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Noninvasive ventilation support during fiberoptic bronchoscopy-guided nasotracheal intubation effectively prevents severe hypoxemia

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ABSTRACT

Purpose: This study investigated the feasibility and efficacy of continuous noninvasive ventilation (NIV) support with 100% oxygen using a specially designed face mask, for reducing desaturation during fiberoptic bronchoscopy (FOB)-guided intubation in critically ill patients with respiratory failure.

Materials and methods: This was a single-center prospective randomized study. All patients undergoing FOB-guided nasal tracheal intubation were randomized to bag-valve-mask ventilation or NIV for preoxygenation followed by intubation. The NIV group were intubated through a sealed hole in a specially designed face mask during continuous NIV support with 100% oxygen. Control patients were intubated with removal of the mask and no ventilatory support.

Results: We enrolled 106 patients, including 53 in each group. Pulse oxygen saturation (SpO_2) after preoxygenation (99% (96%–100%) vs. 96% (90%–99%), $p = .001$) and minimum SpO_2 during intubation (95% (87%–100%) vs. 83% (74%–91%), $p < .01$) were both significantly higher in the NIV compared with the control group. Severe hypoxemic events ($SpO_2 < 80\%$) occurred less frequently in the NIV group than in controls (7.4% vs. 37.7%, respectively; $p < .01$).

Conclusions: Continuous NIV support during FOB-guided nasal intubation can prevent severe desaturation during intubation in critically ill patients with respiratory failure.

Trial registration: ClinicalTrials.gov, NCT02462668. Registered on 25 May 2015, https://www.clinicaltrials.gov/ct2/results?term=NCT02462668.

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1. Introduction

Tracheal intubation of critically ill patients in the intensive care unit (ICU) is associated with multiple complications, such as severe hypoxemia [1-3]. Preoxygenation is commonly used to prevent severe oxygen desaturation during intubation and is effective in patients requiring elective intubation for anesthesia [4]. However, it is less effective in critically ill patients [5], and severe hypoxemia is the most common complication contributing to the increased mortality of critically ill patients [6]. More efficient preoxygenation and maintaining ventilatory support during intubation can theoretically help to prevent hypoxemia. Noninvasive ventilation (NIV) is currently a common first-line management technique for reducing the need for intubation in patients with respiratory failure [7-9]. However, when NIV fails, intubation is inevitable. With conventional intubation, the NIV mask must be removed from the patient to perform the intubation. Nasotracheal intubation is commonly used in patients undergoing surgery, but this practice is less common in the ICU due to the risk of sinusitis [10,11]. Fiberoptic bronchoscopy (FOB)-guided nasotracheal intubation is still frequently used for intubating critically ill patients in China. We hypothesized that the use of a specially-designed NIV face mask would permit continuous NIV support during FOB-guided nasotracheal intubation, thus minimizing oxygen desaturation during intubation. This study aimed to demonstrate the feasibility and efficacy of continuous NIV support with 100% oxygen using a specially designed face mask for reducing desaturation during intubation. The primary outcome was the effectiveness of

Abbreviations: FiO_2, fraction of inspired oxygen; FOB, fiberoptic bronchoscopy; NIV, noninvasive ventilation; PaO_2, arterial blood partial pressure of oxygen; SpO_2, Pulse oxygen saturation.

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continuous NIV support during FOB-guided intubation in preventing severe desaturation in critically ill patients with respiratory failure.

2. Methods

2.1. Study design

This was a prospective randomized controlled trial to evaluate the effectiveness of FOB-guided nasotracheal intubation with and without NIV in critically ill adults. The study was not blinded because of the nature of the technique and procedure. The estimated required sample size was 86 patients, assuming a rate of severe oxygen desaturation of 35% during conventional intubation and an expected reduction in oxygen desaturation of <10%, with a beta risk of 0.2 and alpha risk of 0.05, and an allocation ratio of 1:1. The study protocol was approved by the Ethics Committee of the First Affiliated Hospital of Guangzhou Medical University on 12 May 2015 (approval No. 2015 [24]). Written informed consent was obtained from all the patients or their family members.

