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Unmasking a Role for Noninvasive Ventilation in Early Acute Respiratory Distress Syndrome

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Proposals to use a helmetlike interface for noninvasive positive pressure ventilation (NIV) can be traced back to more than a century ago. Among the earliest descriptions, Brauer and Petersen,[1] in 1904, developed a helmetlike positive pressure ventilation "cabinet" to be placed around the patient's head, with an air-tight seal formed via a soft neck collar. This prescient invention garnered little attention at the time. Instead, negative pressure ventilation via the "iron lung" gained widespread use to treat respiratory failure from polio and was superseded by endotracheal intubation for invasive mechanical ventilation by the 1960s. Although the physics of various mechanical ventilation devices is similar (pressure difference between airway opening and alveolus drives airflow), the interface used can have important implications for features of mechanical support possible, access of health care personnel to the patient, and comfort of the patient that may influence efficacy.

More than 20 years ago, NIV was proven in a multicenter trial to be of clinical benefit for acute respiratory failure due to chronic obstructive pulmonary disease exacerbation. Brochard and colleagues[2] demonstrated NIV delivered via oronasal face mask reduced need for endotracheal intubation, hospital length of stay, and in-hospital mortality. Subsequent work also has shown convincingly clinical benefit for face mask NIV in managing acute cardiogenic pulmonary edema and for prevention in patients at risk of postextubation failure.[3] One unifying theme among these conditions is rapid reversibility, the comparatively short duration of respiratory failure typical of most cases with appropriate treatment.

Minimal data are available on the efficacy of NIV among patients with acute respiratory distress syndrome (ARDS). Although ARDS is an independent predictor of NIV failure requiring intubation,[3] a recent international observational study found 15% of all patients with ARDS received NIV in routine care.[4]

In this issue of *JAMA*, Patel and colleagues[5] report results from a single-center trial of 83 patients with ARDS who were randomly assigned to NIV delivered via a helmet vs a face mask. Eligible patients had received facemask NIV for at least8hours as part of their usual clinical care. Participants were assigned to continue NIV via oronasal face mask or switch to

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NIV delivered via a plastic, transparent helmet. Positive end-expiratory pressure (PEEP), fraction of inspired oxygen (Fio_2), and driving pressure titration were managed with the same protocol in both study groups. The helmet protocol additionally standardized other ventilator settings to help ensure adequate support and improve patient comfort.

Patients assigned to helmet NIV required intubation less often (intubation incidence, 18.2%vs 61.5%; $P < .01$) and were more likely to survive through 90 days (survival, 65.9% vs 43.6%; $P = .02$). Risk of skin ulceration at the device interface was similar between groups. The data and safety monitoring board stopped the trial early, citing superior efficacy of helmet NIV and new data from another trial[6] that raised concerns about the efficacy of facemask NIV in patients with acute hypoxemic respiratory failure.

Previous studies have suggested a role for helmet NIV in carefully selected patients with other forms of acute respiratory failure. A prior multicenter randomized trial demonstrated that helmet continuous positive airway pressure was more effective than Venturi mask oxygen at preventing reintubation among patients with acute hypoxemia after major abdominal surgery,[7] although face mask NIV may also be effective in this setting. At least 3 prior small studies comparing helmet with face mask NIV directly found helmet NIV reduced the intubation rate in mixed forms of respiratory failure, although this finding is far from universal.[8]

Several possible mechanisms may be postulated to explain the findings of Patel et al, which favor the helmet interface rather than the oronasal face mask for NIV in patients with ARDS. The face mask may be a less effective interface than helmet at providing prolonged continuous NIV. Patient intolerance and air leak are encountered frequently with the face mask[9] and may preclude up-titration of applied pressure or require intermittent mask removal. Without sufficient, sustained mechanical support, respiratory muscle fatigue may necessitate intubation. Air leak with the face mask can contribute to discomfort, disrupt sleep, promote patient-ventilator dyssynchrony, and foster unstable breathing patterns.[10] Independent of mechanical support, airflow directed to the face may reduce dyspnea via trigeminal reflexes,[11] potentially improving tolerance of NIV via the helmet. Sedatives administered to promote patient tolerance of NIV may introduce associated risks, including oversedation, aspiration, and delirium.

Noninvasive ventilation, if applied using lung-protective settings such as lower tidal volumes and (perhaps) higher PEEP, without substantial air leak, also may reduce the risk of ventilation-induced lung injury. Adequate PEEP may prevent atelectrauma, the tidal opening and collapse of atelectatic but recruitable lung units that produces high local shear stress. Adequate PEEP also may reduce stress concentration from regional inhomogeneity of lung mechanics. PEEP also may attenuate dispersion of inflammatory or infectious edema fluid to previously spared regions within the lungs, lowering lung injury risk.[12] In the trial by Patel et al, patients receiving helmet NIV, compared with face mask NIV, tolerated higher PEEP and lower driving pressure, settings more consistent with a lung-protective strategy.

