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Comparison of invasive and noninvasive positive pressure ventilation delivered by means of a helmet for weaning of patients from mechanical ventilation ☆

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ABSTRACT

Purpose: The effectiveness of noninvasive positive pressure ventilation delivered by helmet (H-NPPV) as a weaning approach in patients with acute respiratory failure is unclear.
Patients and methods: We randomly and evenly assigned 64 patients intubated for acute respiratory failure to conventional weaning with invasive mechanical ventilation (IMV) or H-NPPV. The primary end point was a reduction in IMV duration by 6 days between the 2 groups. Secondary end points were the occurrence of ventilator-associated pneumonia and major complications, duration of mechanical ventilation and weaning, intensive care unit and hospital length of stay, and survival.
Results: The mean duration of IMV was significantly reduced in the H-NPPV group compared with the IMV group ($P < .0001$), without significant difference in duration of weaning ($P = .26$) and total ventilatory support ($P = .45$). In the H-NPPV group, the incidence of major complications was less than the IMV group ($P = .032$). Compared with the H-NPPV group, the IMV group was associated with a greater incidence of VAP ($P = .018$) and an increased risk of nosocomial pneumonia ($P = .049$). The mortality rate was similar between the groups, with no significant difference in overall intensive care unit ($P = .47$) or hospital length of stay ($P = .37$).
Conclusions: H-NPPV was well tolerated and effective in patients who were difficult to wean.

1. Introduction

Patients with acute respiratory failure (ARF) often require invasive mechanical ventilation (IMV) to unload the respiratory muscles and support gas exchange until pathophysiology leading to ARF improves [1,2]. Despite its effectiveness, prolonged IMV is associated with the development of upper airway complications (eg, upper airway trauma, sinusitis, and otitis) [1,2], volutrauma, barotrauma [3], respiratory muscle weakness [4,5], and ventilator-associated pneumonia (VAP) [1-3,6]. VAP is associated with increased morbidity and mortality [1-3,6]. Minimizing the duration of IMV is an important goal of critical care medicine [1-3]. Noninvasive positive pressure ventilation (NPPV), in which varying levels of pressure support (PS) with or without positive end-expiratory pressure (PEEP) can be applied noninvasively during patient inspiration, may provide a means of reducing the duration of IMV during weaning from mechanical ventilation (MV) of patients with ARF [1-3]. Indeed, recent evidence has demonstrated a consistently positive effect of NPPV on VAP and mortality [1,2,7-12]. Nonetheless, further studies are required to fully elucidate the effectiveness of noninvasive weaning [1-3], particularly because there is no clear consensus opinion about using noninvasive ventilation after extubation [3]. To overcome the risk of discomfort and intolerance related to mask NPPV [13-15], a transparent helmet made from latex-free polyvinyl chloride has been successfully used for NPPV in patients with hypoxemic and/or hypercapnic ARF [13-15]. To our knowledge, there is only one prior report of using NPPV delivered by helmet to wean patients from MV [16]. We conducted a prospective randomized study to investigate the effectiveness of H-NPPV as a weaning approach in patients with ARF considered difficult to wean from MV.

2. Methods

The study was approved by the Ethics Committee of the University Hospital of Padova in March 2010 and registered with ClinicalTrials.gov (NCT01322659) in March 2011. Before recruitment, the intensive care unit (ICU) staff followed a specific training program based on didactic and hands-on training. This training was continued at the bedside and involved all types of patients in need of NPPV. All patients or their families gave signed informed consent before inclusion.

☆ Clinical trial registered with www.clinicaltrials.gov (NCT 01322659).

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2.1. Patient selection

Eligible patients were those with ARF admitted to the 24-bed ICU of the University Hospital of Padova. Patients had to be intubated for at least 48 hours for ARF, regardless of etiology, and had to be clinically stable for at least 24 hours to undergo a spontaneous breathing trial (SBT) after meeting the following weaning criteria based on a daily screening evaluation: Glasgow Coma Scale score of 12 or higher, Pao_2/fraction of inspired oxygen (Fio_2) of 150 mm Hg or higher, PEEP of 5 cm H_2O or less, no vasopressor requirement, temperature less than 38°C, hemoglobin level of 10 g/dL or higher, and no significant electrolytes alterations [17]. SBT trial was performed using pressure support ventilation (PSV) with a PS level of 7 cm H_2O [17]. The patients were included in the study if they exhibited SBT failure within 30 minutes. Spontaneous breathing trial failure was based on one or more among the following clinical and arterial blood gas (ABG) criteria: agitation or impaired consciousness; respiratory rate (RR) greater than 35 breaths per minute or an increase of 25% above baseline; hypoxemia with a decreased Sao_2 greater than 5% and/or Pao_2 less than 60 mm Hg with Fio_2 of 0.35 or less; $Paco_2$ of 60 mm Hg or higher; pH less than 7.35; hemodynamic instability as demonstrated by a systolic arterial pressure less than 90 mm Hg or greater than 180 mm Hg (or increase or reduction greater than 20% of baseline), heart rate greater than 140 and less than 50 beats per minute (or increase or reduction greater than 20% of baseline), or the presence of arrhythmias not controllable with ordinary medical treatment.

For this study, patients who failed a first SBT were considered difficult to wean from MV [18]. Patients were randomized into the 2 groups in case of a failed SBT: a conventional invasive weaning group (IMV group) and a noninvasive weaning group of patients undergoing NPPV through a helmet following extubation (H-NPPV group). Patients were assigned to either group by a computer-generated random table.

