Noninvasive Ventilation Outside the Critical Care Unit

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Cesare Gregoretti, Alessio Mattei, and Annalisa Carlucci

10.1 Introduction

Noninvasive ventilation (NIV) refers to the noninvasive delivery of mechanical ventilation or continuous positive airway pressure (CPAP) through the patient's mouth, nose, or both via different external interfaces. Differently from conventional invasive mechanical ventilation (IMV) delivered via endotracheal tube or tracheostomy, NIV does not impair patient's native upper airway, and overall it does not impair glottis function. As a matter of fact, it is able to reduce work of breathing and improve gas exchange while preserving the ability to cough, swallow, and speak. Furthermore, NIV averts iatrogenic complications associated with endotracheal intubation and reduces the risk of ventilator-associated pneumonia (VAP) [1, 2]. NIV includes both noninvasive positive pressure ventilation (NPPV) and CPAP. During CPAP the pressure applied to the respiratory system is generated exclusively by the patient's respiratory muscles. Consequently, the indications of this technique are limited to patients who, despite an alteration of the ventilation-perfusion (VA/Q), still have a muscular activity sufficient to maintain a spontaneous breath (absence of signs of severe fatigue of the respiratory muscles and ability to develop muscle strength in the face

C. Gregoretti (✉)
Department of Anesthesia Emergency, Citta' della Salute e della Scienza,
C.so Bramante 88, Torino 10126, Italy
e-mail: c.gregoretti@gmail.com

A. Mattei
Cardiothoracic Department, Citta' della Salute e della Scienza,
C.so Bramante 88, Torino 10126, Italy
e-mail: mattei.alessio@virgilio.it

A. Carlucci
Respiratory Intensive Care Unit, Fondazione S. Maugeri, IRCCS,
Via Salvatore Maugeri, 4, Pavia 27100, Italy
e-mail: annalisa.carlucci@fsm.it

D. Chiumello (ed.), *Practical Issues Updates in Anesthesia and Intensive Care*,
DOI 10.1007/978-3-319-18066-3_10

of an increased impedance of the respiratory system). Clinical indications to CPAP are therefore hypoxemia with alterations of the ratio VA/Q without hypercapnia and signs of respiratory distress. Unlike CPAP, during NPPV the inspiratory flow generated in the respiratory system is variably generated by the respiratory muscles and the pressure applied by the ventilator (partial support) or completely generated by the ventilator (total support). Consequently, the possible indications for this technique are patients who have hypoxemia and/or signs of fatigue of the respiratory muscles, paradoxical breathing, or simply insufficient muscular activity to maintain a correct spontaneous breathing and alveolar ventilation.

Noninvasive ventilation (NIV) has found a wide application both in home care and in the hospital setting. However, most of the studies on the acute application of NIV were carried out in the intensive care unit (ICU), emergency room, or in step-down units. These locations represent an "ideal" environment for the safe treatment of patients with moderate to severe acute respiratory failure (potentially with need of airway intubation) for the expertise of the staff and careful monitoring [1].

10.2 NIV Outside the Critical Area: Myth or Reality

Landoni et al. [1] in a recent monograph reported that over the last 15 years, there has been a steady increase in the number of publications on the use of NIV in departments that do not belong to the critical care area. Plant et al. [3] at the beginning of the present century demonstrated the efficacy of NIV in noncritical area during exacerbations of chronic obstructive pulmonary disease (COPD). In a study [4] where all the doctors could order the NIV for patients with acute respiratory failure, the authors reported that 41 % of cases were treated in noncritical departments without having a worse outcome. Surveys in Canada have shown that NIV was applied in departments outside of the critical area [5].

In the United States in a survey [6] conducted in 82 hospitals, 18 % of NIV treatments were initiated in noncritical departments. In a subsequent survey, which involved physicians and respiratory therapists of 63 hospitals, Bierer and Soo Hoo [7] reported that 40 % of respondents claimed the use of NIV in the departments. Interestingly 42 % of them reported of any restriction on the place of use.

