ORIGINAL ARTICLE

Noninvasive ventilation for hypercapnic exacerbation of chronic obstructive pulmonary disease: factors related to noninvasive ventilation failure

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KEY WORDS

chronic obstructive pulmonary disease, hypercapnic respiratory failure, respiratory acidosis, noninvasive ventilation, team expertise

ABSTRACT

INTRODUCTION Noninvasive ventilation (NIV) has changed the prognosis of patients with chronic obstructive pulmonary disease (COPD) suffering from hypercapnic exacerbations.

OBJECTIVES The aim of the study was to evaluate the mortality rate and need for intubation of patients with during hypercapnic COPD exacerbation treated with NIV and to estimate factors related to either success or failure of NIV in a real-life setting.

PATIENTS AND METHODS In a multicenter prospective study conducted over a period of 10 years (2002–2012), we assessed 1809 patients with COPD with hypercapnic exacerbation on admission who were treated with NIV. The primary outcomes were the intubation rate and hospital mortality.

RESULTS In all patients, NIV was conducted by experienced specialists. The intubation rate was 6.6% and the mortality rate was 5.3%. The severity of exacerbations, defined by pH and the Simplified Acute Physiology Score (SAPS II) on admission, worsened during the study period. The presence of comorbidities, SAPS II, pH, the ratio of oxygen arterial pressure to oxygen inspiratory fraction on admission, and, above all, no increase in pH after 1 hour of NIV were closely related to hospital mortality.

CONCLUSIONS Team expertise in NIV and identification of the risk factors for NIV failure may allow to treat patients with more severe hypercapnic exacerbations of COPD during and improve treatment success rates.

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INTRODUCTION Noninvasive ventilation (NIV) is ventilation without an invasive artificial airway. NIV results in unloading of the respiratory muscles, increase in alveolar ventilation, improvement of dyspnea, reduction of respiratory rate, and, finally, improvement of arterial oxygenation, hypercapnia, and related respiratory acidosis.[1] The efficacy of NIV should be determined clinically on the basis of improvement in respiratory distress, patient discomfort, and arterial blood gas values.[1,2]

Several randomized controlled studies, systematic reviews, and meta-analyses have shown good outcomes in terms of better survival and a reduced rate of complications in patients with chronic obstructive pulmonary disease (COPD) treated with NIV for acute exacerbations of chronic respiratory failure.[2,3] Based on the above data, NIV is recommended as the first-line ventilation strategy in COPD exacerbation, with different timing and setting according to the severity of acute respiratory failure (ARF).[1] Most patients

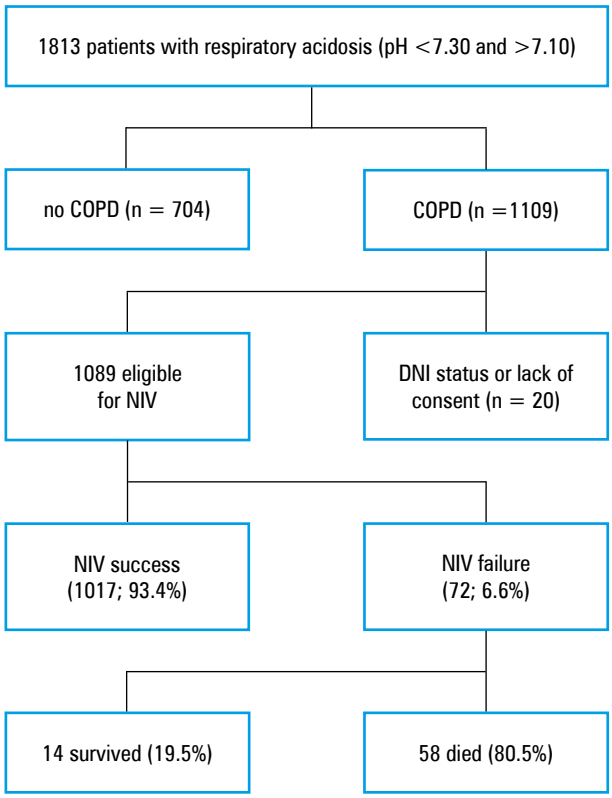

FIGURE Flowchart of patients in the study
Abbreviations: COPD – chronic obstructive pulmonary disease, DNI – "do not intubate", NIV – noninvasive ventilation

requiring NIV should be managed in an intensive care setting.[4]