2.2. Patients

All patients were recruited from the 37-bed medicosurgical ICU of The First Affiliated Hospital of Guangzhou Medical University from 1 June 2015 to 18 June 2017. A flow chart of the patient-recruitment process is shown in Fig. 1. All intubation decisions were made by the attending physician based on worsening respiratory failure (e.g., blood oxygen saturation (SpO_2) < 88% and respiratory rate > 36/min) after adequate therapy, fraction of inspired oxygen (FiO_2) > 60%, intolerance to NIV, neurological deterioration, or copious respiratory secretions. Exclusion criteria were age < 18 years, pregnancy, severe coagulopathy, cardiac arrest, and contraindications for bag-valve-mask (BVM) or NIV preoxygenation.

2.3. Randomization

Eligible patients were randomly assigned using computer-generated random numbers in a ratio of 1:1 to receive BVM preoxygenation and FOB-guided nasal intubation (control group) or NIV preoxygenation and FOB-guided nasal intubation during NIV support (NIV group) (Fig. 2).

2.4. Study treatments

During the screening period, patients received face-mask oxygen therapy with 10–15 l/min oxygen or NIV support with an FiO_2 of 60%–100%, according to the attending physician's decision. After inclusion, patients were randomized to receive BVM or NIV preoxygenation for at least 3 min before intubation. BVM preoxygenation was performed with a BVM driven by 15 l/min oxygen flow (Galemed Corporation, I-Lan, Taiwan), an oxygen reservoir was added to the balloon, and positive end-expiratory pressure was set at 5 cmH_2O. After preoxygenation, the mask had to be removed to allow FOB intubation, and oxygen could

