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Application of improved Glasgow coma scale score as switching point for sequential invasive-noninvasive mechanical ventilation on chronic obstructive pulmonary disease (COPD) with respiratory failure

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Abstract

Background: To compare the efficacy and feasibility of using a modified Glasgow coma scale (GCS) score of 13 or 15 as the criterion for switching chronic obstructive pulmonary disease (COPD) patients with respiratory failure to sequential invasive-noninvasive ventilation.

Methods: COPD patients with respiratory failure who had undergone endotracheal intubation and invasive mechanical ventilation (IMV) between June 2017 and June 2020 at 4 different hospitals in China were included. A total of 296 patients were randomly divided into 2 groups. In group A, the patients were extubated and immediately placed on noninvasive ventilation (NIV) when the modified GCS score reached 13. In group B, the same was done when the modified GCS score reached 15.

Results: No significant differences in the mean blood pressure, oxygenation index, arterial partial pressure of oxygen, and arterial partial pressure of carbon dioxide were seen between groups A and B before extubation and 3 hours after NIV. The re-intubation times were also similar in the 2 groups. Compared to group B, the length of hospital stay, incidence of ventilator associated pneumonia, and time of invasive ventilation were all significantly lower in group A (P = .041, .001, <.001).

Conclusion: Using a modified GCS score of 13 as the criterion for switching from IMV to NIV can significantly reduce the duration of IMV, length of hospital stay, and incidence of ventilator associated pneumonia in COPD patients with respiratory failure.

Abbreviations: COPD = chronic obstructive pulmonary disease, GCS = Glasgow coma scale, IMV = invasive mechanical ventilation, NIV = noninvasive ventilation, OI = oxygenation index, $PaCO_2$ = pressure of carbon dioxide, PaO_2 = pressure of oxygen, PIC = pulmonary infection, VILI = ventilator-associated lung injury.

Key words: chronic obstructive pulmonary disease, Glasgow coma scale, mechanical, respiratory failure, ventilation

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The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

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The study protocol was approved by the Ethics Committee of the Wenling Hospital Affiliated with the Wenzhou Medical University. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. All enrolled patients signed the informed consent form.

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1. Introduction

Bronchopulmonary infections are responsible for 80% to 90% of the acute exacerbations of chronic obstructive pulmonary disease (COPD).[1] Severe acute exacerbations can lead to respiratory failure, which requires treatment with invasive mechanical ventilation (IMV). However, long term use of IMV is associated with hazards such as ventilator-associated pneumonia (VAP) and ventilator-associated lung injury, which significantly affect the prognosis of patients.[2,3] noninvasive mechanical ventilation (NIV) is associated with fewer negative effects than IMV. Sequential invasive-noninvasive ventilation is widely used as an effective treatment for COPD complicated with respiratory failure.[4] The key to successful sequential therapy is finding the best switching point from IMV to NIV. In China, the control window for pulmonary infection (PIC) is often used as the switching point for sequential invasive-noninvasive ventilation with good results. However, PIC diagnosis relies on chest X-ray findings, which often lag behind clinical manifestations and are too focused on infectious factors while ignoring other causes. Internationally, it is common to perform a weaning test after 48 hours of tracheal intubation and IMV and if no signs of spontaneous breathing are observed, NIV is started immediately after removal of the tracheal tube. The problem with using 48 hours after IMV as the switching point is that individual differences and the characteristics of the noninvasive ventilator are ignored. Some clinical trials have found that in COPD patients with respiratory failure, NIV is beneficial and harmless if the patient has good consciousness and cooperation.[5] The modified Glasgow coma scale (GCS) can objectively and quantitatively reflect the overall clinical status of COPD patients with respiratory failure. Some studies have reported positive effects from using the modified GCS to guide sequential invasive-noninvasive ventilation and a score ≥ 15 as the switching point.[6] The modified GCS is widely used clinically in China and has been shown to be an objective and quantitative measure of the clinical condition.[7,8] Our previous studies showed that using a modified GCS score ≥ 13 as the switching point resulted in more benefits.[9,10] The aim of the present study was to compare the clinical results from using a modified GCS score ≥ 13 or 15 points as the switching point for sequential invasive-noninvasive ventilation in COPD patients with respiratory failure.

