ Clinicians and nursing staff should be well versed with the protocols of helmet NIV as this is a relatively newer approach.

The study by Saxena and colleagues has some limitations as being a single-center study with a relatively smaller number of patients, results are not generalizable. So large multicenter trials are required. The blinding was also not possible in the study due to the nature of the interventions. There might be risks of information bias in the study. Strengths of the study include standardized NIV titration technique and predetermined criteria for treatment failure and weaning of ventilation.

There are more studies required to validate the advantages of helmet NIV in COVID-19 AHRF as an alternative respiratory strategy considering the concern of aerosol dispersion with

HFNO and NIV by face mask. Helmet NIV could be an excellent resource in the armamentarium in fight against COVID-19. The need of the hour is to perform accelerated research for a better understanding of NIV strategies in COVID-19 pneumonia.

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