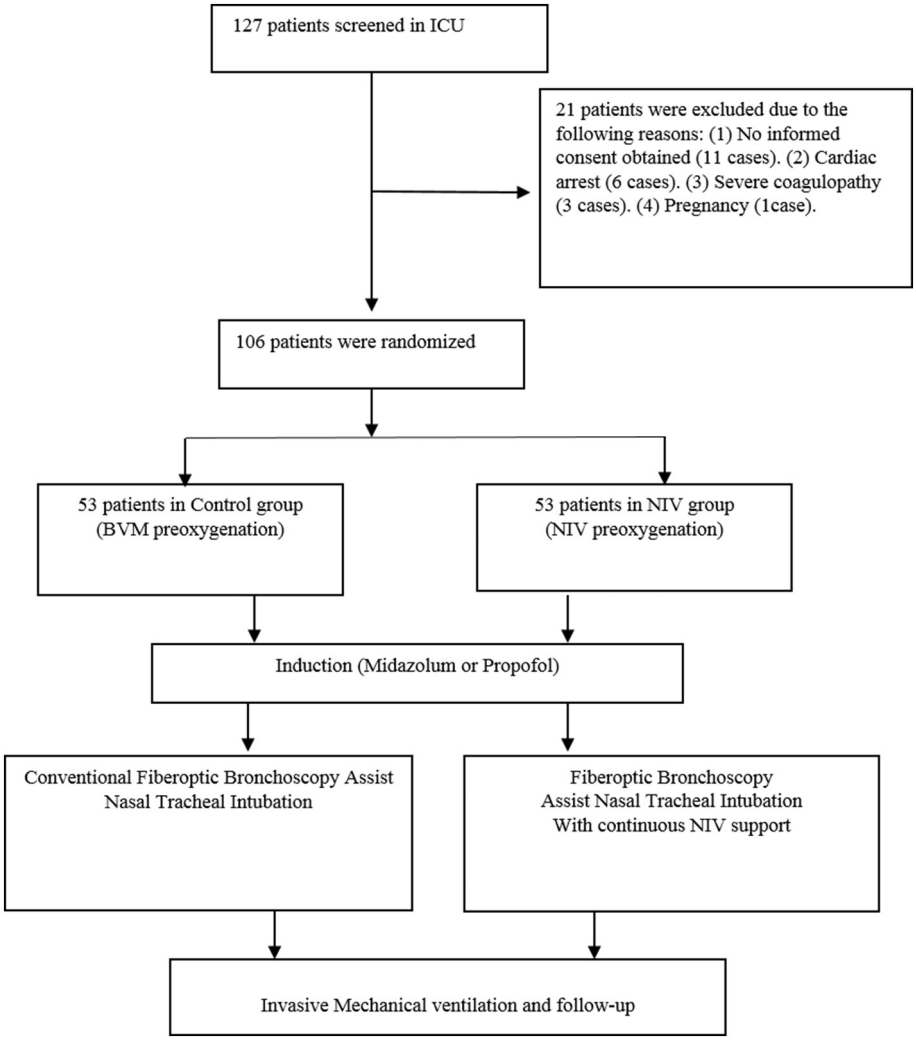

Fig. 1. Flow chart of patient enrollment, randomization, and interventions.

Fig. 2. Photograph showing intubation during noninvasive face-mask ventilation.

only be delivered through the nasal prong with no assisted ventilation during this period. NIV preoxygenation was performed with NIV support (BiPAP Vision®; Philips, Best, Netherlands) with the following settings: mode, S/T; f, 20/min; inspiratory positive airway pressure, 12–20 cmH_2O (adjusted to obtain an expired tidal volume of 7–10 ml/kg); expiratory positive airway pressure, 5 cmH_2O; and FiO_2, 100%. A specially-designed face mask was used to allow FOB-guided nasal intubation to be carried out through a hole in the mask during NIV support. The masks were well sealed in both groups, with special attention paid to ensure patient–ventilator synchronization.

Local ephedrine and lidocaine were applied for nasal preparation before intubation. A size 7-mm or 7.5-mm tracheal tube was chosen and lubricated with medical paraffin oil. After preoxygenation and when the patient was ready for intubation, we administered a hypnotic agent (midazolam, 0.1–0.15 mg/kg or propofol 1.5–2.5 mg/kg) just before intubation, at a dose titrated to maintain the patient's Richmond Agitation Scale score at −5 (no response to voice or physical stimulation). No neuromuscular blocking agent was used. Intubation in the NIV group was performed with continuous NIV support, as described above. After intubation, the mask was removed through the tracheal tube tail. In the control group, bag-mask ventilation was used until the initiation of intubation. During the intubation process, intubation was abandoned and considered to have failed if the SpO_2 dropped to <80%, and preoxygenation was then repeated before another intubation attempt. After intubation, mechanical ventilation was managed by the attending physician according to the patient's underlying condition.

2.5. Data collection

Patients were monitored continuously with a cardiopulmonary monitoring system (IntelliVue MP60, Phillips) during intubation. Arterial blood gas analysis was performed before and after preoxygenation, and at 1 and 30 min after intubation using a portable analyzer (i-STAT; Abbott Laboratories, Abbott Park, IL, USA). Intubation time (defined as the time from injection of the hypnotic agent to ventilator connection), number of intubation attempts, and difficult intubation (defined as two or more intubation attempts or requiring another senior physician for intubation) were recorded for later analysis. Adverse events were monitored and included arrhythmia, cardiac arrest, tachycardia, bradycardia, high- or low blood pressure, and regurgitation. Bronchoscopy and chest radiography were performed after successful intubation to evaluate the position of the intubation tube and the presence of regurgitation. All patients were followed until hospital discharge, death, or 28 days after enrollment.

2.6. Study outcomes

The primary outcome was the effectiveness of continuous NIV support during FOB-guided intubation in preventing severe desaturation in critically ill patients, evaluated by the lowest SpO_2 value and the occurrence of severe hypoxemia ($SpO_2 < 80\%$) during intubation. Secondary outcomes were the incidence of successful first intubation attempts, intubation time, incidence of difficult intubations, safety outcomes, duration of mechanical ventilation, and 28-day survival rate.

