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Efficacy and tolerability of non-invasive ventilation delivered via a newly developed helmet in immunosuppressed patients with acute respiratory failure

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Effizienz und Verträglichkeit eines neuen Helmes zur nicht invasiven Beatmung bei immunsupprimierten Patienten mit akutem respiratorischem Versagen

Zusammenfassung. *Fragestellung:* Überprüfung von Effizienz und Verträglichkeit eines neu entwickelten Helmes für die nicht-invasive Beatmung von Patienten mit akutem respiratorischem Versagen.

Patienten und Methoden: Zehn immunsupprimierte Patienten mit akutem respiratorischem Versagen wurden an unserer Intensivstation aufgenommen und in die Studie eingeschlossen. Bei allen Patienten wurde eine nicht-invasive Beatmung mit dem neuen Helm durchgeführt. Arterielle Sauerstoffsättigung und subjektive Verträglichkeit wurden während der ersten 24 Stunden evaluiert.

Ergebnisse: Alle Patienten tolerierten die Beatmung mit dem neuen Helm sehr gut, es kam zu einer deutlichen Verbesserung der arteriellen Blutgaswerte. Zwei Patienten mussten aufgrund eines septischen Schocks endotracheal intubiert werden, 8 Patienten konnten von der nicht-invasiven Beatmung entwöhnt werden.

Zusammenfassung: Die nicht-invasive Beatmung mit Hilfe des neuen Helmes könnte im Vergleich zur endotrachealen Intubation und der nicht-invasiven Beatmung mittels Standard-Maske eine effektive und besser verträgliche Methode sein.

Schlüsselwörter: Nichtinvasive Beatmung, Helm, akutes respiratorisches Versagen, Effizienz, Immunschwäche.

Summary. *Objectives:* To assess efficacy and tolerability of a newly developed helmet for the delivery of non-invasive ventilation in patients with acute respiratory failure.

Patients and methods: Ten consecutive immunocompromised patients with acute respiratory failure admitted to our intensive care unit were included in the study. The patients were equipped with the helmet and non-invasive ventilation (NIV) was performed. Oxygenation and tolerability were assessed during the first 24 hours of NIV.

Results: All patients tolerated the helmet well and their oxygenation improved. Two patients developed septic shock and had to be endotracheally intubated during the study period, eight patients survived to be weaned from NIV.

Conclusions: NIV delivered via the helmet is effective and may serve as a better tolerated alternative to endotracheal intubation and to NIV via a standard face mask.

Key words: Non-invasive ventilation, helmet, acute respiratory failure, efficacy, immunocompromised.

Introduction

When mechanical ventilation in immunocompromised patients becomes necessary, endotracheal intubation is associated with a high mortality rate [1, 2]. In conscious and cooperative patients, non-invasive ventilation (NIV) can be a safe and effective alternative for treating patients with acute respiratory failure (ARF) [3–5]. Non-invasive continuous positive airway pressure (CPAP) or pressure support (PS) ventilation is usually performed by means of a nasal mask or a tight-fitting facial mask covering the nose and mouth. Despite improvements in facial masks' characteristics, skin necrosis may occur in 7% of patients treated with CPAP for periods exceeding 72 hrs [6]. Moreover, lack of patient compliance because of discomfort and anxiety can make the sustained use of a facial mask difficult. Recently, a new transparent helmet for NIV was developed. Its efficacy in delivering CPAP in ARF was recently tested, and the helmet has been shown to improve gas exchange comparably to a tight-fitting face mask, but was better tolerated by the patients [7, 8]. In particular, immunocompromised patients suffering from ARF could benefit from NIV, since endotracheal intubation and mechanical ventilation have been shown to be associated with poor prognosis [9, 10].

The new device has not previously been evaluated in immunosuppressed patients with respiratory failure. We investigated efficacy and tolerability of the NIV helmet in a group of immunocompromised patients with ARF.

Patients and methods

Ten immunocompromised patients were enrolled into this prospective observational study. Patients´ characteristics are shown in Table 1. For inclusion in the study the patients had to be hemodynamically stable, awake and cooperative. NIV was considered to be necessary if patients suffered from severe dyspnea at rest, active contraction of the accessory muscles of respiration or paradoxic abdominal motion, a respiratory rate > 25 breaths/min, and a $PaO_2/FiO_2 < 200$ while the patient was breathing oxygen through a Venturi mask. Patients with any of the following were not eligible: requirement for emergency intubation for cardiopulmonary rescusitation or respiratory arrest, severe hemodynamic instability, chronic obstructive pulmonary disease (COPD), facial deformities, recent oral, esophageal, or gastric surgery, or neurological impairment with a Glasgow Coma Scale < 14.