Success of NIV depends mainly on the setting in which the procedure is performed. An intensive care unit (ICU) is recognized to be the safest setting in this case, but owing to the shortage of beds and an increasing number of indications for admission to the ICU, NIV is now performed also in other settings, especially in emergency departments and general wards as well as in step-down units and even other settings prior to hospital admission.[5-10] It has been shown that NIV can be safely used in a non-ICU respiratory ward in COPD patients suffering from a mild acute exacerbation with mild respiratory acidosis (pH >7.30).[11] According to a recent Italian survey, NIV is also extensively and successfully used in non-ICU wards in COPD patients with moderate to severe ARF (pH >7.25).[12] In clinical practice, the strategies for NIV may differ between medical centers.[1]

Better outcomes in patients undergoing NIV depend on whether a number of conditions have been met. Most importantly, all patients require close monitoring especially at the beginning of NIV. In addition, a team that performs the procedure should have adequate training and expertise. The ability to perform NIV improves over time and, according to the literature, with increasing experience, the team becomes more skilled to treat more severe episodes of ARF, while maintaining high success rates.[1,13,14]

The aim of our study was to examine the effectiveness of NIV in terms of mortality rates and the need for intubation in a non-ICU setting and to investigate the predictors of NIV success or failure, considering team expertise, characteristics of patients, and setting.

PATIENTS AND METHODS

This was a multicenter, prospective clinical study. Patients were recruited over 10 years from 3 Italian respiratory monitoring units (RMUs): General Hospital in Sestri Levante, U. Parini Hospital in Aosta, and Villa Scassi Hospital in Genoa. The 3 RMUs have 4 noninvasive monitored beds each and admit patients with severe respiratory failure who require NIV. We enrolled 1809 patients admitted for hypercapnic ARF due to COPD exacerbation and treated with NIV. The study was conducted at an RMU from December 2002 to December 2012. It was approved by local ethics committees, and every patient gave written informed consent to participate in the study. Patients who did not give informed consent or who had a "do not intubate" advance directive were excluded from the study. During the study period, we followed all consecutive patients with an exacerbation of COPD undergoing an episode of ARF. Diagnosis of COPD was based on the presence of airflow obstruction in previous pulmonary function tests and the severity of the diseases according to the Global Initiative for Chronic Obstructive Lung Disease criteria.[15] The RMUs were equipped with both a ventilator specifically designed for NIV (Philips Respironics Vision BiPap, Philips Respironics V60, Versamed Ivent 201 AB, Care Fusion Vela, Bellavista Imtmedical) and invasive ventilation (Philips Respironics Esprit, Versamed Ivent 201 IC, Care Fusion Vela, Bellavista Imtmedical), which made it possible to switch from NIV to invasive ventilation at any moment. The criteria for initiating NIV as well as the exclusion criteria were described previously.[16] Expiratory positive airway pressure was initially set at a level of 4 cm H_2O and was increased by 1 to 2 cm H_2O if needed to achieve an oxygen arterial pressure (PaO_2) of 60 mmHg or less or an SpO_2 of 90% or less. Inspiratory positive airway pressure was increased to 10 cm H_2O at increments of 2 to 3 cm H_2O to obtain a tidal volume of 6 to 8 ml/kg and a respiratory rate of 30 breaths/min or less. Moreover, patients scheduled for NIV did not fulfill any criteria for emergency intubation (eg, respiratory pauses, agitation requiring sedation, hemodynamic instability with systolic blood pressure of less than 90 mmHg, and a heart rate of less than 40 bpm). During the study, physician teams and respiratory therapists remained the same in each center, while approximately 25% of the nursing team were substituted. The nurse-to-patient ratio did not change during the study and was 1:4 during the day shift and 1:6 during the night shift. In addition, the number of physicians did not change during the study period (2 chest physicians during the day shift and 1 internal medicine physician during the night shift and a chest physician available on call). Data on sex, age, presence of comorbidities, severity of illness (Simplified Acute Physiology Score [SAPS II]), impaired sensory perception (Kelly–Matthay scale), results of arterial blood gas (ABG) analysis at baseline and after 1 hour of NIV,[16] and ventilator settings

