

# Use of Noninvasive Positive-Pressure Ventilation on the Regular Hospital Ward: Experience and Correlates of Success

Samar Farha MD, Ziad W Ghamra MD, Edward R Hoisington RRT,  
Robert S Butler MSc, and James K Stoller MSc MD FAARC

**BACKGROUND:** Though noninvasive positive-pressure ventilation (NPPV) is efficacious in treating patients with exacerbations of chronic obstructive pulmonary disease, little attention has been given to the optimal venue in which to provide NPPV. The aim of this prospective observational study was to assess the outcomes of NPPV initiated for acute respiratory failure on the regular in-patient ward. **METHODS:** Starting in May 2004, all patients started on NPPV for acute respiratory failure on regular nursing floors of the Cleveland Clinic Hospital were identified. Patients were divided into 2 groups: do-not-intubate (DNI) and non-DNI. NPPV failure was defined as the need to transfer the patient to the intensive care unit (ICU). **RESULTS:** Seventy-six patients were enrolled. The most common cause of acute respiratory failure was exacerbation of chronic obstructive pulmonary disease (41%), followed by pulmonary edema, pneumonia, obesity-hypoventilation, and neuromuscular illness. Of the 62 non-DNI patients, 19 (31%) failed NPPV on the regular ward and required transfer to the ICU. Variables associated with NPPV failure were amount of secretions ( $p = 0.04$ ), etiology of respiratory failure (pneumonia was associated with the highest failure rate,  $p = 0.015$ ), and infiltrate on the chest radiograph ( $p = 0.036$ ). Seven of the 14 (50%) DNI patients died during hospitalization. **CONCLUSIONS:** Results of this observational study show that noninvasive positive-pressure ventilation is frequently used on the regular hospital ward and that the success rate is similar to that reported in series in which NPPV is used in the ICU. *Key words:* noninvasive positive-pressure ventilation, general hospital ward, acute respiratory failure, outcomes. [Respir Care 2006;51(11):1237–1243. © 2006 Daedalus Enterprises]

## Introduction

In the context that noninvasive positive-pressure ventilation (NPPV) has been shown to enhance outcomes in acute respiratory failure (ARF), and especially with exac-

erbations of chronic obstructive pulmonary disease (COPD),<sup>1</sup> use of NPPV has increased, sometimes stretching available intensive care unit (ICU) resources. Indeed, while use of NPPV in the ICU has been studied extensively and official guidelines have recommended that NPPV should be used in the ICU for patients with ARF,<sup>2,3</sup> relatively little attention has been given to using NPPV outside the ICU (eg, on the regular hospital ward), where

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Samar Farha MD, Edward R Hoisington RRT, and James K Stoller MSc MD FAARC are affiliated with the Department of Pulmonary, Allergy, and Critical Care Medicine, The Cleveland Clinic Foundation, Cleveland, Ohio. At the time of this research, Ziad W Ghamra MD was affiliated with the Department of Pulmonary, Allergy, and Critical Care Medicine, The Cleveland Clinic Foundation, Cleveland, Ohio. He is currently affiliated with Carolina Health Care, Florence, South Carolina. Robert S Butler MSc is affiliated with the Department of Quantitative Health Sciences, The Cleveland Clinic Foundation, Cleveland, Ohio.

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Correspondence: James K Stoller MSc MD FAARC, Department of Pulmonary, Allergy, and Critical Care Medicine, Cleveland Clinic Foundation, A90, 9500 Euclid Avenue, Cleveland OH 44195. E-mail: stollej@ccf.org.

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NPPV is being used with increasing frequency. For example, results of a survey regarding use of non-invasive ventilation in 82 acute care hospitals in New England showed that 18% of respondents initiated NPPV for acute respiratory failure on the general ward and that almost two thirds of respondents allowed NPPV to be maintained on the general medical ward.<sup>4</sup>

Because high ICU occupancy has increasingly encouraged application of NPPV outside the ICU and because

relatively few series have addressed this application,<sup>4-14</sup> the present study assesses our experience with NPPV initiated on the regular hospital floor at the Cleveland Clinic Hospital. Specifically, we sought to address the following questions:

1. What is the frequency of using NPPV for ARF on the regular hospital ward?
2. For what types of patients is NPPV begun?
3. What are the outcomes when NPPV is used to treat patients with ARF on the regular hospital ward?
4. What clinical variables are associated with successful use of NPPV on the regular hospital ward?

