Editorial

Non-invasive mechanical ventilation in hypoxemic respiratory failure: Just a matter of the interface?

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In patients with acute respiratory failure the targets of mechanical ventilation are the improvement of pulmonary gas exchange and/or the unloading of the respiratory muscles. This can be achieved either invasively via an endotracheal tube or tracheostomy or noninvasively, for example via a mask. Although attempts of application of ventilation via a mask can be tracked back to the 16th century, undoubtedly non-invasive mechanical ventilation (NIV) applied in the adult intensive care medicine, started some 20 years ago (1) and, in the meantime, has evolved to become the standard of care for many demands regarding pathological respiratory conditions; by avoiding the need for endotracheal intubation, its associated complications can be reduced and outcome is improved in selected patients (2-5). This is well and widely recognized for acute exacerbations of chronic obstructive pulmonary disease (6) as well as congestive heart failure complicated by acute pulmonary edema (7). Furthermore, there is a growing body of evidence for the use of NIV in mild to severe-moderate ARDS (8-10), although this indication cannot be considered common practice these days.

While the practice of noninvasive ventilation has some serious advantages over invasive mechanical ventilation (11-13), NIV failure is common and related to either the patient's underlying conditions or technical causes (14). There are many reasons for the inability to ventilate a patient non-invasively in an efficient way, which finally ends up in NIV failure. These range from the patient's respiratory and general condition, over the choice of the ventilator and chosen ventilator settings to the interface and—last but not least—the experience of the team involved. The most commonly used interface for NIV is the oronasal facemask. Problems associated with its use are mainly mechanical complications due to the tight strapping that is necessary to achieve a sufficient seal to reduce leakage. Thus, there are quite a number of NIV failures due to patient discomfort, claustrophobia or ulcerations of the skin from the facemask device. The drawbacks related to the conventional NIV masks led to the development of a broad range of different and more comfortable interfaces. Currently available interfaces include nasal- and facemasks, helmets, nasal pillows, and mouthpieces. The choice of an appropriate interface is a key issue for the success of NIV (15).

Ventilation helmets are available for use for roughly 15 years and have been tested in various experimental and clinical situations. In an early matched control study by Antonelli *et al*. pressure support ventilation (PSV) was delivered by helmet or face mask in patients with hypoxemic acute respiratory failure. Improvement in oxygenation within the first hour, the total duration of PSV, intubation rate and hospital mortality were similar. But the helmet allowed the continuous application of noninvasive PSV for a longer period of time and complications related to the technique (skin necrosis, gastric distension, and eye irritation) were fewer in the helmet group (16). Today, the helmet is widely accepted and routinely used in some countries such as Italy, while it can't be regarded as a standard NIV interface in others (2).

The study by Patel and coworkers recently published in a current edition of JAMA (17), which aimed to determine whether helmet NIV could reduce the rate of intubation and improve other patient outcomes, might help to change this habit in the future. The authors present the results of a well laid out and conducted randomized controlled

trial performed in adult patients with acute hypoxemic respiratory failure. ARDS patients (PaO_2/FiO_2 <300), ventilated with NIV for at least 8 hours, were randomized to either proceed on NIV with the current, so-called standard of care, a facemask or switched to ventilation with the helmet interface. Patients with a Glasgow coma scale score below 8, impending cardiopulmonary arrest, absence of airway protective gag reflex, elevated intracranial pressure, tracheostomy, or upper airway obstruction, pregnancy, or if refused endotracheal intubation were excluded.

NIV was stopped and invasive ventilation initiated in case of neurologic deterioration, persistent or worsening respiratory failure (e.g., oxygen saturation <88%, respiratory rate >36/min), and intolerance of face mask or helmet, airway bleeding or copious respiratory secretions. They evaluated the effect on intubation rate as primary outcome, as well as alive without mechanical ventilation at 28-days, duration of ICU and hospital length of stay, and hospital and 90-day mortality.

