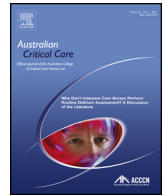




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Research paper

## Optimising non-invasive mechanical ventilation: Which unit should care for these patients? A cohort study

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### ABSTRACT

**Background:** Use of noninvasive ventilation (NIV) has extended beyond intensive care units (ICUs), becoming usual practice in emergency departments (EDs) and general wards.

**Objective:** To analyse the relationship between nursing care and NIV outcome in different hospital units. **Design and settings:** Three university hospitals and one community hospital participated in a prospective observational cohort study.

**Participants:** Ten units participated: 4 ICUs (1 surgical, 3 medical-surgical), 3 recovery (1 postsurgical, 2 EDs, 3 general wards).

**Method:** Treatment success/failure, interface intolerance and complications were evaluated according to patient characteristics, nursing care provided, and procedures used. Complications analysed included bronchoaspiration, pneumothorax, skin lesions, inability to manage secretions, eye irritations, deteriorating level of consciousness, gastric distension, and excessive air losses around the mask.

**Results:** Of 387 patients, 194 (50.1%) were treated in ICU, 121 (31.3%) in ED, 38 (9.8%) postsurgery, and 34 (8.8%) in general wards. Regression analysis, adjusted for APACHE score and NIV indication, showed 3.3 times greater risk of NIV failure (95% CI [1.2–9.2]) in a university-hospital ICU with <50 NIV cases/year, compared to a community hospital ICU. In ICUs and general wards, NIV was suspended in 12% of patients due to interface intolerance. Acute-on-chronic lung diseases (ACLD) had lower risk of NIV failure (OR 0.2 [95% CI 0.06–0.69]) and lack of humidification was not associated with treatment failure (OR 0.2 [95% CI 0.1–0.4]). Poor secretion management was linked to pneumonia (OR 2.5 [95% CI 1.1–5.9]) and early weaning/extubation (OR 3.3 [95% CI 1.2–8.9]). Interface intolerance was associated with conventional ICU ventilators (OR 4.4 [95% CI 2.1–9.2]) and nasal skin lesions with excessive air losses (OR 2.4 [95% CI 1.1–5.3]), especially with oronasal masks (OR 3.5 [95% CI 1.1–11.3]).

**Conclusions:** Acute respiratory failure patients with pneumonia admitted to general wards had increased interface intolerance and NIV failure. Rotating mask types could improve NIV success in any unit administering this therapy.

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## 1. Introduction

Over the past two decades, non-invasive ventilation (NIV) has become the accepted therapy for acute respiratory failure (ARF).<sup>1,2</sup> In an international study by Esteban et al.<sup>3</sup> that included 927 units in 40 countries, NIV use in a 2010 cohort was triple that of a 1998 cohort. In the United States (US), an overall increase in NIV use was reported, from 20% to 38.5% in 11 years,<sup>4</sup> and an annual increase between 2000 and 2009 of 18.1% in patients with ARF and 14.3% in patients with chronic obstructive pulmonary disease (COPD).<sup>5</sup>

There is level A evidence for NIV as first-line therapy in four pathologies, the so-called Fabulous Four: acute COPD exacerbation, acute cardiogenic pulmonary edema (CPE), and pulmonary infiltrates in immunocompromised patients and in the weaning of extubated COPD patients. This evidence may have influenced the increasing frequency of NIV use for immunosuppression in ARF, and as an adjunct to early liberation from mechanical ventilation for patients with COPD.<sup>6</sup> Most patients with ARF present to emergency departments (EDs) for treatment. Among US doctors, 66% use NIV for 20% of COPD and CPE therapy.<sup>7</sup> In Europe, acute hypercapnic respiratory failure (AHRF) is the most frequent indication for NIV.<sup>8</sup>

Numerous studies have identified risk factors for NIV failure, differentiating between ARF and AHRF, and a recent systematic review evaluated NIV complications.<sup>9</sup> There are four particularly important risk factors: (1) a delay in identifying signs of NIV failure, which is related to poor monitoring and a lack of record-keeping during NIV therapy<sup>3,5,10</sup>; (2) patient-ventilator dyssynchrony,<sup>11</sup> which can be avoided by proper basic nursing care that includes selecting the appropriate type and size of interface and correctly positioning it to avoid excessive air losses around the mask<sup>12–14</sup>; (3) patient agitation that requires monitoring of interface tolerance, optimal use of sedatives and analgesics, and limited use of mechanical restraints<sup>15</sup>; and (4) patient inability to manage secretions, which can be addressed by humidification and respiratory therapy.<sup>16</sup> The European Respiratory Society<sup>17</sup> recommends postgraduate training for NIV teams, mainly the nurses, because of their high level of autonomy in implementing this treatment. However, none of these studies assessed the relationship between nursing care during NIV and specific risk factors and complications.