## Methods

Patients were eligible for the study if NPPV was initiated for ARF on a regular nursing floor (ie, not in an ICU, and without respiratory monitoring [eg, capnometry, oximetry, and/or indwelling arterial catheter]) at the Cleveland Clinic. Consecutive patients were recruited between May 1, 2004, and February 28, 2005. The date of study closure was determined a priori.

For each prospectively identified patient on whom NPPV was begun, the respiratory therapist administering NPPV recorded information regarding the time NPPV was initiated, mask type, initial inspiratory and expiratory pressure settings, and initial fraction of inspired oxygen. The respiratory therapist recorded Likert scale ratings of the strength of the patient's cough (0 = very weak to 10 = very strong), amount of secretions (0 = none to 10 = profuse), mental status (0 = awake to 10 = completely unresponsive), and the respiratory therapist's assessment of the patient's initial comfort on NPPV (0 = very uncomfortable to 10 = very comfortable). Also recorded were body mass index, whether continuous positive airway pressure (CPAP) or NPPV was used for chronic conditions at home (eg, obstructive sleep apnea or obesity-hypoventilation), the cause of the patient's respiratory failure (classified as chronic obstructive pulmonary disease exacerbation, pulmonary edema, neuromuscular illness, pneumonia, obesity-hypoventilation syndrome, or drug overdose), findings on the most recent chest radiograph prior to initiating NPPV (classified as clear parenchyma = 1, unilateral infiltrates/consolidation/effusion = 2, or bilateral infiltrates/effusions = 3), and results of serial arterial blood gas tests, starting from the most recent before initiating NPPV through the first 48 hours on NPPV or until NPPV was discontinued, whichever occurred first. To assess why NPPV was initiated on the regular hospital floor (vs in the ICU), we recorded the ICU census and whether the medical ICU was full at the time NPPV was started, as well as the patient's resuscitation status, especially the presence of a do-not-resuscitate or do-not-intubate (DNI) order.

Primary outcomes included NPPV failure on the regular hospital floor, defined as the need for ICU transfer as deemed necessary by the managing clinical service, whether or not endotracheal intubation was undertaken. All decisions regarding test ordering and clinical management (eg, arterial blood gas values, chest radiographs, NPPV settings and duration) were made by the managing team, without influence by the investigators. However, the managing clinicians were aware of their patients' participation in a study.

While decisions regarding transfer of patients from the regular hospital floor to the ICU were made at the individual physician's discretion, a general guideline was to transfer the patient to the ICU if (s)he was deemed unstable, in need of possible intubation or of closer monitoring that outstripped capabilities on the general hospital ward. For example, rhythm monitoring was available on some but not all general wards of this 1,000-bed hospital (with 29 separate general inpatient wards). Nursing staffing ratios on the general wards ranged from 1 nurse to 4 to 6 patients versus 1 nurse per 2 patients in the ICUs of the Cleveland Clinic Hospital, Respiratory therapist staffing on the general wards was generally 1 therapist per 6 to 7 patients (when a patient was receiving NPPV) versus 1 therapist per 6 patients in the ICUs.

All respiratory therapists had extensive experience with NPPV, which has been used at the Cleveland Clinic since approximately 1997.

The data collection and analysis were approved by the institutional review board of the Cleveland Clinic.

## Statistical Analysis

The data were analyzed using both univariate and multivariate statistical methods. Each of the variables of interest was individually tested for significant association with NPPV failure. For both binomial and nominal variables, the univariate test of significance was either the chi-square test or Fisher's exact test, as determined by the number of data available for analysis. For ordinal and continuous variables, the Wilcoxon-Mann-Whitney test was used to test for significance.

After univariate testing, the non-DNI patient variable matrix was examined for co-linearity. Only six of the variables met the criteria for independence: mental status, amount of secretions, change in  $P_{aCO_2}$  from before to after initiating NPPV, home use of CPAP/NPPV, sex, and mask type. For these variables, logistic regression was used to develop a multivariate correlation with NPPV failure.