2.7. Statistical analysis

Categorical variables were compared by χ^2 tests, and nonparametric data were analyzed using Mann–Whitney *U* tests. Nominal data were analyzed by Student's *t*-tests. Data are expressed as mean ± standard deviation or median and interquartile range. All statistical analyses were performed using SPSS version 19.0 (IBM Inc., Armonk, NY, USA). A p value < .05 was considered statistically significant.

3. Results

3.1. Patient enrollment and baseline characteristics

A total of 127 adult patients met the intubation criteria in our ICU during the study period. 21 patients were excluded because they met the exclusion criteria stated in the Methods. (Fig. 1), and randomized the remaining 106 who fulfilled the inclusion criteria to the control group ($n = 53$) or the NIV group (n = 53). The baseline characteristics of the two groups were similar (Table 1). Sixteen patients in the control group and 23 patients in the NIV group had received NIV treatment before randomization.

3.2. Changes in SpO_2 and arterial blood gases during intubation

The dynamic changes in SpO_2 values during intubation are shown in Fig. 3. Baseline SpO_2 before preoxygenation was similar in the NIV and control groups (92% (85%–98%) vs. 91% (85%–98%), respectively, $p = .87$). After preoxygenation, SpO_2 was significantly higher in the NIV group compared with the control group (99% (96%–100%) vs. 96% (90%–99%), respectively, $p = .001$). The median lowest SpO_2 during

Table 1
Patient demographic data and characteristics at baseline.

	Control (n = 53)	NIV (*n* = 53)	p
Age, yr	66.1 ± 13.1	63.4 ± 11.9	0.27
Gender, F/M n	16/37	15/38	0.88
Height, cm	164.0 ± 8.5	163.0 ± 8.3	0.67
Weight, kg	57.3 ± 11.1	56.8 ± 11.3	0.85
Main cause for respiratory failure, n. (%)			
Pneumonia, n. (%)	40 (75.5)	39 (73.6)	0.82
COPD exacerbation, n. (%)	12 (22.6)	11 (20.8)	0.81
Others, n. (%)	1 (1.9)	3 (5.7)	0.31
Co-morbidities			
Interstitial lung disease, n. (%)	7 (13.2)	13 (24.5)	0.14
Asthma, n. (%)	3 (5.7)	2 (3.8)	0.65
Bronchiectasis, n. (%)	4 (7.6)	4 (7.6)	1.0
Lung cancer, n. (%)	3 (5.7)	3 (5.7)	1.0
Coronary heart disease, n. (%)	6 (13.2)	8 (15.1)	0.57
Left heart failure, n. (%)	4 (7.6)	5 (9.4)	0.73
Shock, n. (%)	14 (26.4)	16 (30.2)	0.67
PaO_2/FiO_2, mmHg	127.3 ± 101.8	109.6 ± 72.4	0.81
Heart rate, beat/min	117.8 ± 19.4	112.7 ± 20.4	0.67
Systolic blood pressure, mmHg	126.2 ± 28.6	127.9 ± 23.8	0.74
Respiratory rate, breaths/min	32.1 ± 7.9	33.9 ± 9.2	0.35
APACHE II score	21.5 ± 6.8	21.0 ± 6.2	0.86

F, female; M, male; NIV, noninvasive ventilation; APACHE II, Acute Physiology and Chronic Health Evaluation II; ARDS, acute respiratory distress syndrome; COPD, chronic obstructive pulmonary disease; PaO_2/FiO_2 ratio, ratio of arterial blood partial pressure of oxygen to the fraction of inspired oxygen. Data presented as mean ± standard deviation or absolute number (%).

intubation was significantly higher in the NIV group than in the control group (95% (87%–100%) vs. 83% (74%–91%), respectively, $p < .01$). However, SpO_2 at 1 and 30 min after intubation were similar in both groups (98% (93%–100%) vs. 96% (90%–100%), $p < .51$; and 99% (97%–100%) vs. 100% (96%–100%), $p < .47$, respectively).