In future studies, reporting of interruptions to wearing the prescribed NIV interface continuously, leak severity, biomarkers of lung injury, and sedative administration would

help delineate potential mechanisms. Implications of these challenges of NIV may be heightened by acute lung injury, multiorgan dysfunction, and nonrapid reversibility characteristic of ARDS.

As with conventional invasive mechanical ventilation, how best to deliver NIV support will differ by diagnosis and comorbidities. Very few studies have explored disease-specific NIV titration. Helmet NIV uniquely requires additional considerations when setting the ventilator to offset the large internal volume and compliant material of the helmet.[8] Mechanically, the helmet behaves as a reservoir bag between the ventilator and patient. High flow rate and short inspiratory rise time are required to pressurize the helmet rapidly and prevent flow starvation with increased work of breathing during inspiration. Given the large internal volume of the helmet, carbon dioxide rebreathing is a key concern. High levels of fresh gas flow may reduce carbon dioxide rebreathing; still, helmet NIV should be used with great caution in patients with concomitant hypercapnia pending further study. Delays in ventilator cycling from inspiration to expiration can occur commonly with helmet NIV because the helmet's large internal volume causes a slower rise and fall in measured inspiratory flow. Setting expiratory cycling to begin at a higher percentage of peak inspiratory flow may reduce this cycling dyssynchrony. Patel et al incorporated many of these lessons learned from physiological studies in their intervention design. Still, the optimal approach to setting NIV for patients with ARDS remains to be determined.

Consideration also should be given to generalizability and reproducibility of the study by Patel et al. This preliminary study was performed in a single intensive care unit and enrolled patients for whom clinicians deemed NIV appropriate as part of their usual care prior to enrollment. Without standardizing NIV initiation, it is difficult to ascertain for whom precisely helmet NIV should be considered. Furthermore, identification of the most appropriate patients to consider for NIV will lower the risk of postponing intubation beyond a safe window while still preventing avoidable intubations. Helmet NIV was not compared with high-flow nasal cannula, which is more widely available and was shown recently in a multicenter trial[6] to improve survival for noncardiogenic acute hypoxemic respiratory failure compared with face mask. Although there may be a role for the helmet for otherwise stable patients with mild-moderate ARDS who require low levels of PEEP, low levels of driving pressure, or both in addition to high-flow oxygen, this narrow population remains to be defined.

The role for NIV in ARDS also enters into the ongoing debate about the advantages and disadvantages of spontaneous breathing among patients with ARDS.[13] Preclinical data suggest spontaneous breathing may be beneficial for mild lung injury,[14] even without considering potential downsides of sedation often required for tolerance of invasive ventilation among such patients. However, for patients with severe ARDS, both preclinical data[14] and a recent trial[15] raise concern that spontaneous breathing may exacerbate early lung injury. Adding to this safety concern, a clinically available measure of tidal volume during helmet NIV has yet to be described due to technical considerations from the helmet's internal volume and compliant material. The appropriate threshold is unclear at which there is net benefit to suppressing spontaneous breathing, accepting risks of intubation, sedation, and perhaps neuromuscular blockade to prevent ventilation-induced lung injury.

With all forms of NIV, careful selection of patients is important. Generally accepted contraindications include inability to protect airway or clear respiratory secretions, severe encephalopathy, high aspiration risk (eg, nausea, emesis, upper gastrointestinal tract bleed, ileus, bowel obstruction), upper airway obstruction, severe hemodynamic instability, and respiratory arrest.[3] If NIV is initiated, clinical progression should be monitored closely—evaluating such bedside parameters as change in accessory muscle use, respiratory rate, and blood gas values—to avoid harm from delaying necessary intubation.

Several key clinical messages can be gained from the study by Patel et al? The helmet interface has unique advantages and disadvantages that may influence efficacy of NIV depending on patient and disease characteristics. External validation of the findings by Patel et al and clarification of appropriate eligibility criteria, optimal ventilator settings, and potential mechanisms of effect are needed before clinicians could consider an expanded role for helmet NIV in routine management of select patients with ARDS. Whether helmet NIV affords benefit over high-flow nasal cannula warrants testing in a multicenter trial. Regardless, it is increasingly clear that there may be an important albeit under investigated role for some form of high-level noninvasive respiratory support to prevent intubation, and perhaps mortality, in acute hypoxemic respiratory failure.

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