## Results

Over the 10-month study interval, 68 consecutive patients were prospectively identified to receive NPPV for

Table 1. Baseline Characteristics of the Study Group

Variable	n*	Value
Age (mean ± SD y)	76	63 ± 13
Sex (male/female)	76	31/45
Body mass index (mean ± SD kg/m <sup>2</sup> )	67	31 ± 13
Diagnosis (n)	76	
COPD		31
Neuromuscular disease		8
Pulmonary edema		13
Pneumonia		11
Obesity-hypoventilation syndrome		9
Drug overdose		3
Pulmonary fibrosis		1
Respiratory rate (mean ± SD breaths/min)	73	22 ± 5
pH (mean ± SD)	73	7.24 ± 0.08
P <sub>aCO<sub>2</sub></sub> (mean ± SD mm Hg)	73	77 ± 25
P <sub>aO<sub>2</sub></sub> (mean ± SD mm Hg)	73	94 ± 48
Mental status rating (mean ± SD 0-to-10 awakens scale)	68	5 ± 4
Secretions (0-to-10 Likert scale)	68	2 ± 2
Cough (0-to-10 Likert scale)	68	6 ± 3
Chest radiograph category (n)	75	
1. Clear parenchyma		43
2. Unilateral infiltrate/consolidation/effusion		8
3. Bilateral infiltrates/effusions		24
Home NPPV (yes/no)	76	21/55
IPAP level (mean ± SD cm H <sub>2</sub> O)	76	14 ± 3
EPAP level (mean ± SD cm H <sub>2</sub> O)	76	5 ± 1

IPAP = inspiratory positive airway pressure  
EPAP = expiratory positive airway pressure  
\*n = Number of patients for whom the measure was available. Some values were available only for the 68 prospectively evaluated patients.

ARF on the regular nursing floors of the Cleveland Clinic Hospital. On review of hospital records and the hospital respiratory therapy database (MediServe, Tempe, Arizona) at the end of prospective data collection, an additional 8 patients who escaped prospective identification and for whom NPPV was begun on the regular hospital floor were identified; for this retrospectively identified group, study variables that were retrospectively available were extracted from chart review. Altogether, 14 of the 76 patients (18%) had a DNI order on the chart at the time that NPPV was initiated, and they were considered separately in this analysis.

Table 1 shows the baseline characteristics of all study participants. Fifty-nine percent were female, and the mean ± SD age was 63 ± 13 y. For these 76 patients, the most common etiology of ARF was exacerbation of COPD (41%), followed by pulmonary edema (17%), pneumonia (14%), respiratory acidemia complicating obesity-hypoventilation syndrome (12%), neuromuscular disease (11%), drug overdose (4%), and pulmonary fibrosis (1%).

The mean ± SD arterial blood pH before initiating NPPV (157 ± 425 min before) was 7.24 ± 0.08.

Because ICU transfer and intubation would not be expected with the 14 DNI patients, their NPPV success/failure was evaluated separately from the 62 full-support patients in this series (Table 2). NPPV failure (defined as the need for transfer to the ICU) occurred in 19 (31%) of the 62 full-support patients, of whom 12 required intubation within an hour of ICU arrival. Eight (13%) of these 62 patients died, all of whom had been transferred to the ICU before death.

Univariate analysis showed that variables associated with NPPV failure on the regular floor were:

1. More secretions. The mean secretions score was 3 among NPPV failures, versus 2 among nonfailures ( $p = 0.04$ ).

2. A specific underlying cause of respiratory failure. The highest failure rate (26%) was associated with pneumonia, and the lowest rate (5%) was associated with drug overdose ( $p = 0.015$ ).

3. Baseline chest radiograph on which the parenchyma was not clear. The parenchyma was radiographically clear in 42% of the failure group, versus 74% of the nonfailure group. There were unilateral infiltrates/consolidation/effusions in 21% of the failure group, versus 5% of the nonfailure group. There were bilateral infiltrates/effusions in 37% of the failure group, versus 21% of the nonfailure group ( $p = 0.036$ ).