TABLE 1 Characteristics of patients on admission (n = 1089)

sex	male	567 (52.1)
	female	522 (47.9)
age, y		79.5 ±7.1
body mass index, kg/m²		28 ±6
SAPS II		34.8 ±4.5
arterial blood gases	pH	7.22 ±0.05
	$PaCO_2$, mmHg	93.5 ±14.5
	PaO_2, mmHg	52.5 ±9.0
	PaO_2/FiO_2 ratio	188.4 ±17.3
presence of ≥1 comorbidities		718 (66.0)
previous home oxygen therapy		278 (25.5)
previous home NIV		39 (3.6)
previous ICU admission		52 (4.7)
hospital admission in the previous year		187 (9.8)
cause of exacerbation	respiratory infection	721 (66.3)
	cardiac failure	262 (24.1)
	pulmonary embolism	64 (5.92)
	depressant drug	5 (0.46)
	surgery	20 (1.83)
	unknown	17 (1.57)
patients referred from	emergency department	54.5
	medical ward	13.5
	home (outpatient clinic)	18.3
	other hospitals	13.7

Data are expressed as mean ± standard deviation, number (percentage), or percentage.

Abbreviations: NIV – noninvasive ventilation, $PaCO_2$ – carbon dioxide arterial pressure, PaO_2 – oxygen arterial pressure, PaO_2/FiO_2 – oxygen arterial pressure to oxygen inspiratory fraction ratio, SAPS II – Simplified Acute Physiology Score

were recorded. Failure of NIV was defined as death or need of intubation as previously reported.[16,17] The flowchart of patients in the study is presented in the FIGURE.

Outcomes The primary outcomes were intubation and mortality rates in patients admitted to RMUs during the study period (NIV failure). The secondary outcomes were potential predictors of hospital mortality and the need for intubation. The duration of NIV, length of hospital stay, and 180-day mortality were also considered.

Statistical analysis Continuous variables were analyzed using regression analysis and categorical variables were compared using the χ^2 test. Stepwise logistic regression was used to identify the variables associated with intubation and hospital mortality. A *P* value of 0.05 or less was considered statistically significant. Data analysis was performed using the R-Project version 2.13.2 statistical software.

RESULTS Between 2002 and 2012, a total number of 1813 episodes of ARF were treated by NIV in our centers, of which 1089 (60.0%; 567 men and 522 women; aged 79.5 ±7.1 years) were treated in the RMUs because of hypercapnic exacerbations of COPD and included in the final analysis. The most important cause of exacerbation was respiratory infection (66.3%) followed by cardiac failure (24.1%) and pulmonary embolism (5.92%). The majority of the patients (66.6%) had 1 or more comorbidities; 25.5% of the patients underwent previous long-term home oxygen therapy and 3.6% underwent NIV. The characteristics of the patients on admission are summarized in TABLE 1.

NIV was performed for 62 ±29 hours and daily application lasted more than 20 hours for the first 24 hours and was then gradually reduced until weaning was achieved. The most used types of ventilation were pressure support ventilation (45. 6%) and bilevel positive airway pressure / spontaneous-timed (38. 6%).

Considering that we have almost a constant annual number of patients treated with NIV at our centers, we have noted that the severity of the ARF episodes defined by the severity of acidosis ($PaCO_2$ and pH on admission) and illness (SAPS II) worsened progressively and significantly during the study period with a difference between the first 5 years (December 2002 – December 2007) and the following years (January 2008 – December 2012): pH 7.26 ±0.04 vs. 7.19 ±0.08, respectively, $P \leq 0.001$, and SAPS II 32 ±3 vs. 36 ±5, respectively, $P \leq 0.01$.

