# Should we carry out noninvasive ventilation using a helmet in acute respiratory distress syndrome?

## Rémi Coudroy, Jean-Pierre Frat, Arnaud W. Thille

CHU de Poitiers, Service de Réanimation Médicale, Poitiers, France, INSERM CIC 1402 (ALIVE group), Université de Poitiers, Poitiers, France *Correspondence to:* Arnaud W. Thille, MD, PhD. Service de Réanimation Médicale, CHU de Poitiers, 2 rue la Milétrie, 86021 Poitiers Cedex, France. Email: aw.thille@gmail.com.

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In a recent issue of the Journal of American Medical Association, Patel and colleagues compared two different interfaces to carry out noninvasive ventilation (NIV) in patients admitted to ICU for acute hypoxemic respiratory failure (1). Among them, only those who met the criteria for acute respiratory distress syndrome (ARDS) according to the Berlin definition (2) could be included, i.e., those having had worsening of respiratory symptoms within the previous week, a PaO<sub>2</sub>/FiO<sub>2</sub> ≤300 mmHg with positive endexpiratory pressure (PEEP) at least 5 cmH<sub>2</sub>O, and bilateral pulmonary infiltrates, after excluding those with cardiogenic pulmonary edema. However, patients were included after at least 8 hours of NIV as first-line therapy with a standard face mask. They were then randomized to continue NIV with either face mask or helmet. Although the authors planned to enroll 206 patients to detect a 20% reduction of intubation rate with helmet, the study was stopped for reasons of efficacy after only 83 patients had been included (44 treated with helmet and 39 with face mask). In the first interim analysis, the intubation rate observed in patients treated with helmet was markedly lower than in those treated with face mask: 18% (8 of 44 patients) vs. 62% (24 of 39 patients), P<0.01. In-hospital mortality was also significantly reduced (27% vs. 49%, P=0.04) as well as mortality at day 90 (34% vs. 56%, P=0.02). Although the results from this prospective randomized controlled trial study may seem spectacular, definite conclusions should not be drawn too hastily.

### Use of NIV in acute hypoxemic respiratory failure and ARDS

The use of NIV as a first-line strategy of oxygenation

in patients with acute hypoxemic respiratory failure is controversial. Several randomized controlled trials have found a reduction in intubation rate of patients treated with NIV as compared to standard oxygen (3-5). However, most of these studies included either hypercapnic patients with underlying chronic obstructive pulmonary disease (3,4) or patients with cardiogenic pulmonary edema (5), conditions for which the benefits of NIV in terms of intubation and mortality are supported by a strong level of evidence (6-8). In another study including patients with non-hypercapnic acute respiratory failure, no difference was found between continuous positive airway pressure and standard oxygen (9). Moreover, NIV has also been found to be associated with poor outcomes (10,11). The first randomized controlled trial that showed NIV to have deleterious effects included ICU patients who developed acute respiratory failure after planned extubation (10). In this study including more than 200 patients, notwithstanding strictly similar rates of reintubation, mortality was higher in patients treated with NIV than in those treated with standard oxygen, and the only difference between the two groups was a longer delay before reintubation in patients treated with NIV (10). One of the potentially deleterious effects of NIV could arise from this prolonged delay by masking signs of respiratory distress or the ventilator-induced lung injury generated by high tidal volumes and subsequent high transpulmonary pressures. A recent cohort found that patients with acute hypoxemic respiratory failure presenting large tidal volumes (>9.5 mL/kg predicted body weight) under NIV had an increased risk for intubation as compared to the others (12). A recent large multicenter randomized controlled trial including more than 300 patients compared three strategies of oxygenation in management of patients with acute

hypoxemic respiratory failure admitted to ICU: standard oxygen, high-flow nasal cannula oxygen and NIV (11). Patients with hypercapnia or cardiogenic pulmonary edema were excluded to avoid overestimation of the beneficial effects of NIV. Overall mortality and rate of intubation among severe patients were significantly lower in patients treated with high-flow oxygen than in those treated with standard oxygen or NIV (11). Patients treated by NIV received high-flow oxygen between NIV sessions. Therefore, poor outcomes in patients treated with NIV suggest deleterious effects of NIV as compared to patients treated with high-flow oxygen alone. As the delay before intubation did not differ between groups, we hypothesize that the deleterious effects might indeed be due to high tidal volumes and high transpulmonary pressures promoted by NIV (13). Although nearly three-fourths of the patients included met the accepted criteria for ARDS, tidal volumes exceeded 9 mL/kg in mean 1 hour after NIV initiation. In fact, it is well-established that mortality of patients with ARDS is lower using low tidal volumes approximating 6 mL/kg of predicted body weight (14). Even in patients not meeting the criteria for ARDS, use of low tidal volumes may reduce the risk of developing ARDS (15).