The noninclusion criteria were as follows: SBT success, after which the patient was extubated; uncooperative patient; respiratory and/or hemodynamic instability; ineffective cough on suctioning and/or persistent bronchial hypersecretion (need for tracheobronchial suctioning less than 2 hours) at the time of weaning; contraindications for using a helmet (eg, claustrophobia); recent gastrointestinal surgery; tracheostomy; and refusal of consent to participate in the study.

2.2. Weaning procedure after randomization

Conventional invasive weaning was performed using PSV with PEEP and progressive decrease in PS level until 7 cm H_2O or less and PEEP 5 cm H_2O or less (Ventilator: Servo 300 ventilator; Siemens/Maquet, Cinisello Balsamo, MI, Italy) [17]. Patients whose SBT was successful were extubated. Otherwise, patients were reventilated according to the ventilator mode previously used, and invasive weaning was continued with daily SBT.

For the H-NPPV group, SBT failure was followed by a reventilation period of at least 30 minutes, and extubation was followed by immediate H-NPPV (Helmet: CaStar; Starmed, Mirandola, MO, Italy; Ventilator: Servo 300 ventilator). Noninvasive positive pressure ventilation delivered by helmet was delivered in PSV starting with 10 cm H_2O and PEEP, which was increased from 5 to 7 cm H_2O in steps of 2 to 3 cm H_2O up to a maximum of 12 cm H_2O. The settings of H-NPPV were adjusted primarily to obtain a Pao_2 greater than 60 mm Hg and a peripheral oxygen saturation greater than 90%, with RR less than 35 breaths per minute, $Paco_2$ less than 60 mm Hg and pH 7.35 or higher and secondarily to ensure the patient's comfort and tolerance and to eliminate air leaks if they occurred. H-NPPV was initially performed continuously in a semisitting position for 24 hours. Only brief interruptions were allowed for eventual adjustments, if needed. These interruptions lasted no more than a few minutes, after which H-NPPV was immediately restarted. Subsequently, each patient was evaluated daily for 30 minutes while breathing supplemental oxygen by a Venturi mask with an FIO_2 of 0.35 without ventilatory support. H-NPPV was reapplied if the patients did not meet criteria for discontinuation. Criteria to discontinue H-NPPV included respiratory stability, with RR less than 35 breaths per minute, Pao_2 greater than 60 mm Hg, $Paco_2$ less than 60 mm Hg, and pH 7.35 or higher.

One-to-one monitoring was adopted by an experienced physician supported by a skilled, trained, and dedicated nurse. For both groups, the decision to stop weaning was based on one of the following major criteria: consciousness deterioration, upper airway obstruction, excessive airway secretions, inability to protect the airways, occurrence or worsening of ARF (tachypnea, cyanosis, involvement of accessory respiratory muscles, paradoxical abdominal motion, and/or respiratory acidosis impairment), cardiac failure and/or ischemia, hemodynamic instability requiring vasopressors, severe cardiac arrhythmia, respiratory or cardiac arrest, development of septic shock and multiple-organ failure, and intolerance to helmet or claustrophobia and/or major air leaks under H-NPPV.

In all patients, the standard vital signs monitoring and arterial blood gases analysis were adopted during the weaning from MV. Patient comfort, ventilatory parameters, leaks, and patient-ventilator synchrony were also strictly monitored. Medical treatment determined by the attending physician was optimized in light of the underlying conditions and the cause of ARF responsible for intubation. Successful weaning was considered a discontinuation from mechanical support for at least 48 hours.

The diagnosis of VAP was made in the presence of a new and persistent (more than 48 hours) or progressive radiographic infiltrate plus two of the following: (1) fever (greater than 38°C) with no other recognized cause; (2) leukopenia (less than 4 white blood cell count $10^3/\mu L$) or leukocytosis (equal or greater than 12 white blood cell count $10^3/\mu L$); (3) purulent secretions, changed and/or increased respiratory secretions, worsening gas exchange, increased oxygen requirements, and/or increased ventilator support [19]. *Hospital-acquired pneumonia* was defined as pneumonia that occurred 48 hours or more after admission [19]. Diagnosis of sepsis, septic shock, and multiple-organ failure was made according to international guidelines [20,21].

Percutaneous dilational tracheostomy was performed after reintubation if patients could not clear or remove their secretions or in case of difficult weaning and/or projected prolonged MV [22].

2.3. Data collection and evaluation criteria

The following characteristics were recorded on admission: demographic data, Acute Physiology and Chronic Health Evaluation II scoring, and cause of ARF. The following characteristics were collected on randomization: duration of IMV before SBT and clinical and ABG data before and after SBT failure, if available.

We evaluated the weaning/extubation results according to the weaning strategy allocated. The primary end point of the study was the reduction of the duration of IMV of 6 days between the 2 groups based on previous studies and its clinical impact [6,9,11]. Causes and time to weaning failure and reintubation were recorded.

The secondary end points were occurrence of VAP, septic shock and multiple-organ failure, and incidence of percutaneous dilational tracheostomy. We also considered duration of the total ventilatory support and weaning, complications, ICU and hospital length of stay (LOS), and survival.

2.4. Statistical analysis

Considering the primary end point and based on our previous experience used for prestudy power analysis (IMV vs H-NPPV, 15 ± 10 vs 9 ± 5 days), the sample size was calculated in 32 patients in

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