The helmet (CaStar, Starmed, Italy) is made of transparent latex-free PVC (Fig. 1). The helmet is secured by two armpit braces at two hooks (one anterior and the other posterior) on the metallic ring that joins the helmet to a soft collar [7]. The collar adheres to the neck and allows a sealed connection. The pressure increase during ventilation makes the soft collar seal comfortably to the neck and the shoulders, avoiding air leakage. The helmet is available in three different sizes to ensure comfort and a proper seal: a small size for patients whose neck collar is between 28 and 33 cm, a medium size for collars between 34 and 39 cm, and a large size for those between 40 and 45 cm. The apparatus is connected to the ventilator by means of a conventional respiratory circuit. The helmet has two ports acting as inlet and outlet for the gas flows. The inspiratory and expiratory valves are those of the mechanical ventilator. The transparency of the device allows the patient to see, read, and interact with the environment. The occurrence of the air leaks is rare if the helmet fits correctly. However, if leaks do occur there are the following options: a) readjustment of the helmet; b) changing the size to a smaller one; c) reduction of the level of PS and/or positive end-expiratory pressure (PEEP) if clinically compatible.

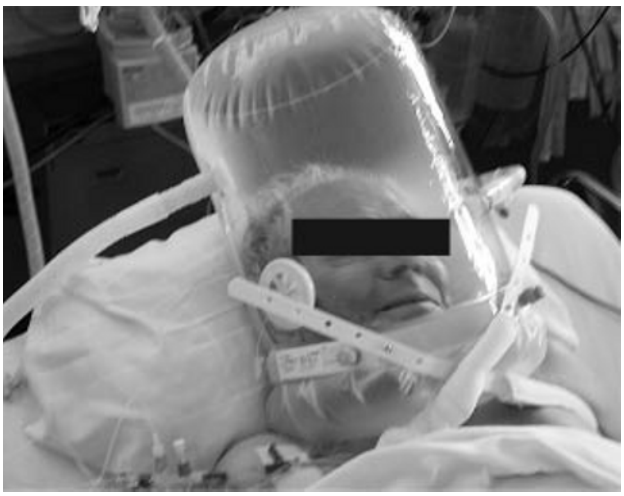

Fig. 1. Noninvasive ventilation via the CPAP-Helmet

All patients were monitored using electrocardiography (ECG), pulse oximetry, and an indwelling arterial line. Selectable patients were informed about the necessity for NIV, and the new device and the purposes of the study were explained. If consent was obtained, the patients were equipped with the helmet. The respiratory ports of the helmet were then connected to a high-flow CPAP system (Dräger-CF800, Lübeck, Germany). FiO_2 was set to achieve an arterial oxygen saturation of 92–95% measured by pulse oximetry. PEEP was usually applied with 7.5 cm H_2O.

Blood gases were analysed prior to NIV while the patients were breathing oxygen through a Venturi mask and were subsequently analysed at least 1, 4, 12 and 24 hours after the start of NIV. Respiratory rate, and signs of dyspnea-like active contraction of the accessory muscles of respiration or paradoxic abdominal motion were recorded. The impression of the patients themselves with regard to comfort and dyspnea was recorded regularly.

Patients who failed NIV underwent endotracheal intubation and were sedated and mechanically ventilated. Pre-determined criteria for endotracheal intubation were: failure to maintain a PaO_2/FiO_2 ratio > 100, severe hemodynamic or elec-

Table 1. Baseline characteristics and causes of acute respiratory failure

Patient	Age	Sex	Diagnosis	Cause of ICU admission	Cause of respiratory failure
1	24	M	NTX	ARF	Pneumonia (*Pneumocystis carinii*)
2	34	F	AML	ARF	Interstitial pneumonia
3	52	M	AML	ARF	Pneumonia
4	58	M	Agranulocytosis	ARF	ARDS
5	45	M	AML	ARF	Pneumonia
6	59	M	AML	ARF	Hyperleukocytosis syndrome
7	65	F	AML	ARF	Hyperleukocytosis syndrome
8	40	M	ALL	ARF	Pneumonia
9	44	M	ALL	ARF	Pneumonia
10	75	M	NHL	ARF	Cardiogenic lung edema

NTX kidney transplantation; *ARF* acute respiratory failure; *AML* acute myelocytic leukemia; *ALL* acute lymphoblastic leukemia; *COPD* chronic obstructive pulmonary disease; *ARDS* adult respiratory distress syndrome; *NHL* non-Hodgkin's lymphoma.

trocardiographic instability, inability to correct dyspnea, and inability of the patient to tolerate the helmet because of discomfort, claustrophobia or pain.