## **Use of helmet for NIV**

Poor tolerance is frequent during NIV and may lead to failure of the technique and subsequent intubation (16,17). Several studies have found better tolerance with helmet than with face mask and possible continuous application of NIV during longer periods of time (18,19). Indeed, use of helmet may decrease facial pressure points and skin necrosis, eye irritation and gastric distension. However, due to a large amount of dead space, helmet is less efficient than face mask to decrease work of breathing and to improve carbon dioxide elimination (20,21). Patient-ventilator asynchronies are markedly more frequent with helmet than with face mask (20,22) and the high noise levels reported with helmet may cause patient discomfort (23). To improve patient-ventilator synchrony and to reduce patient effort, both pressure-support (PS) and PEEP levels need to be significantly increased (22). In the study by Patel and colleagues, the PEEP level was higher in patients with helmet than in those with face mask that could promote alveolar recruitment and improve hypoxemia. However, PS level was surprisingly markedly lower with helmet than with face mask (8.0 vs. 11.2 cmH<sub>2</sub>O, P<0.01) (1). The low PS level may increase patient work of breathing as compared

to face mask. On the other hand, use of helmet may avoid alveolar derecruitment by allowing long sessions of NIV without disconnection thanks to good tolerance, and may limit ventilator-induced lung injury due to lower PS levels and lower tidal volumes. Unfortunately, monitoring of the real tidal volume delivered to the patient is not possible with helmet because of a continuous inspiratory flow-rate explaining large erroneous tidal volumes indicated on the ventilator screen.

# Validity of the results

Patel and colleagues found a spectacular decrease in intubation and mortality rates with helmet as compared to face mask (1). However, the external validity of the results may be compromised given that the intubation rates reported in this single-center study are not completely in keeping with the literature. First, the 18% intubation rate in patients treated with helmet is particularly low, and contrasts pronouncedly with the 40% to 60% rate observed among patients with ARDS or hypoxemic patients in high-skilled units (24,25). Second, the 62% intubation rate in patients treated with face mask is particularly high compared to the 46% rate reported in a previous cohort of 147 patients with ARDS (25), or to the 50% rate reported in a recent multicenter trial including 110 patients treated with NIV for acute respiratory failure, most of whom had ARDS (11). A similar intubation rate of 61% was previously reported in a cohort including ARDS patients treated with face mask (26). However, patients included in the study by Patel and colleagues had previously received at least 8 hours of NIV with face mask, meaning that those intubated within the first hours (number not specified by the authors) were not counted in the intubation rate, and that the real intubation rate was therefore significantly underestimated.

Furthermore, the mortality rate of 56% at day-90 was markedly higher that the 28% rate recently observed in patients treated by NIV with face mask (11). As mentioned by the authors in the discussion section, their patients were particularly severely ill as indicated by high simplified acute physiology scores (SAPS) II and a high proportion of immunocompromized patients. However, these scores were calculated under NIV taking into account the oxygenation criterion (PaO<sub>2</sub>/FiO<sub>2</sub> ratio). In studies comparing different strategies of oxygenation, severity scores are usually calculated at baseline without NIV, and therefore, without taking into account this oxygenation criterion (PaO<sub>2</sub>/FiO<sub>2</sub>

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ratio), which is to be measured only under mechanical ventilation. Consequently, in the recent study by Frat and colleagues (11), the SAPS II rose from  $26\pm9$  at baseline to  $35\pm10$  when recalculated under NIV. We believe that this issue shall represent a major limitation in future studies to comparison of the patients treated with or without NIV, especially those treated with high-flow oxygen therapy.

To conclude, the results of this study seem promising but need to be confirmed in a large multicenter controlled trial with the aim of comparing helmet versus face mask and/or high-flow oxygen therapy.

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