Primary outcomes Of the 1089 patients, 1017 (93.4%) were successfully treated with NIV and 72 (6.6%) were intubated. Of the 72 patients who underwent intubation, 58 died and 14 survived with a hospital mortality rate of 5.3%. The cause of death was respiratory failure in 40 patients (69.0%) and multi-organ failure in 18 patients (31.0%).

Secondary outcomes The severity of illness on admission was as follows: SAPS II, 34 ±4; Kelly–Matthay scale, 2 ±1; pH, 7. 22 ±0.06; carbon dioxide arterial pressure ($PaCO_2$), 93 ±15; PaO_2, 43 ±9; the ratio of oxygen arterial pressure to oxygen inspiratory fraction (PaO_2/FiO_2), 186 ±17; and respiratory rate, 30 ±3. ABG values 1 hour after NIV were as follows: pH, 7.28 ±0.05; $PaCO_2$, 78 ±5; PaO_2, 65 ±9; and the PaO_2/FiO_2 ratio, 253 ±35. The respiratory rate decreased to 26 ±4. pH, $PaCO_2$, and respiratory rate improved significantly after 1 hour of NIV ($P < 0.001$).

The mean duration of hospital stay was 17 ±4 days. The rate of patient readmission to the hospital during the follow-up period was 21.7% and 180-day mortality, 15.2%. Respiratory and ventilator characteristics, complications related to NIV, and patient outcomes are summarized in TABLE 2.

Factors associated with hospital mortality Because most patients who were intubated died (58 of 72 [80.5%]), we considered the factors associated with intubation and hospital mortality together. The stepwise regression analysis including

TABLE 2 Respiratory and ventilator characteristics, complications related to noninvasive ventilation and patient outcomes

Kelly–Matthay score on admission		2 ±1
respiratory rate on admission		30 ±3
heart rate on admission		100 ±21
pH on admission		7.22 ±0.05
$PaCO_2$ on admission, mmHg		93.5 ±14.5
PaO_2 on admission, mmHg		52.5 ±9.0
PaO_2/FiO_2 rate on admission		188.4 ±17.3
HCO_3 on admission, mEq/l		30 ±4
respiratory rate at 1 hour		26 ±4[a]
heart rate at 1 hour		96 ±5
pH at 1 hour		7.28 ±0.06[a]
$PaCO_2$ at 1 hour, mmHg		78 ±10[a]
PaO_2 at 1 hour, mmHg		65 ±9
PaO_2/FiO_2 at 1 hour		253 ±35
HCO_3 at 1 hour, mEq/l		29 ±3
type of ventilation	PSV	497 (45.6)
	BiPAP ST	421 (38.6)
	APCV	89 (8.2)
	AVAPS	82 (7.6)
maximum IPAP		19 ±6
maximum EPAP		5 ±1
NIV duration, h		62 ±29
complications of NIV		132 (12.1)
skin breakdown		56 (42.5)
eye irritation		26 (19.7)
claustrophobia		24 (18.2)
gastric distension		22 (16.6)
vomiting		2 (1.5)
bronchial aspiration		2 (1.5)
endotracheal intubation		72 (6.6)
hospital mortality		58 (5.3)
causes of death	respiratory failure	40 (69.0)
	multiple organ failure	18 (31.0)
readmission		21.7
180-day mortality		15.2

Data are expressed as mean ± standard deviation, number (percentage), or percentage.

a *P* value <0. 001

Abbreviations: AVAPS – average volume assured pressure support ventilation, BiPAP – bilevel positive airway pressure/spontaneous-timed, EPAP – expiratory positive airway pressure, HCO_3 – bicarbonate, IPAP – inspiratory positive airway pressure, PCV – pressure controlled ventilation, PSV – pressure support ventilation, SAPS II – Simplified Acute Physiology Score, others – see TABLE 1

the factors used in the univariate analysis showed that SAPS II on admission, the presence of comorbidities, pH on admission and after 1 hour of NIV, and the PaO_2/FiO_2 ratio on admission were independently associated with hospital mortality in the overall population (TABLE 3).