Statistical Analysis: blood gas values were analyzed using a non-parametric ANOVA for repeated measures (Friedman test). A p-value < 0.05 was regarded as statistically significant.

Results

Ten consecutive immunocompromised patients with acute hypoxemic respiratory failure met the enrollment criteria and were treated with NIV using the helmet. All patients suffered from marked dyspnea at admission and gave consent to enrollment into the study. Each patient was equipped with a helmet of adequate size, and none of the helmets showed clinically relevant air leakage during the ventilation test. During the first four hours oxygenation improved in all patients, and both CO_2 values and the respiratory rate declined (Fig. 2). The improvement in oxygenation and respiratory rate was statistically significant.

None of the patients suffered from discomfort during the first hours of NIV, and all patients had the impression of improvement of dyspnea with NIV.

During treatment with NIV two patients developed septic shock with severe hemodynamic and neurological impairment and had to be endotracheally intubated. Both patients died within 24 hours after intubation. Eight patients could be weaned from NIV after 48–96 hours and four of these patients survived the ICU stay. The deaths of the other four patients, who were weaned from NIV were not due to respiratory failure (hemorrhage in two patients, septic shock in the other two).

Discussion

Immunocompromised patients in whom respiratory failure develops often require intubation and ventilatory assistance. Endotracheal intubation is associated with numerous complications [11, 12], and in immunocompromised patients mechanical ventilation is associated with significant mortality and morbidity, with in-hospital rates as high as 90% to 97% [13, 14]. It is not completely clear if mechanical ventilation itself leads to this high mortality rate, e.g. by predisposing the patients to potentially lethal infectious complication, or if the need for mechanical ventilation is merely a sign of ongoing multiorgan failure. Most likely, both hypotheses are true and

