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Factors predicting successful noninvasive ventilation in acute lung injury

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Abstract
Purpose. Noninvasive ventilation (NIV) has been successfully used to treat various forms of acute respiratory failure. It remains unclear whether NIV has potential as an effective therapeutic method in patients with acute lung injury (ALI). The aims of this study were to determine factors predicting the need for endotracheal intubation in ALI patients treated with NIV, and to promote the selection of patients suitable for NIV.
Methods. We conducted a retrospective study of all patients admitted to the intensive care unit (ICU) of the Nippon Medical School Hospital from 2000 to 2006 with a diagnosis of ALI, in whom NIV was initiated.
Results. A total of 47 patients with ALI received NIV, and 33 patients (70%) successfully avoided endotracheal intubation. Patients who required endotracheal intubation had a significantly higher Acute Physiology and Chronic Health Evaluation (APACHE) II score and a significantly higher Simplified Acute Physiology Score (SAPS) II, and a significantly lower arterial pH. The respiratory rate decreased significantly within 1 h of starting NIV only in patients successfully treated with NIV. An APACHE II score of more than 17 ($P = 0.022$) and a respiratory rate of more than 25 breaths·min^{-1} after 1 h of NIV ($P = 0.024$) were independent factors associated with the need for endotracheal intubation. Patients who avoided endotracheal intubation had a significantly lower ICU mortality rate and in-hospital mortality rate than patients who required endotracheal intubation.
Conclusion. We determined an APACHE II score of more than 17 and a respiratory rate of more than 25 breaths·min^{-1} after 1 h of NIV as factors predicting the need for endotracheal intubation in ALI patients treated with NIV.

Key words Acute lung injury · Endotracheal intubation · Noninvasive ventilation · Respiratory rate · APACHE II score

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Introduction

Noninvasive ventilation (NIV) refers to ventilation without an endotracheal tube, and it has been successfully used for the treatment of various forms of acute respiratory failure [1]. NIV has been proven to reduce the necessity for endotracheal intubation and to reduce the mortality rate, especially for chronic obstructive pulmonary disease (COPD) [2–4] and acute cardiogenic pulmonary edema [5–8]. There is strong evidence to support the use of NIV in these conditions.

Although acute lung injury (ALI) is a common and serious clinical problem, the efficacy of NIV for ALI remains controversial [9–11]. It has been recognized that there is weak evidence for the use of NIV in patients with ALI [1]. It remains unclear whether NIV has potential as an effective therapeutic method in ALI patients, and there are no generally accepted criteria for the application of NIV in ALI patients.

The success of NIV is related to the ability of the medical team to select appropriate patients for NIV. For example, it is necessary to perform endotracheal intubation prior to using NIV in cardiogenic shock, even if there is cardiogenic pulmonary edema, for which there is strong evidence for using NIV. At present, the effectiveness of NIV as a treatment for ALI is estimated to be about 50% [12]. It may be possible to achieve a better prognosis if we choose ALI patients who receive NIV appropriately, so as to benefit from the advantages of NIV, such as a reduction in nosocomial infections. The aims of this study were to determine factors predicting the need for endotracheal intubation in ALI patients treated with NIV, and to promote the selection of patients suitable for NIV.

Methods

The data of patients admitted to the intensive care unit (ICU) of Nippon Medical School Hospital with a diagnosis of ALI were analyzed retrospectively. The 7-year study period extended from January 1, 2000, to December 31, 2006. We conducted a retrospective and observational study of all eligible patients, including all patients admitted for ALI in whom NIV was used in the ICU as initial ventilatory support.

ALI was defined according to the American-European Consensus Conference on ARDS [13]. The indication for NIV in patients with ALI was determined by the physician in charge and required the following clinical or physiologic criteria: severe respiratory distress with dyspnea, respiratory rate more than 20 breaths·min^{-1}, typical findings on chest radiograph, signs of acute respiratory distress defined by hypoxemia ($Pa_{O_2}/F_{I_{O_2}}$ < 40 kPa), and at least one of the following: use of accessory muscles, extensive diaphoresis, or marbled skin. Patients with associated diagnoses such as COPD, bronchial asthma, or malignancy, with a poor short-term prognosis, and those with a do-not-resuscitate or do-not-intubate order on admission, were not included. Patients presenting with coma or shock were also not included. Coma was defined by a Glasgow Coma Scale score of less than 10 on admission.