DISCUSSION Chandra et al.[18] reported the outcome data covering a period of more than 10 years (1998–2008) and including over 7.5 million admissions for COPD from a database of 1000 hospitals in the United States. They demonstrated a 4-fold increase in the use of NIV, which represented an increase from 1.0% to 4.5% of all admissions. There was a corresponding decrease of 42% in patients undergoing NIV, from 6.5% to 3.5%, and a reduction in mortality of patients with COPD.[18,19] In a smaller Italian study, De Michelis et al.[20] demonstrated a significant reduction of ICU admissions, length of stay, increase in survival rates, and decrease in the number of tracheotomies related to COPD exacerbations. Therefore, NIV is recommended as an effective tool in the management of acute exacerbations of COPD, together with antibiotics and bronchodilators,[21] but patient monitoring is crucial if the procedure is to be successful. Specifically, early identification of NIV failure is essential to reduce mortality, and careful consideration is needed before switching to invasive ventilation late in the course of an exacerbation.[1,19]

Predicting outcomes, particularly negative ones, following the use of NIV in the acute setting, is essential to assist physicians with decision making.[19] Several studies have demonstrated that patients with severe acidosis, lower scores of daily living activities, and associated complications of critical illness are less likely to benefit from NIV.[1,2,19,22-25] However, ventilator interface and tolerability with an improvement in arterial pH, respiratory rate, and hemodynamic stability indicate a short-term favorable outcome.[1,2,13,17,19,22-25] In a study of 240 unselected patients undergoing ward-based NIV, Miller et al.[26] demonstrated that an improvement in pH within 1 hour after NIV predicted survival until hospital discharge with a sensitivity of 82%, which is in line with our findings.[19,26]

Our "real-life" data have shown that patients with fewer comorbidities, less severe illness, and an improvement in ABG parameters within 1 hour after NIV are more likely to have a successful outcome. The intubation and hospital mortality rates (6.6% and 5.3%, respectively) were generally among the lowest reported in the literature[27] and decreased gradually over the study period, while patients in progressively more severe conditions were admitted to our RMUs. Our data have also confirmed the importance of a chart of failure risk described by Confalonieri et al.[28] Patients with more severe illness, and particularly those in whom pH does not improve to 7.25 or higher within 2 hours after NIV, have a high risk of failure.[16,29,30] On the other hand, the probability of NIV success increases in relation to the appropriate choice of ventilator modality and interface, the level of team experience, the level of patient's understanding, and advanced age.[1,16,29,31-33]

Ozyilmaz et al.[33] identified the following nonpatient related risk factors for NIV failure: 1) timing (ie, when NIV is performed); 2) the setting (ie, where NIV is performed) and choice of ventilator (dedicated NIV ventilators perform better than ICU ventilators, particularly in terms of leak compensation and patient-ventilator synchrony); and

TABLE 3 Variables independently associated with hospital mortality in all patients

Variable	OR	95% CI	*P* value
SAPS II	1.007	1.003–1.01	<0.001
pH on admission	0.692	0.504–0.95	<0.03
pH at 1 hour after NIV	0.481	0.320–0.72	<0.001
PaO_2/FiO_2 on admission	1.001	1.000–1.002	<0.01
comorbidities	1.066	1.035–1.10	<0.01

Abbreviations: CI – confidence interval, OR – odds ratio, others – see **TABLE 1**