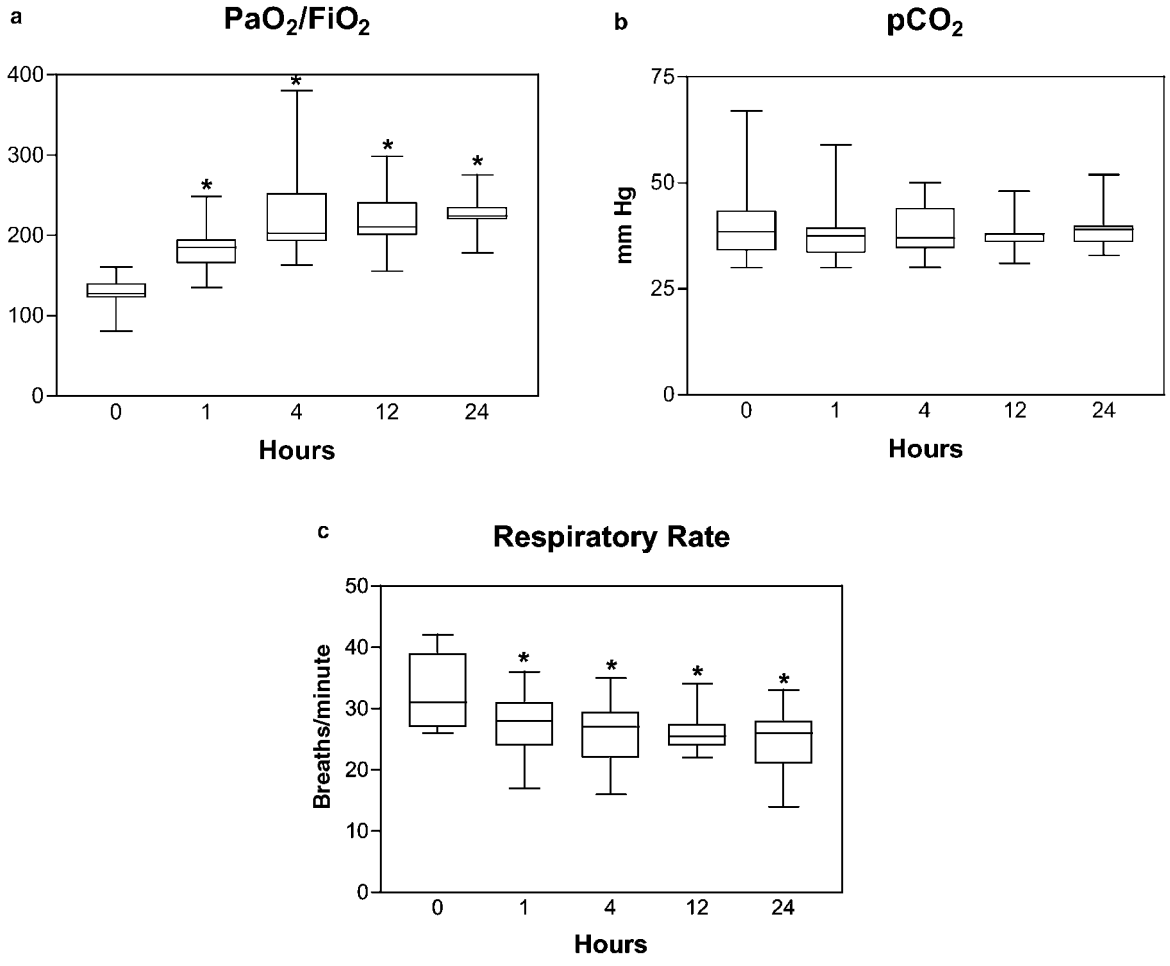

Fig. 2. Course of paO_2/FiO_2 ratio (**a**), CO_2 values (**b**) and respiratory rate (**c**) over the first 24 hours of NIV. Boxes denote median and 25th to 75th quartile, whiskers denote range. Asterixes (*) denote statistically significant differences to baseline

apply to the individual patient to different extents. Hypothetically, if endotracheal intubation could be avoided, both the severity and number of associated complications and the mortality numbers could be lowered. This hypothesis is strengthened by recent reports of improved survival in immunocompromised cancer patients using NIV instead of standard mechanical ventilation [9, 10]. NIV was reported to be successful in individual cases of patients undergoing bone marrow transplantation (BMT) [15, 16], however no prospective studies comparing NIV with standard mechanical ventilation via an endotracheal tube in patients with ARF after BMT have yet been published. NIV has also been shown to improve survival in patients with COPD [17]. In our patients, the acute respiratory problem was successfully treated in 8/10 cases. Two patients had to be endotracheally intubated because of evolving septic shock, despite adequate blood gases. Both patients died of refractory multi-organ failure within the following 24 hours. Four of the remaining patients died during their ICU stay despite respiratory improvement, thus 4 out of 10 (40%) patients can be regarded as ICU survivors. In a large cohort of patients suffering from malignant disease, the survival rate was lower than 30% in immunocompromised and mechanically ventilated patients [18]. However, a positive effect on survival cannot be derived from our data, since the low patient numbers and the design of the study do not allow such conclusions.

PS ventilation or CPAP is usually used for NIV. Both methods have been proved to be effective in correcting abnormalities of gas exchange and in reducing the need for endotracheal intubation [19, 20]. NIV can be performed using a nasal mask or a tight-fitting facial mask. The nasal mask is usually better tolerated but the facial mask is more appropriate for patients with severe hypoxemia who are commonly mouth breathers. Mask intolerance because of pain, discomfort, or claustrophobia is common and may require discontinuation of NIV and hence endotracheal intubation [4, 21, 22]. A recently published study compared NIV via the helmet with a matched group of patient treated by NIV via a facial mask. Improvement in oxygenation was comparable, but the helmet was tolerated significantly better [7]. All of our patients tolerated the helmet satisfactorily. We did not compare the new device with a face mask, but Antonelli, et al report an incidence of 38% severe intolerance leading to endotracheal intubation when using such a mask [7]. Achieving a better tolerance for NIV by using the helmet could lead to higher rate of successful NIV treatment and should theoretically improve survival rates in patients at a high risk of dying during standard mechanical ventilation via an endotracheal tube. A randomized, prospective trial to compare the two different ventilation strategies in hematologic patients should therefore be an urgently considered matter.

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