Schettino et al. [8], in a single-center prospective observational study, reported that among 449 treated patients, NIV was introduced in noncritical departments in 33 % of cases. In addition, 35 % of the NIV treatments (some of which started in the critical area) were then run in noncritical units. The outcome of these patients led to a rate of intubation of 27.3 %; out of them 14.9 % died.

The effectiveness and feasibility of positive results have also been reported in other countries [9–14]. Carlucci et al. [9] reported that with the acquisition of a greater confidence to the use of NIV, there was a greater tendency to treat more severe acute exacerbation of COPD patients in a noncritical area. Cabrini et al. [10] reported, in a survey carried out in Italy and specifically related to the use of NIV outside the ICU, that 65 % of respondents claimed that NIV was applied in general wards and 28 % has allowed the use of NIV in every ward.

An observational study in a single center on 129 consecutive patients treated with the medical emergency team (MET) [1, 15–18] service in the medical and surgical wards has shown a high success rate, with only a few minor complications. However, the workload related to the NIV for a medical emergency team demonstrated to be intense with a high commitment in terms of time [17].

Recently, there have been published reports of centers with a medical emergency team similar to that managed by nonmedical health personnel (CCOT) [18].

In a randomized controlled trial, an NIV service managed by a medical emergency team in a hematology department was associated with a reduced risk of death [19].

10.3 Rational Use of NIV Outside the Critical Care Area

The intensive care unit is considered to be the safest environment to deliver NIV in a hypoxemic patient especially if suffering from "de novo acute respiratory failure" [20].

The failure of NIV in such patients seems linked to increased mortality rate. The critical area provides monitoring, experienced staff, and a high nurse-patients ratio [21], in the face of high costs. However, if the use of NIV is only allowed in the ICU, you run the risk of its underuse [1, 22].

The use of NIV outside the critical area as in general wards may allow certain categories of patients (e.g., COPD and neuromuscular patients) to be treated at an early stage. This is less cost-effective, and patients present a lower risk of problems as "posttraumatic distress disorders" [23]. NIV in general wards has been used in "not to intubate" patients. Interestingly, approximately 50 % of patients survive acute events [21, 24].

In patients with terminal disease, NIV may be indicated to relieve the symptom of dyspnea that can be compared to pain or as a therapeutic option to allow you to save time and allow the patient to consent to diagnostic or therapeutic procedures [25].

There is also a general consensus that the effectiveness of NIV is greatest when treatment is started at the beginning of deterioration of pulmonary function to avoid the need for endotracheal intubation [1, 19, 21, 26–31]. This is particularly true in acute hypoxemic patients [20]. Paus-Jenssen et al. [4], in a prospective study in which NIV was introduced in all hospital wards without a formal protocol and with no prior training in response to financial constraints and limitations of beds, concluded that "patients in whom NIV was introduced outside the ICU did not seem to have worse outcomes" compared to similar patients treated in intensive care.

There is no doubt that the use of NIV outside the critical area should theoretically lead to greater cost-effectiveness as demonstrated in two studies [3, 9]. Plant et al. [3], in a prospective randomized study of 118 patients (NIV vs standard therapy) performed in "general ward," showed that the introduction of an NIV service for the treatment of mild exacerbations of COPD has saved about 70,000 euro. In addition the mortality rate in the group treated with NIV was halved.

Carlucci et al. [9] observed a daily reduction of 90 € for each NIV treatment (comparing patients treated in critical vs noncritical area) over a period of 8 years.

The savings according to the authors was due to a greater percentage of patients treated in noncritical area. So, provided that the safety of the patient and the effectiveness of the technique are retained, the use of NIV outside the critical area could also reduce the costs [1].

As mentioned earlier the use of NIV outside of departments of critical care [3, 4, 9] allows to anticipate the medical act and to improve the cost-effectiveness. It must be stressed, however, that the concept of intubation delay remains valid especially in the hypoxemic patient. In COPD patients, it has been shown that delaying intubation did not increase mortality in patients who failed NIV [32].