On the other hand (see Table 2), there were no significant differences between patients managed successfully versus unsuccessfully on the regular nursing floor, with regard to age, sex, body mass index, baseline pH, baseline P<sub>aCO<sub>2</sub></sub>, baseline P<sub>aO<sub>2</sub></sub>, mental status rating before NPPV, baseline cough, use of CPAP or NPPV at home (26% in the failure group vs 30% in the nonfailure group), inspiratory or expiratory pressure, change in pH or P<sub>aCO<sub>2</sub></sub> from baseline to the first measurement on NPPV, comfort ratings on NPPV, or use of NPPV at home.

Multivariate analysis was undertaken with the group of 57 prospectively identified full-support patients, because missing values for the 5 retrospectively identified full-support patients precluded their inclusion in the models. In the multivariate analysis regarding correlates of failure in the 57 prospectively identified non-DNI patients, none of the variables achieved significance at a value of  $p < 0.05$ , though the amount of secretions approached significance at  $p = 0.053$ .

To evaluate the circumstances under which the decision was made to initiate NPPV on the regular floor, we tracked whether the 18-bed medical ICU was fully occupied when NPPV was begun. We reasoned that a lack of ICU bed availability would strongly encourage initiating NPPV on the regular floor if such support was needed. The ICU team was consulted for 24 of the 57 prospectively identi-

## NPPV ON THE REGULAR HOSPITAL WARD

Table 2. Baseline Features of the 62 Patients Who Did Not Have a Do-Not-Intubate Order, With Stratification by Outcome\*

	Number of Patients	All Patients	Number of Successes	Success Group Feature	Number of Failures	Failure Group Feature	p
Age (y)	62	62 ± 13	43	63 ± 11	19	62 ± 16	0.89
Sex (male/female)	62	24/38	43	17/26	19	7/12	0.84
Body mass index (kg/m <sup>2</sup> )	56	32 ± 13	38	30 ± 12	18	34 ± 15	0.33
Diagnosis [ <i>n</i> / <i>n</i> (%)]	62		43		19		0.015
COPD		27		24 (56)		3 (16)	
Neuromuscular disease		6		3 (7)		3 (16)	
Pulmonary edema		10		7 (16)		3 (16)	
Pneumonia		7		2 (5)		5 (26)	
Obesity-hypoventilation syndrome		9		5 (11)		4 (21)	
Drug overdose		3		2 (5)		1 (5)	
Respiratory rate (breaths/min)	60	22 ± 5	41	21 ± 5	19	23 ± 7	0.47
pH	60	7.25 ± 0.06	41	7.26 ± 0.06	19	7.25 ± 0.08	0.82
P <sub>a</sub> CO <sub>2</sub> (mm Hg)	60	73 ± 19	41	73 ± 16	19	73 ± 25	0.66
P <sub>a</sub> O <sub>2</sub> (mm Hg)	60	93 ± 39	41	93 ± 40	19	94 ± 38	0.88
Mental status rating (0-to-10 awakesness scale)	57	5 ± 3	38	4 ± 3	19	7 ± 3	0.12
Secretions (0-to-10 Likert scale)	57	2 ± 2	38	2 ± 2	19	3 ± 3	0.04
Cough (0-to-10 Likert scale)	57	6 ± 3	38	6 ± 4	19	5 ± 3	0.17
Chest radiograph category [ <i>n</i> / <i>n</i> (%)]	61		42		19		0.036
1. Clear parenchyma		39 (64)		31 (70)		8 (42)	
2. Unilateral infiltrate/consolidation/effusion		6 (10)		2 (5)		4 (21)	
3. Bilateral infiltrates/effusions		16 (26)		9 (24)		7 (37)	
Home NPPV [ <i>n</i> / <i>n</i> (%)]	62	18 (29)	43	13 (30)	19	5 (26)	0.75
IPAP level (cm H <sub>2</sub> O)	62	13 ± 3	43	13 ± 3	19	13 ± 3	0.87
EPAP level (cm H <sub>2</sub> O)	62	5 ± 1	43	5 ± 1	19	5 ± 1	0.64

\*Values are mean ± SD or *n* unless otherwise noted.

NPPV = noninvasive positive-pressure ventilation

IPAP = inspiratory positive airway pressure

EPAP = expiratory positive airway pressure

fied non-DNI patients in this series (42%). The ICU was full on 38% of the days during which NPPV was begun on the wards. Whether or not the medical ICU was full at the time of initiating NPPV was statistically unrelated to the likelihood of success; the medical ICU was full in 33% of instances in the success group and 42% of instances in the failure group (*p* = 0.67).