In our ICU, NIV was performed according to a standardized procedure. Patients received NIV with BiPAP Vision (Respironics, Murrusville, PA, USA) via a full- or total-face mask. The initial positive end-expiratory pressure (PEEP) was 4 to 10 cm H_2O, and was adjusted to improve patient comfort. The fraction of inspired oxygen ($F_{I_{O_2}}$) was adjusted to achieve a Sp_{O_2} of more than 95%, and the pressure support was adjusted to maintain a tidal volume of 6 to 10 ml·kg^{-1}. The head of the bed was raised to 30–45° during ventilation to minimize the risk of aspiration.

A clinical assessment (heart rate, blood pressure, level of consciousness, Sp_{O_2}, and respiratory rate) was performed regularly, as well as an assessment of patient discomfort, air leaks around the mask, gastric distension, pressure sores, or facial skin necrosis. Arterial blood gases were tested prior to the initiation of and every hour for the first 2 h of NIV. We also tested arterial blood gases when patients were weaned from NIV or intubated. Successful NIV was defined as a rapid improvement in the clinical status and gas exchange, with return to the earlier stable respiratory condition. Failure of NIV was defined as the need for endotracheal intubation and mechanical ventilation during the ICU stay, irrespective of the reason.

We collected the following information: age; sex; primary diagnosis; risk factors, including diabetes mellitus and hypertension; Glasgow Coma Scale score, Acute Physiology And Chronic Health Evaluation (APACHE) II score, and Simplified Acute Physiology Score (SAPS) II on admission; and outcomes, including endotracheal intubation, ICU mortality, and in-hospital mortality. Arterial blood gases, heart rate, arterial blood pressure, and respiratory rate were recorded prior to the initiation of, and within 1, 2, and 6 h of NIV, and when weaning from NIV or performing endotracheal intubation. Pressure support levels, PEEP, and $F_{I_{O_2}}$ were also recorded. We recorded the reasons for endotracheal intubation and renal replacement therapy if they were required.

A two-way analysis of variance and the Bonferroni multiple comparisons procedure were performed to distinguish within-group differences over time. The Mann-Whitney test was performed to evaluate differences within the same time period, and differences in patient characteristics between the groups. Fisher's exact test or the χ^2 test was used to compare the rates of endotracheal intubation, ICU mortality rates, and final in-hospital mortality rates, and to determine differences in patient characteristics. Factors independently associated with endotracheal intubation were identified using a logistic regression model. Receiver operating characteristic (ROC) curves were constructed and the areas under the curves were compared. The best thresholds to discriminate between patients with and without endotracheal intubation were determined with the ROC curves. Sensitivity and specificity were calculated. Statistical analyses were performed using SPSS II (Abacus Concepts, Berkeley, CA, USA). All values are reported as means ± SD, and all *P* values less than 0.05 were considered to be statistically significant.

Results

A total of 47 ALI patients received NIV, and 33 patients (70%) successfully avoided endotracheal intubation (Table 1). Patients who required endotracheal intubation had a significantly higher APACHE II score, SAPS II, and pressure support level, and were more likely to receive renal replacement therapy (Table 1).

Fourteen patients (30%) required endotracheal intubation, and the mean time between the initiation of NIV and endotracheal intubation was 50 ± 54 h (Table 2). Five patients (36%) in this group were intubated within 12 h. More than half of the endotracheal intubations were for hypoxemia or dyspnea.

The overall ICU mortality rate was 19%, and all ICU deaths occurred in patients who required endotracheal intubation (Table 3). Patients who required endotracheal intubation had a significantly higher ICU mortality rate and in-hospital mortality rate (Table 3).

The changes in hemodynamics, blood gas values, and respiratory rates are shown in Table 4. The heart rate decreased only in the group successfully treated with NIV. The arterial pH was lower in patients who required endotracheal intubation than in those who were