Squadrone and Coll [33] have shown that the early use of CPAP in "general ward" may decrease the incidence of tracheal intubation and other complications in patients who develop respiratory failure after major abdominal surgery. The same author [19] demonstrated that in hematologic patients undergoing helmet CPAP in the hematologic department, the setup of NIV by a dedicated service team had a lower need for ICU admission (4 vs 16 patients, $P = 0.0002$). The CPAP reduced the relative risk of intubation 0.46 (95 % confidence interval 0.27–0.78). This study suggests that the early use of a "simple" CPAP in a noncritical area in this patient population can reduce the rate of intubation.

10.4 NIV Relationship Between Training and Results

The training and experience of the staff are considered the most important factors that determine the effectiveness of the NIV [25] beyond the choice of a proper setting on where to start it. Although many centers have applied the NIV outside the ICU, without any education program [1, 4, 10], "noncritical" health-care personnel may not have specific experiences on acute respiratory failure and NIV [1].

Training on NIV should be considered mandatory before introducing this technique in medical wards [1, 6, 34, 35] to achieve maximum effectiveness while maintaining patient safety. Although the NIV can be easily applied, its success is highly dependent on many factors. Patient's intolerance to the treatment is a common reason for the NIV failure [36]. In particular, the ward staff should be able to recognize promptly the failure of the technique without delaying tracheal intubation especially in hypoxemic patients [20].

It is clear that if the department staff cannot reach the required level of knowledge and experience in optimizing the effectiveness of NIV, a lower efficacy can be expected compared to the treatment of the patient in the critical care area. In addition, a periodic retraining of personnel should be carried out in particular, if one considers the often high staff turnover [1, 5, 31].

The requirements of basic training should include [1, 25, 34, 35]:

- The basis of mechanical ventilation
- Assembly of the NIV setup
- Understanding of the functioning of the ventilator or CPAP systems

- The choice of the interface
- The decision to start treatment
- General and specific indications and contraindications to NIV
- Prevention and treatment of its complications
- Patient selection and safety

The training should also take into account the local organization of the service of NIV (i.e., if the NIV is prescribed by a medical emergency team, a respiratory therapist, or by an attending physician of the department) [1]. The decision to start treatment is particularly critical, since it must be based on an overall assessment of the patient's condition, the human and technical resources, and the possible alternatives, in order to balance risks and benefits [1]. As a result, operators prescribing the NIV should be fully trained and experienced on its use, on local resources, and their reliability.

Finally, whenever possible and if the patient's condition permits, training on the use of NIV should be offered to him and his family, in order to increase patient compliance and to allow careful monitoring even by relatives. This concept is also very important when dealing with children. This would also result in an economization of human resources.

The resolution of the problems and the solution of serious matters (sudden desaturation, patient intolerance, coma, respiratory failure during NIV) should be addressed in simulated scenarios [1]. The need for tracheal intubation in a mixed population undergoing NIV outside the critical area ranges from 19 to 27 % [8, 17].

When the NIV is applied at an early stage of the disease, the failure rate seems significantly lesser [3, 19, 29]. However, in all studies, a significant percentage of patients had to be transferred to intensive care, while another subgroup, considered "do not intubate," died in the ward [1]. According to an Italian survey [10], the perception of physicians and respiratory therapists on the success rate of NIV (reported as low as about 50 %) confirms this data. However, these results were always found in hospitals with extensive experience regarding the use of NIV, and the worst results could be expected in other centers. Only two prospective studies from the same center reported data on complications during the application of NIV in the ward departments [17, 29].

Of a total of 214 patients, the only major complication was an episode of arterial hypotension which resolved immediately after discontinuation of NIV; minor complications (about 10 %) were skin lesions and patient discomfort. The most common problems, without consequences for patients, were about technical or organizational issues, such as the nonideal positioning of the mask, excessive air leakage, ventilator malfunctioning, and the omission of prescribed ventilation cycles. However, two subsequent investigations of the same hospital showed a different picture. Ninety ward nurses have reported a high incidence of potentially serious complications such as desaturation and sudden ventilator malfunctioning. The identification of the problem or medical intervention has an average delay of more than 5 min in one-third of cases [31]. However, although nurses reported a

very low incidence of errors in the management of NIV by the staff, only 23 % reported that the NIV prescribed cycles have always been administered, while 18 % said that the NIV was quite often interrupted with some delay, and 6 % reported that NIV was stopped too soon.