3) expertise of the staff. In addition, much attention has been paid to the development of new interfaces to increase tolerance and patient comfort, since mask intolerance remains the major cause of NIV failure.[33] An oro-nasal mask is generally the most common, followed by a nasal mask, helmet, and mouthpiece. These interfaces have a number of advantages and disadvantages, and, in case of poor tolerance, it is reasonable to apply the so called rotating strategy.[33] In this context, a skilled and experienced staff may treat more severe patients with better outcomes.[13,31] Moreover, an expert team may be more experiences in the management of pain, agitation, and sleep disturbances caused by prolonged duration of mechanical ventilation.[34] To our knowledge, only 1 study has examined the importance of a team's experience and skill in NIV.[35] Although it is difficult to define an experienced team, it should be more often considered as an important factor in the outcome of NIV treatment together with various other clinical factors.[36]

Our study has several limitations. First, the causes of respiratory infections were not investigated and the data are not available. The presence of pneumonia has already been reported as a predictor of NIV failure, together with a lack of improvement of pH.[29,36] Second, the criteria of intubation were not standardized a priori, as for a randomized controlled trial, but each center followed its institutional guidelines (which reflects the "real-life" setting). Third, we only considered the presence or absence of comorbidities, without investigating their type or number in individual patients or their role in determining NIV failure. Finally, the study was performed by teams experienced in NIV and used to manage a large number of patients per year using dedicated NIV ventilators. Therefore, our data cannot be generalized.

In summary, this observational study has highlighted the factors associated with patient outcome when using NIV for a hypercapnic exacerbation of COPD in the "real-life" setting. The expertise of the team as well as the identification of risk factors for NIV failure may allow to treat patients with more severe exacerbations and improve success rates.

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Contribution statement AN designed the study; analyzed and interpreted the data, and drafted and revised the manuscript. LF designed the study, analyzed and interpreted the data, and revised the manuscript. MS designed the study and revised the manuscript. MF-B conducted the statistical analysis. MDF interpreted the data and drafted and revised the manuscript. FS interpreted the data and revised the manuscript. All authors approved the final version of the manuscript.

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Nieinwazyjna wentylacja mechaniczna w hiperkapnicznych zaostrzeniach przewlekłej obturacyjnej choroby płuc – czynniki związane z niepowodzeniem NIV

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SŁOWA KLUCZOWE

doświadczenie zespołu, hiperkapniczna niewydolność oddechowa, kwasica oddechowa, nieinwazyjna wentylacja mechaniczna, przewlekła obturacyjna choroba płuc

STRESZCZENIE

WPROWADZENIE Nieinwazyjna wentylacja mechaniczna (*noninvasive ventilation* – NIV) zmieniła rokowanie u pacjentów z hiperkapnicznymi zaostrzeniami przewlekłej obturacyjnej choroby płuc (POChP).

CELE Celem badania była ocena współczynników umieralności i potrzeby intubacji u chorych z hiperkapnicznym zaostrzeniem POChP leczonych za pomocą NIV oraz identyfikacja czynników związanych z powodzeniem lub niepowodzeniem NIV w warunkach codziennej praktyki.

PACJENCI I METODY W wieloośrodkowym badaniu prospektywnym prowadzonym przez 10 lat (2002–2012) oceniano 1809 chorych przyjętych z powodu zaostrzenia POChP z hiperkapnią i leczonych z użyciem NIV. Główne punkty końcowe stanowiły częstość intubacji i umieralność wewnątrzszpitalna.

WYNIKI U wszystkich chorych NIV była stosowana przez doświadczony personel. Częstość intubacji wyniosła 6,6%, a umieralność 5,3%. Ciężkość zaostrzeń, określana przez pH i wynik w skali SAPS II (Simplified Acute Physiology Score) przy przyjęciu, narastała przez okres trwania badania. Z umieralnością wewnątrzszpitalną ściśle wiązały się: obecność chorób współistniejących, wynik w skali SAPS II, pH i stosunek PaO_2/FiO_2 przy przyjęciu, oraz – przede wszystkim – brak wzrostu pH po 1 h NIV.

WNIOSKI Doświadczenie zespołu stosującego NIV oraz zidentyfikowanie czynników ryzyka jej niepowodzenia mogą stopniowo pozwolić na leczenie w ten sposób coraz cięższych hiperkapnicznych zaostrzeń POChP i na poprawę wyników.

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