Among the 14 DNI patients who were treated with NPPV for ARF on the regular hospital floor (Table 3), the causes of respiratory failure included COPD exacerbation (*n* = 4), pneumonia (*n* = 4), pulmonary edema (*n* = 3), neuromuscular disease (*n* = 2), and idiopathic pulmonary fibrosis (*n* = 1). Seven of the 14 patients with a DNI order died in the hospital; none was transferred to the ICU. Notably, 3 of the 5 DNI patients with COPD managed with NPPV on the regular hospital floor were treated successfully and were discharged home. Univariate analysis of variables associated with failure among these DNI patients showed no significant associations.

## Discussion

Our main findings are:

1. NPPV was frequently initiated for treatment of ARF on the regular hospital ward. In this series, and in keeping with expert recommendations regarding NPPV,<sup>2,3,15</sup> COPD exacerbation was the most frequent underlying cause of ARF.

2. Treatment with NPPV for ARF on the regular hospital ward frequently, but not invariably, obviated ICU transfer or management. NPPV failure with subsequent ICU admission occurred in 31% of the non-DNI patients managed with NPPV in this series.

3. Variables associated with NPPV failure on the regular hospital floor included more secretions, a cause of ARF other than COPD, and infiltrates on initial chest radiograph.

In the context that guidelines recommend initiating NPPV for ARF in the ICU setting,<sup>2,3</sup> only a few series

## NPPV ON THE REGULAR HOSPITAL WARD

Table 3. Baseline Features of the 14 Patients Who Had a Do-Not-Intubate Order\*

	Number of Patients	Prospectively Identified Group	Number of Patients	Retrospectively Identified Group
Age (y)	11	66 ± 17.3	3	64 ± 12.1
Sex (male/female)	11	6/5	3	1/2
Body mass index (kg/m <sup>2</sup> )	10	29 ± 12	1	23
Diagnosis [ <i>n</i> / <i>n</i> (%)]	11		3	
COPD		3 (27.3)		1 (33.3)
Neuromuscular disease		1 (9.1)		1 (33.3)
Pulmonary edema		3 (27.3)		0 (0)
Pneumonia		3 (27.3)		1 (33.3)
Pulmonary fibrosis		1 (9.1)		
Respiratory rate (breaths/min)	11	22.5 ± 5	2	21 ± 4.2
pH	10	7.20 ± 0.11	3	7.12 ± 0.17
P <sub>a</sub> CO <sub>2</sub> (mm Hg)	10	104 ± 39	3	71 ± 26
P <sub>a</sub> O <sub>2</sub> (mm Hg)	10	104 ± 89	3	90 ± 31
Mental status rating (0-to-10 awakeness scale)	11	4 ± 4	0	NA
Secretions (0-to-10 Likert scale)	11	1 ± 2	0	NA
Cough (0-to-10 Likert scale)	11	5 ± 4	0	NA
Chest radiograph category [ <i>n</i> / <i>n</i> (%)]	11		3	
1. Clear parenchyma		3 (27.3)		1 (33.3)
2. Unilateral infiltrate/consolidation/effusion		2 (18.2)		0 (0)
3. Bilateral infiltrates/effusions		6 (54.5)		2 (66.7)
Home NPPV [ <i>n</i> / <i>n</i> (%)]	11	3 (27.3)	3	0 (0)
IPAP level (cm H <sub>2</sub> O)	11	16 ± 4	3	18 ± 2
EPAP level (cm H <sub>2</sub> O)	11	6 ± 2	3	5 ± 0

\*Values are mean ± SD or *n* unless otherwise noted.