In a study carried out by interviewing 45 patients after successful treatment of the NIV, all patients reported at least one complication (with a worsening of breathing during NIV in 18 % of cases). In addition 28 patients reported to have suffered a medical emergency, and four have detected expectations of help from the staff, for more than 3 min [37].

It should be also noted that there is any agreement on patient selection and choice of monitoring. Hypoxemic patients, as mentioned above, are particularly at risk [1, 20] given that the deterioration can be very rapid. NIV failure may increase the risk of death [20]. As stressed in a recent monograph [1], patients who present the following conditions should not be considered suitable for a general ward [1, 21, 36]:

- Have known risk factors for failure of NIV as acute respiratory distress syndrome (ARDS)
- Have multiple or severe morbidity factors
- Have low tolerance or no improvement after first 1–2 h of treatment
- Are unable to maintain spontaneous breathing for at least 15–60 min without the aid of NIV

In conclusion, waiting for more data [1], all noncritical departments, with the possible exception of the departments of pulmonary rehabilitation, are commonly inadequate to safely monitor patients treated with NIV [38, 39].

Finally, it has been correctly stated [1] that the workload required by the NIV could adversely affect the safety (and quality of care) of the other patients in the wards.

10.5 How to make safe and effective NIV outside the Critical Area

The first and most important requirement is the presence of a multidisciplinary motivated group [1, 34], within the hospital or within the department where the NIV is implemented.

Two main organization models have been reported [1, 3, 4] although there are no studies comparing their pros and cons [1–11]:

1. NIV can be prescribed by an attending physician of the department and fully managed by the staff of the department.
2. Alternatively, it can be prescribed by a qualified health-care personnel outside the department which is better trained in the use of NIV (pulmonologist, respiratory therapist, medical emergency team, etc.). Once started, the treatment is then managed in collaboration with the staff of the ward [1, 17].

With the exception of respiratory departments, Landoni et al. [1] suggest that given the complexity of the use of NIV and especially the need for an expert assessment of the risk/benefit ratio, the decision to prescribe the NIV should be carried out by well-trained and experienced external departments of general medicine that are always present in hospitals.

It is also mandatory [1] that an emergency service able to assist the patient in case of clinical deterioration and capable of performing tracheal intubation be immediately available within the hospital.

Simple global guidelines [1] should include indications, contraindications, complications, mode of start and end of the NIV, and solutions to common problems. The real problem is to know when to start, how to proceed, and when to stop [1]. The main factors to be taken into account when starting NIV include:

- The risks of failure (the cause and severity of acute respiratory failure, comorbidities, patient safety, the nurse-patient monitoring adequate experience and training of staff, state of consciousness, and autonomy of the patient without NIV)
- Possible alternatives (is the patient considered unsuitable for intensive care?) [1, 17, 34, 35, 40]
- Adequate ventilators and interfaces [41, 42]

Although turbine-driven ventilators have outperformed compressed air-driven ICU ventilators, few of them have the possibility to administer a constant oxygen inspiratory fraction (FiO_2) [43, 44]. During the treatment of mild to moderate acute hypoxemic respiratory failure, physicians need to compute the PaO_2/FiO_2 ratio in order to follow up their patients [45]. To deliver CPAP, cheaper devices as "high continuous flow" may be used.

A wide range of interfaces with different sizes and models [21] (helmets, face masks, nasal masks, etc.) should also be available. If humidification is requested, active heated humidifiers are recommended. The monitoring should be dictated by the severity of the patient's illness and the resources available.

At the very least, pulse oximetry and continuous electrocardiogram (preferably telemetry) must be available for every patient [25] although, in selected cases, regular assessment of vital signs may be sufficient [1].

Conclusions

There are insufficient data to date to indicate an indiscriminate use of NIV outside the critical area. Until now, we know very little about the outcome of patients treated with NIV in ordinary wards; in a national survey, some form of data collection was carried out only by 18 % of hospitals with NIV outside of the intensive care unit [10]. Since departments and the organization for the administration of NIV are heterogeneous, only the analysis of local data can be informative for individual centers.

Multicenter studies are needed to explore the limits and possibilities of NIV outside the ICU.

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