2. Materials and methods

2.1. Subjects

The present study was designed as a prospective randomized controlled trial. COPD patients with respiratory failure who underwent endotracheal intubation and IMV between June 2017 and June 2020 were recruited from 4 hospitals in China: Wenling Hospital Affiliated with Wenzhou Medical University, the First Affiliated Hospital of Wenzhou Medical University, Changsha Central Hospital, and the First People's Hospital of Jingmen. According to previous sample size calculations, the minimum number of patients that needed to be recruited for each group was 76.

The inclusion criteria were as follows: Patients receiving IMV for Respiratory failure, COPD diagnosed according to the diagnostic criteria published by the Respiratory Diseases Branch of the Chinese Medical Association in 2007,[11] with partial oxygen pressure < 60 mm Hg (1 mm Hg = 0.133 kPa) on blood gas analysis and no absolute contraindications for NIV[12]; Age ≥ 18 years old.

The exclusion criteria were as follows: Acute respiratory failure caused by stroke (acute stage), acute pulmonary embolism, or acute cardiogenic pulmonary edema; Death within 3 days; Active upper gastrointestinal bleeding; Family members terminated treatment; Admission to the ICU in the past 3 months.

2.1.1. A flow chart of the study design is shown in Figure 1. The study protocol was approved by the Ethics Committee of the Wenling Hospital Affiliated with the Wenzhou Medical University. All enrolled patients signed the informed consent form.

2.2. Methods

2.2.1. Sequential invasive-noninvasive ventilation. The patients were randomly divided into 2 groups (A and B) with equal sizes using the random number table method. All patients were treated with broad-spectrum antibiotics, spasmolytic, antiasthma medication, glucocorticoids, expectorant, nutritional support, analgesia and sedation, homeostasis maintenance therapy, etc. Ventilator parameters were adjusted according to the results of arterial blood gas analysis and disease progression. The ventilation mode was synchronous intermittent mandatory ventilation + pressure support ventilation (PSV) or auxiliary/control ventilation ($A_{max}C$). The respiratory rate was 13:18 beats/minute, the tidal volume (V_T) was 8:10 mL/kg, and the arterial partial pressure of carbon dioxide ($PaCO_2$) was maintained at 35 to 50 mm Hg. The inhaled oxygen concentration (FiO_2) and positive end-expiratory pressure were adjusted to keep blood oxygen saturation (SpO_2) ≥ 90%.

Once the patients reached the switching point, they were removed from the invasive ventilator, extubated, and switched to a noninvasive ventilator (Philips Medical Systems, Inc). The initial parameters were positive inspiratory airway pressure at 12 to 14 cm H_2O (1 cm H_2O = 0.098 kPa) and positive expiratory airway pressure (EPAP) at 5 cm H_2O. Appropriate levels were gradually reached within 5 to 20 minutes. The switching point for group A was defined as when modified GCS stabilized at ≥ 13 for 3 hours; the switching point for group B was defined as when modified GCS stabilized at ≥ 15 for 3 hours.

2.2.2. Modified GCS score.[13] Eye opening: 4 points for spontaneous eye opening, 3 points for eye opening in response to voice, 2 points for eye opening in response to pain, and 1 point for inability to open the eyes; The best motor response: 6 points for obeying commands, 5 points for locating pain, 4 points for withdrawal response to pain, 3 points for flexor response to pain, 2 points for extensor response to pain, and 1 point for immobility; Language response: 5 points for correct speech comprehension, 4 points for slow speech comprehension, 3 points for misunderstanding speech, 2 points for response to loud calls, and 1 point for no response to speech. The sum of the 3 components comprised the modified GCS score. The modified GCS was evaluated every morning starting from the 3rd day of endotracheal intubation and IMV. The detailed definition of the modified GCS is shown in Table 1.