NA = not applicable

NPPV = noninvasive positive-pressure ventilation

IPAP = inspiratory positive airway pressure

EPAP = expiratory positive airway pressure

have described NPPV use for ARF on the regular hospital floor.<sup>4-14</sup> Our literature search identified only 11 series that describe the use of NPPV for ARF on the regular hospital ward. In one randomized controlled trial conducted in the United Kingdom, Plant et al reported lower mortality (20% versus 10%) and a lower intubation rate (27% versus 15%) in patients with COPD exacerbations and mild-to-moderate acute respiratory acidemia (pH 7.25–7.35) managed with NPPV on the regular wards of 14 British hospitals.<sup>5</sup> Their approach was supported by the reported lack of ICU beds and by the managing physician's desire to initiate therapy quickly. In another British randomized controlled trial that included 60 patients managed on the regular wards of 3 British hospitals, Bott et al<sup>6</sup> reported that NPPV was associated with better survival and a lower mortality rate (3.9%). In a small (*n* = 17 patients) randomized trial from Scotland that compared NPPV to doxapram for patients with acute ventilatory failure complicating COPD on a respiratory ward,<sup>7</sup> Angus et al reported that NPPV was more effective in improving

ventilation. In another small (*n* = 24 patients) randomized trial of NPPV for COPD exacerbation, conducted in Spain, Barbe et al<sup>8</sup> reported that NPPV could be used on the regular ward but that no benefits were conferred, compared with standard therapy. In an Italian pseudo-randomized trial of NPPV for COPD exacerbation (*n* = 30 patients), Bardi et al<sup>9</sup> reported no deaths and 1 episode of intubation in the NPPV-treated patients, and the trend favored use of NPPV. In an observational study from Canada, Paus-Jenssen et al managed 31 patients managed with NPPV or CPAP over a 5-month period.<sup>10</sup> Also, in a recent survey-based review of 385 Canadian physicians regarding use of NPPV, Burns et al indicated that 6% of respondents initiated and continued use of NPPV in nonmonitored settings (eg, outside the ICU).<sup>11</sup> Schettino et al reported using NPPV to treat ARF in 131 DNI patients, of whom 64% were managed on general medical/surgical hospital wards.<sup>12</sup> Confalonieri et al<sup>13</sup> reported use of NPPV for 1,033 consecutive patients with exacerbations of COPD, of whom 176 (17%) were managed on a general medical

ward and in whom the rate of failure was 13.6%. In another Italian series, Carlucci et al<sup>14</sup> reported their experience with 208 patients with exacerbations of COPD treated with NPPV over 8 years. Over time, patients with pH > 7.28 were increasingly managed on the general medical ward, such that by 1999, more than 70% were managed there. Finally, in a survey of 82 acute care hospitals in Massachusetts and Rhode Island, Maheshwari et al<sup>4</sup> reported that 18% of respondents initiated NPPV for acute respiratory failure on the regular hospital ward and that nearly two thirds allowed continued use of NPPV there.

The present study extends those earlier reports by evaluating correlates of successful NPPV use on the regular hospital ward for non-DNI patients, and is, to our knowledge, the first such series from the United States. Our findings suggest that NPPV is frequently used, albeit not always successfully, on the regular hospital floor, which highlights the importance of baseline predictors of success and close vigilance with NPPV patients.

Our findings agree with others' observations in some ways, and differ in others. For example, that more secretions and poorer mental status was associated with a lower rate of NPPV success is not surprising and has been cited by others as a reason for NPPV failure to avert intubation.<sup>16</sup> On the other hand, in contrast to others' findings,<sup>16-18</sup> we were surprised by the lack of association between the change in the patient's baseline pH or  $P_{CO_2}$  from before to after initiating NPPV with NPPV failure, as defined in this series. Possible reasons for this lack of association include the absence of a protocol for ordering blood gas tests at specific intervals. In fact, there was substantial variability in the time interval between initiating NPPV and drawing the blood gas (from 10 min to 17 hours).

Specific comparison of our results with those of Confalonieri et al,<sup>13</sup> who developed a multivariate scale for assessing NPPV success, indicates several differences that confound the comparison. For example, their series considers only patients with exacerbations of COPD, who comprised 41% of the patients in our series. Also, at least 5% of the patients in their series carried a "do not intubate" order, whereas such patients were considered separately in our analysis. Finally, the majority (83% of 1,033) of patients contributing to the predictive model in the series by Confalonieri et al were managed either in the intensive care unit or in a respiratory intermediate care unit, and only 17% ( $n = 176$ ) were managed on a regular hospital ward. That patients were selected for management on the regular ward was suggested by markedly different rates of failure in the 2 settings (50% in the intensive care unit vs 13.6% on the regular ward). Though defined slightly differently, the 31% failure rate of NPPV in our series is between these rates, in keeping with the mixed population in our series.