Changes in arterial partial pressure of oxygen (PaO_2) during intubation were similar to the changes in SpO_2 (Table 2). However, PaO_2 improved more in the NIV group compared with the control group after preoxygenation (163.1 ± 90.8 mmHg vs. 107.5 ± 86.6 mmHg, respectively, $p = .001$), but PaO_2 was similar in both groups at 1 and 30 min after successful intubation.

3.3. Procedural characteristics and clinical outcomes

The procedural characteristics and clinical outcomes are shown in Table 3. Intubation was successful during the first attempt in most patients in both groups (90.57% in controls vs. 92.45% in the NIV group), but the mean intubation time was longer and severe hypoxemia ($SpO_2 < 80\%$) occurred significantly more often in the control group compared with the NIV group (37.74% vs. 7.40%, respectively, $p < .01$).

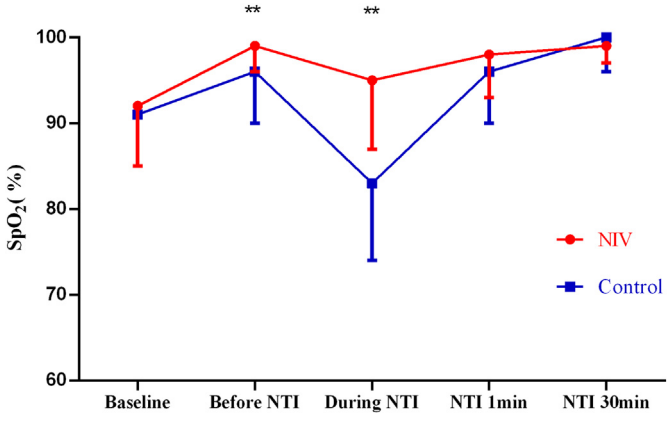

Fig. 3. Dynamic changes in SpO_2 during preoxygenation and nasotracheal intubation (NTI).

Table 2
Arterial blood gases at baseline, after preoxygenation, and after intubation.

Blood gases	Control (n = 53)	NIV (n = 53)	p
Before preoxygneation			
PaO_2 mmHg	75.1 ± 41.0	75.8 ± 32.6	0.53
$PaCO_2$ mmHg	44.9 ± 19.7	49.2 ± 21.8	0.16
PH	7.41 ± 0.11	7.38 ± 0.11	0.11
SaO_2, %	90.1 ± 8.0	91.0 ± 7.5	0.60
After preoxygenation			
PaO_2 mmHg	107.5 ± 86.7	163.1 ± 90.8	0.001*
$PaCO_2$ mmHg	51.0 ± 22.7	55.8 ± 24.5	0.20
PH	7.38 ± 0.11	7.35 ± 0.10	0.19
SaO_2, %	92.8 ± 7.2	97.6 ± 3.3	<0.001*
After intubation at 1 min			
PaO_2 mmHg	143.7 ± 99.6	136.6 ± 91.4	0.83
$PaCO_2$ mmHg	56.9 ± 22.5	60.3 ± 22.0	0.34
PH	7.3 ± 0.1	7.3 ± 0.1	0.49
SaO_2, %	94.5 ± 8.0	94.8 ± 6.1	0.74
After intubation at 30 min			
PaO_2 mmHg	184.4 ± 113.5	171.2 ± 98.5	0.73
$PaCO_2$ mmHg	50.8 ± 16.5	54.0 ± 20.3	0.74
PH	7.37 ± 0.09	7.36 ± 0.08	0.54
SaO_2, %	97.5 ± 3.8	97.4 ± 3.4	0.76

SaO_2, arterial oxygen saturation; PaO_2, partial pressure of arterial oxygen; $PaCO_2$, partial pressure of arterial carbon dioxide; NIV, noninvasive ventilation; NTI, nasotracheal intubation. Data presented as mean ± standard deviation. *$p < .05$.