Out of the 83 patients included into the study, sixty patients (72%) had a PaO_2/FiO_2 ratio of less than 200. The reason for acute respiratory failure was pneumonia in 36% (facemask) and 52% (helmet) and pneumonia due to immunosuppression in 36% (facemask) and 34% (helmet) respectively. About half of the patients in each group were immunocompromised by virtue of cancer or transplant. Severity of illness was high in both groups (median APACHE II score of 26 in the facemask and 25 in the helmet group).

Patel and coworkers found reduced intubation rates in the helmet group compared to the facemask (61.5% *vs*. 18.2 %) which resulted in a subhazard score for the helmet in favor of the helmet even after adjusting for the APACHE II score (HR =0.24; 95% CI: 0.11–0.50; P<0.001). The helmet group showed a significant increase in ventilator-free days (28 *vs*. 12.5), a reduced ICU length of stay (4.7 *vs*. 7.8 days). Hospital (27.3% *vs*. 48.7%) and 90-day mortality (34.1% *vs*. 56.4%) were significantly lower if patients were ventilated with the helmet device.

This trial presented by Patel *et al*. very impressively shows that it is very well possible to apply NIV in hypoxemic ARDS patients safely, and, that these patients may benefit even more from non-invasive support, if a ventilation helmet device is used. Thus it supports the implicit conclusion to rethink our current practice of non-invasive ventilation. Especially in terms of patient comfort the helmet shows some serious advantage compared to the facemask such as improved tolerability, a fixation system with a lower risk of cutaneous injury and the possibility of fitting it to any patient, regardless of the face contour.

Appealing is the fact, that the installed safety monitoring board stopped the trial at the first interim analysis due to predefined efficacy criteria. Furthermore, they considered the results of another trial, where the facemask group showed increased mortality compared to high-flow nasal cannula (18). They drew the courageous conclusion, that the facemask group could be exposed to an increased risk of death and stopped the trial. One has to recognize, that the data provided allows for this stride and supports the conclusion.

One potential reason is the higher PEEP tolerated in the helmet group. They also report that the higher PEEP was better sustained throughout the trial period, which is due to less leakage. By improving tolerability and thus enhancing the potential time constantly spent on NIV, it might be possible to enhance the indications for NIV into the area of more severe hypoxemic respiratory failure. In these patients, ensuring oxygenation by stabilizing the alveolar gas space is essential. Adding and keeping a positive endexpiratory pressure for a prolonged time might reverse lung collapse and loss in functional residual capacity at least in those patients with recruitable lung tissue. Due to the very short time constant that leads to alveolar collapse and atelectasis (19) an interface with a high potential of leakage and consecutive pressure loss is problematic. Regarding this aspect the helmet has the potential to overcome the obvious problems associated with conventional NIV interfaces. The positive effect of the helmet compared to the mask in this trial is also evident in the respiratory rate, which was lower compared to baseline in the helmet group but slightly increased in the facemask group. The reason can be found in the more effective pressure support delivered via helmet, pressure support is reported to be significantly less in the helmet group at non-differing baseline characteristics, in the trial at hand.

However some aspects should be taken in account when scratching the limits applying NIV in more severe cases of hypoxemic respiratory failure and when using the helmet as an NIV interface.

With regard to the study by Patel *et al*. it should be recognized that, as an inclusion criteria, patients had to be noninvasively ventilated for a minimum of 8 hours via face mask, before they were considered for inclusion. On one hand this approach excluded patients with a less severely altered respiratory state. On the other hand it might also have led to the exclusion of those that failed NIV within the

first eight hours before even being eligible for inclusion. 62% of the patients did not reach the "eight hour NIV" entry criteria or suffered from hypercarbic respiratory failure (5%), while about 16% met >1 exclusion criteria and about 6% declined to participate. From 740 patients with respiratory failure that required NIV only 83 were finally randomized into the study. Thus over a study period of 3 years, only 11% of the patients that received NIV for acute respiratory failure were included. Therefore one should be cautious when transferring these positive findings to the own clinical routine of care. The general spectrum of patients with hypoxemic respiratory failure might not be treated as effective compared to the group of patients included into the study by Patel *et al*. Moreover it is not possible to extract the information from the presented data if the success rate was equally distributed over the whole range of severity of respiratory failure. Whenever NIV is applied the technique should not postpone endotracheal intubation and invasive ventilation if indicated. Although, in the experienced hands of a team dedicated to NIV-therapy, it is worth trying to avoid intubation by applying noninvasive ventilation, the patient's condition should be critically analyzed to decide the safest treatment type. A close monitoring of these patients is pivotal in order to ensure patient safety.