Table 1. Patient characteristics

	Successful	Required intubation	*P* value
Number of patients (%)	33 (70%)	14 (30%)	
Age, years	68 ± 12	70 ± 10	0.99
Sex: male/female	25/8	9/5	0.49
APACHE II score	15 ± 5	20 ± 3	0.002
SAPS II	37 ± 11	44 ± 8	0.016
GCS	14 ± 1	14 ± 1	0.17
Etiology of ALI; *n* (%)			0.43
Pulmonary	6 (18%)	4 (29%)	
Extrapulmonary	27 (82%)	10 (71%)	
DM; *n* (%)	12 (36%)	4 (29%)	0.61
HT; *n* (%)	20 (61%)	6 (43%)	0.26
Renal replacement therapy; *n* (%)	8 (24%)	10 (71%)	0.002
NIV mode; *n* (%)			0.08
CPAP	16 (48%)	3 (21%)	
Bilevel-PAP	17 (52%)	11 (79%)	
PEEP level (cm H_2O)	7.3 ± 2.4	6.9 ± 1.9	0.73
IPAP level (cm H_2O)	5.6 ± 1.8	8.4 ± 1.5	0.001

Data values are means ± SD, or number (*n*) of patients
APACHE, Acute Physiology and Chronic Health Evaluation; SAPS, Simplified Acute Physiology Score; GCS, Glasgow Coma Scale; ALI, acute lung injury; DM, diabetes mellitus; HT, hypertension; NIV, noninvasive ventilation; CPAP, continuous positive airway pressure; Bilevel-PAP, bilevel-positive airway pressure; PEEP, positive end-expiratory pressure; IPAP, inspiratory positive airway pressure

Table 2. NIV duration and causes of tracheal intubation

	Total	Successful	Required intubation	*P* value
Duration of NIV, h (range)	44 ± 40 (7–185)	42 ± 34 (7–140)	50 ± 54 (9–185)	0.97
Duration of tracheal intubation with mechanical ventilation, days			7.9 ± 5.4	
Causes of intubation; *n* (duration of NIV, h)				
Hypoxemia	8 (3 h, 5 h, 7 h, 8 h, 16 h, 26 h, 56 h, 69 h)			
Dyspnea	1 (12 h)			
Nasal bleeding	1 (25 h)			
Septic shock	1 (37 h)			
Pneumothorax	1 (64 h)			
Pulmonary bleeding	1 (147 h)			
Mucous plugging	1 (185 h)			

Data values are means ± SD, or number (*n*) of patients
NIV, noninvasive ventilation

Table 3. Patient outcome

	Total	Successful	Required intubation	*P* value
ICU mortality; *n* (%)	9 (19%)	0 (0%)	9 (64%)	<0.001
In-hospital mortality; *n* (%)	13 (28%)	3 (9%)	10 (71%)	<0.001

Data values are means ± SD, or number (*n*) of patients
ICU, intensive care unit

successfully treated with NIV. Although Pa_{O_2}/FI_{O_2} was significantly improved within 1 h in both groups, it decreased over time in patients who required endotracheal intubation. The respiratory rate was significantly lower in patients who were successfully treated with NIV, and if decreased significantly with NIV only in this group.

The following variables were independent factors associated with the need for endotracheal intubation in a multivariate logistic regression analysis: APACHE II score (odds ratio, 1.409; 95% confidence interval [CI], 1.050 to 1.889; $P = 0.022$) and respiratory rate after 1 h of NIV (odds ratio, 1.322; CI, 1.038 to 1.685; $P = 0.024$). The ROC curves of the APACHE II score and the

Table 4. Changes in hemodynamics, blood gas values, and respiratory rates

	Group	Baseline	Within 1 h	Within 6 h	Discontinuation of NIV
Heart rate (bpm)	Successful	104 ± 23	98 ± 20	$91 \pm 17^{2*}$	$90 \pm 17^{2*;3*}$
	Required intubation	108 ± 26	102 ± 20	99 ± 21	105 ± 24
Systolic blood pressure (mmHg)	Successful	123 ± 31	120 ± 22	125 ± 20	120 ± 20
	Required intubation	122 ± 30	120 ± 31	116 ± 16	113 ± 24
pH	Successful	$7.39 \pm 0.06^{4*}$	$7.41 \pm 0.05^{2*;4*}$	$7.43 \pm 0.04^{2*;4*}$	$7.44 \pm 0.03^{2*;4*}$
	Required intubation	7.31 ± 0.08	7.34 ± 0.06	$7.36 \pm 0.06^{2*}$	7.34 ± 0.08
Pa_{O_2}/FI_{O_2} (mmHg)	Successful	122 ± 43	$232 \pm 102^{2*}$	$245 \pm 83^{2*}$	$284 \pm 66^{2*;4*}$
	Required intubation	125 ± 51	$208 \pm 78^{1*}$	$211 \pm 82^{1*}$	153 ± 88
Pa_{CO_2} (mmHg)	Successful	40 ± 9	38 ± 8	39 ± 7	40 ± 6
	Required intubation	36 ± 11	37 ± 12	36 ± 10	$46 \pm 19^{1*}$
Respiratory rate (breaths·min^{-1})	Successful	28 ± 7	$22 \pm 5^{2*;4*}$	$21 \pm 5^{2*;4*}$	$21 \pm 4^{2*;4*}$
	Required intubation	30 ± 5	27 ± 6	27 ± 6	30 ± 9