There was no significant difference in any other complications between the groups. The final outcomes, including 28-day mortality and duration of mechanical ventilation, were similar in both groups. Among the 106 study subjects, 30 patients with suspected sinusitis underwent sinus computed tomography, of whom 19 (28.8%) were diagnosed with sinusitis (six patients with mild sinusitis). Tracheostomy was performed in seven patients, 10 patients were extubated within 2 weeks, and two patients died soon after diagnosis. No patients required sinus drainage.

4. Discussion

This was the first prospective randomized controlled trial of a specially designed face mask allowing continous NIV during intubation to minimize desaturation in critically ill patients. Use of the face mask significantly reduced the percentage of patients with severe hypoxemia compared with the control group (7.4% vs. 37.7%).

Critically ill patients in the ICU often have underlying cardiopulmonary disease, multiple comorbidities, or serious complications, and are therefore at higher risk of developing severe hypoxemia during intubation, compared with patients receiving elective intubation for anesthesia and surgery [3,12,13]. Severe hypoxemia is considered to be the most important factor for patient safety during intubation. During

Table 3
Procedural characteristics and clinical outcomes.

	Control (n = 53)	NIV (*n* = 53)	p
Intubation time(min)	2.2 ± 2.5	1.6 ± 1.3	0.01*
<3 min, n. (%)	45 (84.9)	49 (92.5)	0.36
Successful Intubation in First attempt	48 (90.6)	49 (92.5)	1.00
Rate of difficult intubation, n. (%)	7 (13.2)	4 (7.5)	0.53
Intubation attempt ≥2, n. (%)	5(9.4)	4 (7.5)	1.00
Intubated by senior physician, n. (%)	2(3.8)	0	0.50
$SpO_2 < 80\%$, n. (%)	20 (37.74)	4 (7.40)	<0.01*
SBP < 90 mmHg, n. (%)	9 (16.98)	8 (15.09)	0.79
SBP > 140 mmHg, n. (%)	13 (24.53)	7 (13.21)	0.14
Tachycardia, HR > 120(beats/min), n. (%)	23 (43.40)	19 (35.85)	0.43
Duration of mechanical ventilation, days	20.82 ± 20.29	20.62 ± 18.93	0.86
28 days survival rate, n. (%)	39 (73.58)	38 (71.70)	0.34

SpO_2, pulse oxygen saturation; SBP, systolic blood pressure; HR, heart rate. Data presented as mean ± standard deviation or absolute number (%). *p < .05.

conventional intubation, BVM ventilation must be interrupted during laryngoscopic intubation. Although a brief period of apnea is safe after proper preoxygenation in most patients, individuals with preexisting pulmonary disorders may develop severe hypoxemia very rapidly, and maintaining ventilatory support and oxygen supply during intubation may thus be beneficial for patients at risk of severe hypoxemia. Casey et al. showed that using BVM ventilation in critically ill patients between induction and laryngoscopy resulted in higher oxygen saturation and a lower incidence of severe hypoxemia compared with patients receiving no ventilation[14]. Miguel-Montanes et al. reported that high-flow nasal cannula (HFNC) oxygenation significantly improved preoxygenation and reduced the prevalence of severe hypoxemia during tracheal intubation compared with BVM [15]. However, HFNC only provides constant oxygen flow through the nose during oral intubation. The mechanism resulting in reduced oxygen desaturation during tracheal intubation is referred to as the 'apneic oxygenation' effect [16,17]. HFNC has no effect in providing ventilatory support, and another study showed that HFNC had no effect on reducing oxygen desaturation during intubation [18]. Semler et al. compared HFNC with conventional laryngoscopic intubation and found that HFNC had no benefit on arterial oxygenation in critically ill patients [19]. Current evidence thus suggests that HFNC may have minimal effect on maintaining oxygenation during intubation in critically ill patients [15,18,20].