2.2.3. Observational indicators. The baseline Acute Physiology and Chronic Health Enquiry II score, modified GCS score, mean blood pressure, and oxygenation index (OI) were recorded the next morning following endotracheal intubation under nonsedated conditions. MBP, OI, arterial partial pressure of oxygen (PaO_2), and $PaCO_2$ were recorded both before extubation and 3 hours after NIV. The time of IMV, incidence of re-intubation, incidence of VAP, and total length of stay were recorded in both groups.

VAP was defined in patients with IMV for more than 48 hours who showed the following signs within 48 hours after extubation: new or progressive infiltrative lesions on chest X-ray and 2 of the following 3 clinical indicators (leukocytes > 12×10^9/L, body temperature greater than or equal to 38.3°C, and purulent bronchial secretion).

Re-intubation criteria[14]: Blood pH ≤ 7.20 and $PaCO_2$ showing a progressive increasing trend; Difficult-to-correct hypoxic state; Severe symptoms of disturbance of consciousness such

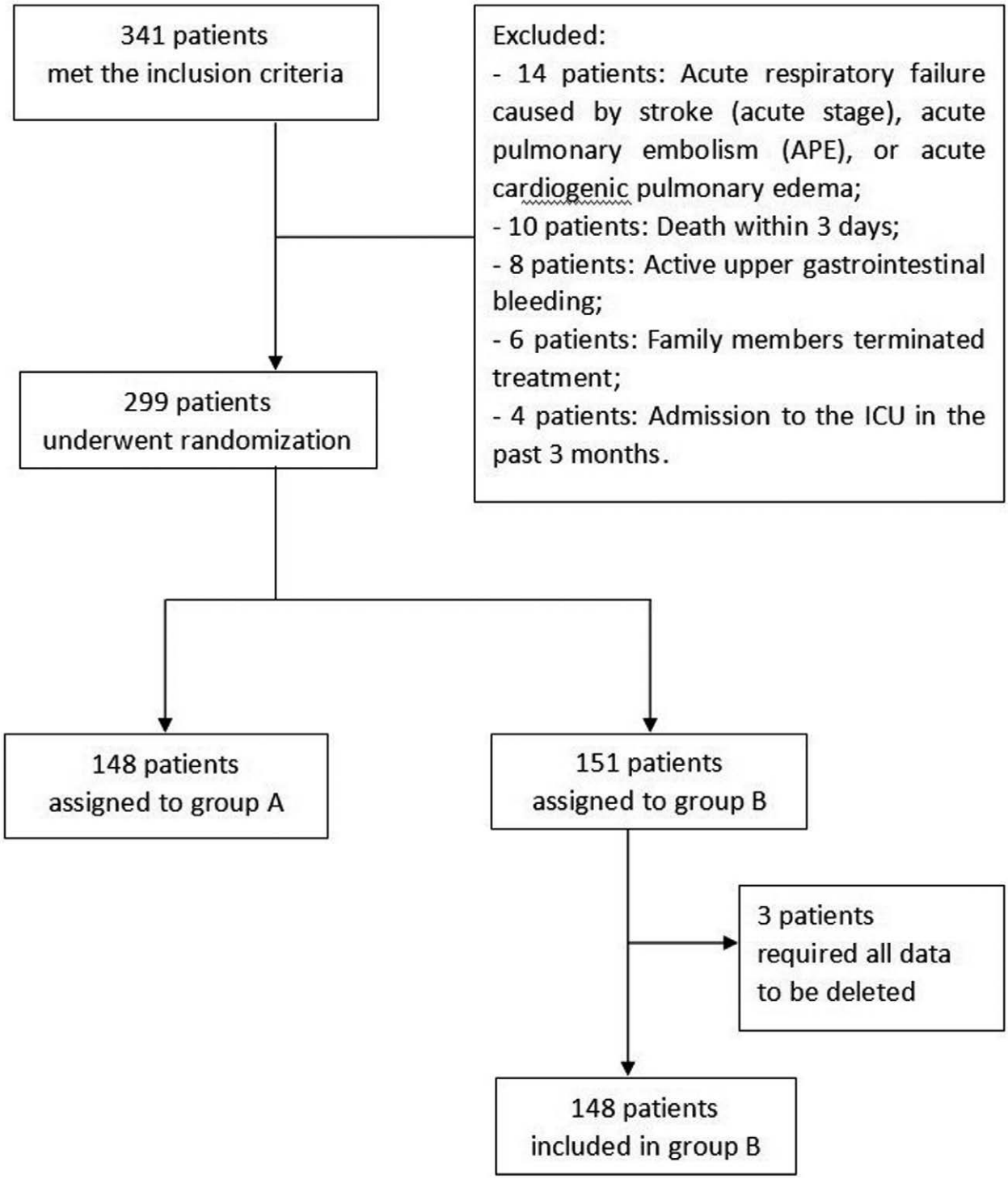

Figure 1. Flowchart of the study design.

as coma, lethargy or delirium; Respiratory or cardiac arrest; Respiratory depression or severe dyspnea.

2.3. Statistical methods

All data were analyzed with SPSS 25.0 (for Windows; IBM Corp). Continuous variables are expressed as the mean ± (SD),categorical variablesare expressed as the ratios (n%). The independent sample *t* test was used for comparisons between the 2 groups. The paired sample *t* test was used for comparisons within a group. The chi squared test was used for analysis of the categorical variables. Differences were considered statistically significant when $P < .05$.

3. Results

3.1. Comparison of baseline clinical data

The total number of patients was 296, including 175 men and 121 women. The age range was from 20 to 87 years old, and the average age was 52.3 ± 8.7 years. There was no significant difference in gender, age, baseline Acute Physiology