The objective of the present study was to analyse nursing care provided in a cohort of patients treated with NIV in different hospital units and evaluate its relationship with treatment success/failure and complications.

## 2. Methodology

A prospective observational cohort study in patients with NIV was carried out at 3 university hospitals and 1 community hospital in Spain between February 2012 and December 2014. Ten units participated in the study: 4 ICUs (1 surgical, 3 medical-surgical), 3 recovery units (1 postsurgical, 2 in emergency departments [EDs]) and 3 general wards.

**Inclusion criteria:** All patients treated with NIV during the study period were consecutively included until the estimated sample size was reached.

**Exclusion criteria:** We excluded any patient who declined to provide signed informed consent for access to medical records (or, in the case of non-communicative patients, when the patient's legally authorised representative declined participation), following the requirements of the clinical research ethics committee in each participating hospital. In addition, we excluded all patients treated with NIV therapy for less than 2 h because of the "immediate failure index" related to improper NIV indication, inappropriate selection

of the interface or ventilator, and poor adjustment of the mask, all of which are a consequence of inadequate staff training.

By including patients after the first hour and up to 48 h of NIV therapy, our study covered the early failure index (from 2 h to 12 h) and late failure index (beyond 12 h), both caused by the same factors. Nearly 65% of NIV failures occur within this interval, which has received the most attention in studies assessing predictors of NIV failure.<sup>16</sup> This timepoint is associated with rapid disease progression, inappropriate etiological approach, dyssynchrony, and uncompensated hypoxemia.

Based on the hypothesis that high variability in care provided during NIV is related to NIV failure, mainly in patients treated outside the ICU in units with a higher patient-to-nurse ratio, the study analysed the following variables:

### 2.1. Primary outcome

**Causes of NIV interruption:** success (defined as gasometry improvement and/or respiratory improvement such that NIV was no longer required), failure (return to NIV required within 48 h of NIV cessation, or need for endotracheal intubation and invasive mechanical ventilation), and withdrawal due to interface intolerance (agitation and inability to leave the mask in place).

### 2.2. Secondary outcome

**Type of NIV complications:** bronchoaspiration, pneumothorax, skin lesions, inability to manage secretions, eye irritations, deteriorating level of consciousness, gastric distension, and excessive air losses around a mask.

### 2.3. Independent variables

- Patient characteristics: age, sex, diagnosis at admission, comorbidity, acute-on-chronic lung diseases (ACLD) such as COPD, asthma, obstructive sleep apnea syndrome, or obesity hypoventilation syndrome, Acute Physiology and Chronic Health Evaluation II (APACHE II) score, Sepsis-related Organ Failure Assessment (SOFA), length of hospital and ICU stay, "do not intubate" or "do not resuscitate" (DNI/DNR) status, reason for NIV indication.
- Unit where NIV was administered: frequency of vital signs monitoring, nurse/patient ratio, type of cardiopulmonary monitoring, type and frequency of nursing care (management of bronchial secretions, skin protection, eye care, mouth hygiene, pain and anxiety management).
- NIV administration procedures: type of ventilator and interface used, humidification, existence of NIV protocols, sedation type and dosage, use of analgesic and neuroleptic drugs, percentage of affirmative response to covering expiratory port and pressing the mask to the patient's face.

These data were drawn from a previous survey of these same units by the research team to construct an independent variable for the present study: the percentage of doctors and nurses at each unit who responded affirmatively to a question about whether covering the expiratory port and pressing the mask against the patient's face is an appropriate strategy to improve patient-ventilator synchronisation. This mistaken belief could lead to skin lesions and a deteriorating level of consciousness due to reinhaling carbon dioxide; both of these are potential NIV complications.

## 3. Sample calculation

Given previously observed differences in NIV use between the units participating in the study (unpublished data), the present sample was stratified by hospital based on the following codes

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