The ventilator chosen in the two groups differed. While the helmet group was treated with a high end ICU ventilator (Engström Carestation, GE Healthcare), the facemask group received a single-limb noninvasive ventilator (Philips Respironics V60). On the first glance this might be an aspect of minor relevance. However, it is well known that ventilator performance might differ considerably (20,21). Thus it can't be fully excluded that the chosen ventilator might have had an impact on the success rate of the two different NIV-approaches. The same is true for the chosen ventilator settings with regard to the trigger sensitivity (on- and off-cycling), pressure rise time and inspiratory flow.

The ventilation helmet itself, used as a NIV interface for assisted mechanical ventilation, is not as simple as it seems. Especially for the novice caution needs to be exercised. Due to its large internal volume and elastic properties, ventilator settings need to be carefully adjusted (22); otherwise patient-ventilator interaction can be poor. In a lung model study, it has been shown that delay times during NIV were more than twice as long with the helmet compared to the facemask or during invasive ventilation, but decreased with increasing the CPAP or pressure support levels (23). To achieve the same effects of NIV delivered by a helmet or facial mask, both PEEP and pressure support need to be considerably increased (24). Patient-ventilator asynchrony can be reduced by applying a fast inspiratory ramp and expiratory trigger (25) or by applying modes of ventilation, that don't primarily rely on pneumatic triggering (24). Furthermore, CO_2-rebreathing happens easily, but can be prevented if a higher flow is assured (25). The impressive results by the study of Patel *et al*. can be in part related to the caution they spent, adjusting NIV with the helmet in order to improve patient-ventilator interaction and CO_2 elimination (high inspiratory flow, ventilator pressurization time of 50 milliseconds and cycling off delay set to 50% of maximal inspiratory flow).

As the intensive care community gains more and more knowledge of what measures induce and worsen ventilator induced lung injury (VILI), lung-protective ventilation strategies become a conditio sine qua non (26). On the same lines, non-invasive ventilation has advanced to be an easy to use and effective way to bridge a phase of respiratory failure for many patients. Even our sickest patients, those suffering from ARDS, seem to have mostly benefits from this measure (27). However it remains to be fully elucidated if the fact that the concept of lung protective ventilation can't be fully assured during NIV and especially not when using the helmet interface, imposes a risk, at least to those patients with a more severe ARDS, that might not be outweighed by the benefits of NIV.

Within this context it has to be underlined that tidal volumes and pressures are difficult to monitor since the helmet acts like a pressure chamber where the tidal volume transmitted to the lungs is only a fraction of the volume transmitted to the helmet and the same might be true for the peak inspiratory pressure. Simply spoken, the ventilators monitoring is partially blinded for its measured variables due to the helmet that is set in-between the ventilator and the patient.

Thus with regard to the ARDS patient, applying non-invasive ventilation via a facemask or helmet might be good or better than invasive ventilation for sure, but it is far from perfect in some regards.

Taking the trial by Patel *et al*. presented in JAMA and the growing experience in the field of new non-invasive ventilation interfaces into account, it becomes evident that selecting the appropriate interface is essential. The helmet interface definitely broadens the spectrum of devices available for NIV which—in some patients—might be even used interchangeably. Moreover it broadens the spectrum of

causes of acute respiratory failure where NIV can be applied instead of invasive ventilation. Although ambiguous, the study by Patel leads to the question: "*Is the current practice of non-invasive ventilation using a facemask outdated and do we enter the era of the ventilation helmet as the standard of care for non-invasive ventilation in hypoxemic respiratory failure?*" This question however needs further investigation and should finally be answered by a well-designed multicentric randomized controlled trial.

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Footnote

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