Table 1

Modified GCS score.

Score	Eye	Language	Motor
1	Does not open eyes	No response to speech	Makes no movements
2	Opens eyes in response to painful stimuli	Response to loud call	Extension to painful stimuli
3	Opens eyes in response to voice	Misunderstanding of speech	Abnormal flexion to painful stimuli
4	Opens eyes spontaneously	Slow understanding of speech	Flexion/withdrawal from painful stimuli
5	N/A	Correct understanding of speech	Localizes painful stimuli
6	N/A	N/A	Obeys commands

The modified GCS evaluates 3 parameters: Eye, language, and motor responses. The separate scores for these 3 parameters as well as the sum of the scores are considered. The lowest possible overall modified GCS score is 3 (deep coma or death), whereas the highest is 15 (fully conscious person). GCS = Glasgow coma scale, N/A = not applicable.

and Chronic Health Enquiry II score, modified GCS score, body mass index, heart rate, respiratory rate, MBP, OI, PaO_2, $PaCO_2$, or blood pH value between groups A and B. Likewise, there were no significant differences with respect to concomitant diseases such as cardiovascular diseases, cerebrovascular diseases, diabetes, and chronic kidney disease between the 2 groups (Table 2).

3.2. Comparison of oxygenation indicators

Groups A and B (switching point modified GCS ≥ 15) had similar MBP, OI, PaO_2, and $PaCO_2$ before extubation. Three hours after NIV, the MBP remained stable in both groups A and B. The OI and PaO_2 decreased slightly whereas the $PaCO_2$ increased slightly in both groups, but the change did not reach statistical significance. There was no significant difference between switching when modified GCS ≥ 13 (group A) and when modified GCS ≥ 15 (group B). The MBP, OI, PaO_2, and $PaCO_2$ values at 3 hours after NIV were similar in groups A and B (P = .864, .730, .425, .784, see Table 3).