At the same time, our suspicion that unavailability of ICU beds was an important impetus for using NPPV on the regular hospital floor was challenged by the observation that the ICU was full on only 38% of the days when NPPV was initiated on the regular floor. Clearly, this practice belies our sense that the ICU was the preferred venue for managing NPPV initiated for ARF. On the other hand, the high NPPV success rate we observed on the regular floor in this series challenges the need for automatic transfer to the ICU, as long as close observation of the patient on the regular hospital floor can be assured. We suspect that nearly two thirds of survey respondents who permitted continued use of NPPV for acute respiratory failure on the regular hospital ward<sup>4</sup> share this view.

Importantly, the NPPV failure rate on the regular hospital floor in this series resembles that of NPPV failure in the ICU in other series. For example, Ambrosino et al<sup>16</sup> reported the use of NPPV in 59 ARF episodes in patients with COPD. Failure was defined as need for intubation or death during NPPV. NPPV was successful in 78% of the episodes, and the overall mortality rate in patients managed with NPPV was 8.5%. In another series, Kramer et al reported their experience with using NPPV for patients in acute hypercapnic respiratory failure (pH < 7.35 and  $P_{aCO_2}$  > 45 mm Hg) in an ICU or step-down unit.<sup>19</sup> Compared with standard therapy, the intubation rate was lower in patients managed with NPPV (31%) than in those managed without NPPV (73%), and that failure rate is identical to the current series (31%).

Finally, in comparing NPPV to standard therapy for patients with COPD exacerbations in the ICU, Brochard et al reported a lower intubation rate (26% vs 74%) and lower mortality (9% vs 29%) in patients who received NPPV.<sup>20</sup> Though the similarity of the rates in those ICU series and the present series cannot be construed as evidence that NPPV for ARF has equal efficacy on the regular hospital floor as in the ICU, the similarity of rates prompts consideration of a randomized controlled trial to compare NPPV management in the ICU versus on the regular hospital floor and suggests that ethical concerns about such a trial may be unfounded.

Several important limitations of this study warrant discussion. Bias in analyzing the correlates of NPPV success on the regular hospital ward is clearly introduced by the fact that the managing physicians elected to manage these patients on the regular hospital ward rather than in the ICU. Indeed, the current study is an observational series rather than a randomized controlled trial of ICU care versus regular hospital floor for patients receiving NPPV for ARF. Definitive resolution of the question about where NPPV should optimally be administered would require such a randomized controlled trial.

A second bias is that the high rate of managing these patients on the regular floor may reflect the fact that the

patients developed ARF while already on the regular floor and that the managing physician desired to initiate therapy quickly, before ICU transfer could be accomplished. In this circumstance, the patient's favorable response to NPPV and stability on the regular floor may have encouraged continued floor observation. On the other hand, had the patients presented to the emergency department in ARF, it seems likely that ICU admission would have been sought whenever beds were available. At the same time, we suggest that our experience with NPPV on the regular hospital ward, while not commonly reported in the United States, has been shared by others, especially when management demands outstrip available ICU beds, as was sometimes the case in this series.

Finally, a third and important limitation of this study is that failure of NPPV was defined operationally, ie, by physician judgment to transfer the patient to the ICU rather than according to explicit criteria or according to a protocol or algorithm. Also, to the extent that the success of NPPV on the regular hospital ward reflects the level of clinicians' experience with NPPV, staffing ratios, and monitoring capabilities on the regular ward, our results may apply to wards with staffing and monitoring capabilities resembling those at the Cleveland Clinic Hospital but less well to settings in which the staffing and monitoring capabilities vary. On this basis, determining the generalizability of these findings will require replication in other series, using such explicit criteria. On the other hand, the similarity of the failure rate in this series to those in earlier randomized controlled trials of NPPV in the ICU supports the generalizability of these conclusions.

### Conclusions

NPPV is frequently used on general hospital wards. Keeping in mind the aforementioned important limitations, the success rate of NPPV on regular nursing floors was comparable to that in series in which NPPV was used in the ICU. We conclude that NPPV can be used outside the ICU. Also, we believe that these findings invite performance of additional studies in which ICU transfer decisions are based on explicit criteria or protocols, in order to enhance the generalizability of our conclusions.

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