$^{1*}P < 0.05$, $^{2*}P < 0.01$ from baseline, $^{3*}P < 0.05$, $^{4*}P < 0.01$ between successful group and required-intubation group
Data values are means ± SD
NIV, noninvasive ventilation

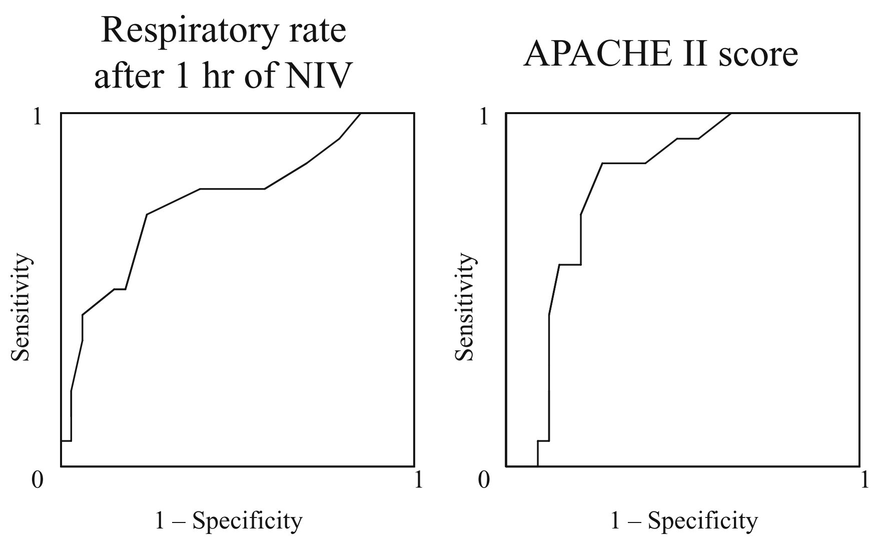

Fig. 1. Receiver operating characteristic (ROC) curves of the Acute Physiology And Chronic Health Evaluation (*APACHE*) II score and respiratory rate after 1 h of noninvasive ventilation (*NIV*) as independent factors associated with the need for intubation. The areas under the ROC curves were 0.792 for the APACHE II score and 0.752 for the respiratory rate after 1 h of NIV

respiratory rate after 1 h of NIV, as independent factors associated with the need for endotracheal intubation, are shown in Fig. 1. The areas under the ROC curves were 0.792 for the APACHE II score (86% sensitivity and 73% specificity) and 0.752 for the respiratory rate after 1 h of NIV (71% sensitivity and 76% specificity). The best cutoff values were 17 for the APACHE II score and 25 breaths·min^{-1} for the respiratory rate after 1 h of NIV.

Discussion

In this study, NIV rapidly improved oxygenation and respiratory rate, and allowed avoidance of endotracheal intubation in 70% of patients. We found that an APACHE II score of more than 17 and a respiratory rate of more than 25 breaths·min^{-1} after 1 h of NIV in ALI patients were independently associated with the need for endotracheal intubation.

Antonelli et al. [14] reported that acute respiratory distress syndrome (ARDS) patients who required endotracheal intubation had a higher PEEP and higher level of pressure support ventilation. L'Her et al. [15] concluded that a pressure support level above PEEP diminished the respiratory muscle effort in ALI patients. In our study, as in the study of Antonelli et al. [14], patients who required endotracheal intubation had significantly higher pressure support levels. This may have been due to their low lung compliance, which is a sign of more severe ALI.

The avoidance of endotracheal intubation was associated with a lower ICU mortality rate and a lower in-hospital mortality rate. This result was similar to results in other recent studies [14–16]. On the other hand, the ICU mortality rate of the patients who required endotracheal intubation was very high (64%). We do not think that this high mortality was due to the undetected progression of respiratory distress. More than half of the patients who required endotracheal intubation were intubated because no improvement was observed in their respiratory condition. The remainder of the patients were intubated immediately following an event such as shock or bleeding. In addition, the entire in-hospital mortality rate (28%) seems to be a good outcome for ALI. It is thought that the mortality rate was high because the original general condition of the patients who required the endotracheal intubation was extremely severe.