Table 2

Comparison of the baseline clinical data between the 2 groups

Variables	Group A (148)	Group B (148)	t (χ^2) value	P-value
Male (%)	94 (63.51)	81 (54.73)	1.783a	.182
Age (years)	58.32 ± 8.19	55.27 ± 10.34	0.713	.485
APACHE II	24.61 ± 4.27	23.88 ± 5.13	0.828	.409
Modified GCS score	7.65 ± 1.91	7.26 ± 2.04	0.871	.379
BMI (kg/m^{-2})	20.37 ± 3.43	21.89 ± 2.72	0.671	.516
Heart rate (bpm)	88.19 ± 14.03	86.62 ± 16.25	0.417	.815
Respiratory rate (bpm)	22.03 ± 4.66	20.39 ± 4.71	1.273	.214
OI (mm Hg)	157.97 ± 33.22	160.04 ± 27.85	0.446	.792
MBP (mm Hg)	101.70 ± 19.65	97.21 ± 20.07	0.942	.351
PaO_2 (mm Hg)	55.86 ± 9.75	57.97 ± 10.52	1.253	.237
$PaCO_2$ (mm Hg)	83.03 ± 17.99	88.10 ± 18.06	0.128	.193
Blood pH value	7.31 ± 1.87	7.23 ± 1.56	1.645	.112
Cardiovascular disease	27 (18.24%)	24 (16.22%)	0.213	.644
Cerebrovascular disease	21 (14.19%)	31 (20.95%)	2.333	.127
Diabetes	27 (18.24%)	20 (13.51%)	0.461	.497
Chronic kidney disease	8 (5.41%)	11 (7.43%)	0.506	.477

APACHE = acute physiology and chronic health enquiry, BMI = body mass index, GCS = Glasgow coma scale, MBP = mean blood pressure, OI = oxygenation index, $PaCO_2$ = arterial partial pressure of, PaO_2 = arterial partial pressure of O_2.

3.3. Comparison of related medical indicators

Only a few patients required re-intubation in both groups (6.1% in group A and 10.1% in group B). Although the re-intubation rate was slightly higher in group B (modified GCS ≥ 15 used as a switching point), the difference did not reach statistical significance (P = .201). However, the length of hospital stay and duration of IMV in group A (modified GCS ≥ 13 used as a switching point) were significantly shorter than those in group B (P = .041, <.001). The duration of IMV was 2.7 days shorter in group A and the length of hospital stay was 6.9 days shorter. The incidence of VAP in group A was only 34% of that seen in group B (P = .001, see Table 4).

4. Discussion

Acute respiratory distress syndrome with respiratory failure is associated with a mortality rate of over 40% despite nearly 20 years of research and the adoption of protective lung ventilation strategies and optimal management practices.[15–17] Patients with long-term endotracheal intubation easily develop lower respiratory tract infection and VAP. Bacterial contamination along the tracheobronchial tree, sputum suction, and downflow of the air bag can lead to the aggravation of lower respiratory tract infection, prolongation of the duration of IMV, and difficulties in weaning from the ventilator.[18,19] Long-term IMV is also associated with other complications such as airway injury and tracheoesophageal fistula, which have significant impacts on the overall survival.[20] The prognosis is significantly worse if the mode of mechanical ventilation cannot be adjusted in a timely and reasonably manner.[21] In the present study, a sequential invasive-noninvasive ventilation strategy was employed to enable early extubation and minimize the duration of IMV as much as possible, thereby avoiding serious complications and improving the outcomes.

Accurate identification of the optimal time point for switching to NIV from IMV is the key to successful sequential ventilation.[22] In 2007, the European Respiratory Association, American Thoracic Association, European Association of intensive Care Medicine, American Association of critical Care Medicine (SCCM), and French Institute of Terminology Revision (SRLF) all advocated the use of the autonomous breathing test (SBT) as an important diagnostic test to judge the success of weaning and indicated that the duration of SBT should be 30 to 120 minutes.[23] However, the optimal SBT time for mechanically ventilated patients with different underlying diseases has not been determined. Later studies found that SBT often led to the delayed withdrawal of IMV and increased the risk of VAP, which subsequently increased mortality.[24] In China, the switching point is identified based on the clinical picture of PIC. The problem with this approach is that it does not take into account the lag in imaging presentation behind clinical manifestations and noninfectious factors (the cause of acute exacerbation of COPD is difficult to determine)[25]; therefore, PIC is not suitable for all patients with acute exacerbation of COPD. Some countries use 48 hours after IMV as the switching point, but this ignores the patients' state of consciousness, compliance, individual differences, ethnic differences, and other factors.

To be able to use NIV, patients are required to have a clear consciousness, a certain degree of cooperation and understanding, and good compliance. Assessment of the consciousness state of patients is therefore important. The GCS score is widely used for the assessment of consciousness. However, intubated patients cannot speak, which makes it impossible to use the verbal response portion of the original GCS score. In the modified GCS, the verbal response portion is replaced with the understanding of language

Table 3

Comparison of the MBP, OI, PaO_2, and $PaCO_2$ between the 2 groups.