NIV has been shown to improve ventilation and oxygenation in patients with respiratory failure secondary to a variety of etiologies, thus reducing the need for intubation [21,22]. FOB with NIV support reduced oxygen desaturation in hypoxemic patients [23-25]. NIV has also been used for preoxygenation, resulting in better preoxygenation and less oxygen desaturation during subsequent intubation [26]. However, conventional intubation requires the withdrawal of NIV, which might attenuate its effect. To resolve this problem, Barjaktarevic et al. reported continuous nasal NIV during FOB-assisted oral tracheal intubation and showed that NIV improved SpO_2 during intubation [27]; however in their study, the NIV face mask used for preoxygenation had to be replaced with a nasal mask, thus disrupting ventilation. Furthermore, the patient's mouth remains open during oral intubation, which also interferes with the efficacy of nasal NIV.

To the best of our knowledge, the current study was the first to evaluate intubation during continuous NIV with 100% FiO_2 and no apneic time during the entire intubation process. There was no interruption between preoxygenation and intubation using this technique, which effectively reduced severe oxygen desaturation during the intubation process in critically ill patients.

FOB-guided intubation is a well-documented technique for managing difficult airway anatomies [27-30]. Our results showed that continuous NIV support during FOB-guided intubation with a specially designed face mask was more effective for reducing severe hypoxemia than conventional FOB-guided intubation.

Regarding the safety of this novel method, our results showed that there were no additional complications compared with the conventional approach. Aspiration is one of the most concerning complications of NIV and endotracheal intubation [13,26]. NIV may result in gastric distension secondary to positive airway pressure in critically ill patients, thus increasing the risk of gastric regurgitation and aspiration during intubation. The risk of regurgitation increases if the inspiratory pressure is >20 cmH_2O, which is easily achieved by conventional BVM [31]. In the current study however, the inspiratory pressure did not exceed 20 cm H_2O during NIV, and there was no evidence of regurgitation based on clinical observations and bronchoscopy.

NIV support during FOB-guided intubation requires a specially designed face mask, an NIV ventilator capable of providing 100% inspired oxygen, appropriate NIV set-up, and staff training, in order to use this method successfully. If these conditions are met, NIV support during FOB-guided intubation can be used routinely in daily practice.

The use of NIV during the entire intubation period may have several advantages. First, this approach completely avoids apneic time and provides continuous ventilatory support with 100% FiO_2 during intubation, resulting in less frequent and less severe oxygen desaturation events. Second, there is less pressure to perform tracheal intubation quickly in critically ill patients. Third, this approach may reduce the risk of infection of medical staff who perform intubation in patients with infectious diseases, such as severe acute respiratory syndrome or influenza.

This study had some limitations. First, it was single-center unblinded design, which could have affected the results and thus limit their internal and external validity. Second, FOB-guided nasotracheal intubation was used in all patients in the study because this has been a routine intubation technique in our ICU since 1993, and we therefore did not evaluate the technique in patients with oral intubation. However, FOB-guided nasotracheal intubation is a common practice in critically ill patients, and the primary outcome of our study was the effectiveness of continuous NIV support during FOB-guided intubation for preventing severe desaturation in critically ill patients. The results prove that the concept and methodology of continuous NIV support with 100% oxygen during the whole process of intubation was possible and effectively reduced severe desaturation in critically ill patients. Further studies should be conducted to demonstrate the effectiveness of this technique during oral intubation. Third, severe sinusitis related to nasal intubation was not evaluated carefully in our study. However, a prospective comparative study between oral and nasal intubations is necessary to clarify the impact of sinusitis in nasally intubated patients. Fourth, we recruited 106 cases, which exceeded the planned 86 cases; however, during the course of the study, we considered that some of the included cases might be invalid, with incomplete data. The calculated number of subjects required for the study might also be affected by the rate of severe desaturation. We therefore increased the number of cases.

5. Conclusion

The results of this study showed that using a specially designed face mask for continuous NIV support during FOB-guided nasotracheal intubation was effective in preventing severe oxygen desaturation in critically ill patients with respiratory failure.

Declaration of Competing Interest

None.

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