Regardless of the cause of respiratory failure, a greater severity of illness, as indicated by the APACHE II score and SAPS II, has been reported to predict the need for endotracheal intubation [14,17–22]. Recent studies have also reported that a greater severity of illness in ALI is a predictor of the need for endotracheal intubation [14,20]. In the present study, the APACHE II score and SAPS II were significantly higher in patients who required endotracheal intubation than in those who were successfully treated with NIV. An APACHE II score of more than 17 was an especially good predictor of the need for endotracheal intubation. Antonelli et al. [14] reported that a SAPS II of more than 34 was independently associated with endotracheal intubation in their prospective, randomized study. It was reported that organ failure was a risk factor for a poor prognosis in ALI/ARDS [23,24]. Only 9%–16% of the ALI/ARDS patients died due to respiratory failure; most died because of progressive organ failure [23,24]. Therefore, evaluation of the severity of illness may be very important when we treat ALI patients using NIV.

Antonelli et al. [14] also reported that the Pa_{O_2}/FI_{O_2} after 1 h of NIV at 23.3 kPa or less was a predictor of the need for endotracheal intubation. In our study, the Pa_{O_2}/FI_{O_2} improved significantly in both groups and was not a predictor of the need for endotracheal intubation. Thirty-six percent of the patients who required endotracheal intubation were intubated within 12 h of starting NIV. However, more than half of the remainder were intubated more than 24 h after starting NIV, and it seems that their initial oxygenation improved. The time course of Pa_{O_2}/FI_{O_2} was similar to that reported by Antonelli et al. [14], and the Pa_{O_2}/FI_{O_2} deteriorated again after the discontinuation of NIV in patients who required endotracheal intubation. In the present study, a respiratory rate of more than 25 breaths·min^{-1} after 1 h of NIV was an independent risk factor for the need for endotracheal intubation. In COPD and acute cardiogenic pulmonary edema, for which there is strong evidence to support the use of NIV, a decrease is observed in the respiratory rate of patients successfully treated with NIV, and this is recognized as a measure of therapeutic effect [2–8]. As with improved oxygenation, it is thought to be significant that the respiratory rate decreases when respiratory distress decreases.

We found that arterial pH was lower in patients who required endotracheal intubation than in those who were successfully treated with NIV. The Pa_{CO_2} was not high in either group, and there was no respiratory acidosis. In short, it seems that the necessity for endotracheal intubation is related to both the degree of improvement in oxygenation and the improvement of the underlying disease that caused the ALI, as shown by the APACHE II score and SAPS II.

In the present study, the percentage of patients able to avoid endotracheal intubation was higher than that in past reports (15%–54%) [13–14,18,22–25]. The reason for this difference was thought to be the retrospective design of the study. Because of our previous experience, we probably selected patients who responded well to NIV.

Outcome predictors are important for the identification of patients who are less likely to improve with NIV. This is particularly important for patients with severe hypoxemia, in whom unnecessary delays in endotracheal intubation may mean loss of the chance of survival. On the other hand, Girou et al. [26] showed that, among patients with similar severity scores, the use of NIV was associated with a decreased risk of nosocomial infections, lower antibiotic use, and decreased length of ventilatory support, ICU stay, and ICU mortality. In other words, there is a possibility that, in patients who can be treated with NIV, the prognosis would be improved more by treatment with NIV compared with endotracheal intubation. Criteria to predict the need for endotracheal intubation would help medical staff to choose between NIV and endotracheal intubation as the first treatment for ALI patients. As our study was retrospective, its ability to evaluate the predictors of the need for endotracheal intubation is limited. However, we think this study provides valuable information for the treatment of ALI.

In conclusion, we determined an APACHE II score of more than 17 and a respiratory rate of more than 25 breaths·min^{-1} after 1 h of NIV as factors predicting the need for endotracheal intubation in ALI patients treated with NIV. We think that NIV is not adequate as a routine first-line treatment for ALI and the selection of patients suitable for NIV is important. It may be worth trying NIV with careful observation, for patients with mild cases of ALI that respond quickly.

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