Variables	MBP (mm Hg)				OI (mm Hg)				PaO_2 (mm Hg)				$PaCO_2$ (mm Hg)			
	Before extubation	3 hours after NIV	Paired *t* value	*P*-value	Before extubation	3 hours after NIV	Paired *t* value	*P*-value	Before extubation	3 hours after NIV	Paired *t* value	*P*-value	Before extubation	3 hours after NIV	Paired *t* value	*P*-value
Group A (148)	107.8 ± 18.6	102.8 ± 21.7	1.296	.193	224.1 ± 41.3	212.6 ± 33.2	0.697	.488	88.0 ± 17.5	82.7 ± 20.0	1.017	.324	43.4 ± 11.1	46.9 ± 14.0	1.282	.209
Group B (148)	106.6 ± 16.3	103.5 ± 19.6	1.043	.305	228.0 ± 41.3	214.9 ± 33.3	.881	.387	88.9 ± 18.8	86.0 ± 23.5	1.253	.217	44.1 ± 9.3	47.6 ± 10.8	1.082	.293
t value	0.453	0.172			0.615	0.346			0.262	0.812			0.342	0.275		
P-value	0.651	0.864			0.537	0.730			0.794	0.425			0.333	0.784		

MBP = mean blood pressure, NIV = noninvasive ventilation, OI = oxygenation index, $PaCO_2$ = arterial partial pressure of CO2, PaO_2 = arterial partial pressure of O_2.

Table 4

Comparison of the related medical indicators between the 2 groups.

Variables	Duration of IMV (days)	Re-intubation (n, %)	Incidence of VAP (n, %)	Length of hospital stay (days)
Group A (148)	4.1 ± 1.0	9 (6.1)	11 (7.4)	15.8 ± 4.6
Group B (148)	6.8 ± 1.0	15 (10.1)	32 (21.6)	22.7 ± 5.8
t (χ^2) value	13.500	1.632a	11.999a	2.138
P-value	<.001	.201	.001	.041

IMV = invasive mechanical ventilation, VAP = ventilator-associated pneumonia.

and speech to better suit the conditions of an intubated patient. Luo Xianhai et al[26] proposed the use of the modified GCS score to guide sequential invasive-noninvasive ventilation and used a score ≥ 10 as the switching point. Zheng Dawei et al[6] proposed that a modified GCS score of 15 can be used as the switching point for invasive-noninvasive sequential therapy, which can significantly improve the therapeutic effect for COPD patients with respiratory failure. Other researchers have also attempted to use a modified GCS score of 15 as the switching point.

In this study, the authors found that a modified GCS score that is stable for 3 hours at ≥ 13 is a better switching point for sequential invasive-noninvasive ventilation than a score ≥ 15. Although there was no difference in MBP, OI, PaO_2, and $PaCO_2$ between the 2 groups at 3 hours after extubation and NIV, the duration of IMV, length of hospital stay, and incidence of VAP was all lower in group A, the group in which a modified GCS score ≥ 13 was used as the switching point. After early extubation and switching to NIV, the patients experienced no discomfort, restlessness, or pain. Voice communication and self-consciousness improved and there was also increased trust and coordination among the medical staff. The success rate of withdrawal was high, which shortened the time of hospitalization and reduced medical expenses.

There are several limitations to this study. The modified GCS is widely used clinically in China, but is less well-known outside China. Only objective data were collected in the study, and the subjective comfort of the patients was not studied. Patient discomfort and pain should be evaluated in future studies.

5. Conclusions

In conclusion, in patients with COPD who develop respiratory failure and require IMV, it is safe and feasible to switch to NIV if the modified GCS score remains stable at ≥ 13 for 3 hours. Using a modified GCS score ≥ 13 as the switching point for sequential invasive-noninvasive ventilation therapy can reduce the duration of IMV, duration of hospital stay, and the incidence of VAP compared to using a modified GCS score ≥ 15.

Author contributions

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