



# A randomised controlled study: efficacy of ICU nursing risk management combined with the cluster nursing model and its effect on quality of life and inflammatory factor levels of patients with acute respiratory distress syndrome and ventilator-associated pneumonia

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**Background:** The purpose was to investigate the effect on quality of life and inflammatory factor levels of patients with acute respiratory distress syndrome (ARDS) and ventilator-associated pneumonia (VAP).

**Methods:** A total of 110 ARDS patients with VAP were randomly divided into an experimental group and control group. The control group received routine nursing while the experimental group received ICU nursing risk management combined with the cluster nursing model to compare the clinical efficacy in the two groups of patients.

**Results:** There were no significant differences in general information ( $P>0.05$ ). The total clinical effective rate of patients in the experimental group was significantly higher than that of the control group ( $P<0.05$ ). The Acute Physiology and Chronic Health Evaluation (APACHE II) scores of all patients after nursing were significantly lower than those before nursing ( $P<0.001$ ), and the APACHE II score in the experimental group after nursing was significantly lower than that in the control group ( $P<0.001$ ). The interleukin-8 (IL-8), interleukin-6 (IL-6), and tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ) levels of all patients after nursing were significantly lower than those before nursing ( $P<0.001$ ), and the levels in the experimental group after nursing were significantly lower than those in the control group ( $P<0.001$ ). The vital capacity (VC), total lung capacity (TLC), and forced expiratory volume 1 second ( $FEV_1$ )/forced vital capacity (FVC) levels of all patients after nursing were significantly higher than those before nursing ( $P<0.001$ ), and the levels in the experimental group after nursing were significantly higher than those in the control group ( $P<0.001$ ). The MOS 36-item short form health survey (SF-36) scores of all patients after nursing were significantly higher than those before nursing ( $P<0.001$ ), and the scores in the experimental group after nursing was higher than that in the control group ( $P<0.001$ ).

**Conclusions:** ICU nursing risk management combined with the cluster nursing model can effectively and significantly reduce inflammatory reactions, improve pulmonary function, and enhance the quality of life of ARDS patients with VAP, making it worthy of promotion and application.

**Trial registration:** Chinese Clinical Trial Registry ChiCTR2100048112.

**Keywords:** Risk management (ICU nursing risk management); cluster nursing; acute respiratory distress syndrome (ARDS); ventilator-associated pneumonia (VAP); efficacy

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## Introduction

Acute respiratory distress syndrome (ARDS), a common respiratory disease, is mostly caused by severe trauma, infection, and other factors. Patients often show intractable hypoxemia and respiratory failure. ARDS is one of the serious respiratory diseases endangering human life and health (1,2). ARDS patients are mostly dependent on mechanical ventilation, and ventilator-associated pneumonia (VAP) is a common complication of mechanical ventilation. Clinical studies have found that the incidence of VAP in ARDS patients is 24.6–27.5% (3). VAP will aggravate the condition of patients, prolong the treatment time, and increase the pain of patients. Therefore, effective clinical nursing is of great significance to reduce the incidence of VAP and improve the clinical efficacy of treatment. The condition of ICU patients is complex and variable, and their lives are in danger. Many factors are involved in the changes in patients' conditions, which lead to great difficulty in clinical nursing and a high requirement for professional technology. ICU nursing risk management is an emerging management method to study the occurrence rule of ICU risk in patients and carry out risk control, which reduces the risk of clinical adverse events through risk identification, risk assessment, and risk evaluation, mobilizing the work enthusiasm of medical staff and establishing a good nurse-patient relationship (4-6). Cluster nursing is a nursing concept based on evidence-based medicine, which can provide comprehensive and comfortable health services for patients with severe diseases, minimize the suffering of patients, and improve prognosis (7,8). Based on this, in order to further explore the effect of ICU nursing risk management combined with the cluster nursing model on the quality of life and inflammatory factor levels of ARDS patients with VAP, 110 ARDS patients with VAP treated in Wuhan Jinyintan Hospital from June 2018 to June 2019 were selected as the study subjects, and data were summarized and reported as follows. We present the following article in accordance with the CONSORT reporting checklist (available at <http://dx.doi.org/10.21037/apm-21-1192>) (9).

## Methods

### General information

The study was a two-parallel study. A total of 110 ARDS patients with VAP treated in Wuhan Jinyintan Hospital from June 2018 to June 2019 were selected as the study subjects, and randomly divided into the experimental group and control group, with 55 cases in each group (Figure 1). The allocation ratio is 1:1. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by ethics board of Wuhan Jinyintan Hospital (No. 2018051207).

### Inclusion criteria

(I) Compliance with the diagnostic criteria of ARDS; (II) mechanical ventilation time ( $\geq 48$  h) and the occurrence of VAP; (III) complete clinical data; (IV) this study was approved by the ethics committee of Wuhan Jinyintan Hospital, and the patients and their families knew the purpose and process of this experimental study, and signed the informed consent.

### Exclusion criteria

(I) Expected survival time less than 3 months; (II) combination with other respiratory diseases; (III) cognitive impairment such as mental disorders; (IV) acute hemorrhage and intracranial hypertension.

### Study methods

The control group received routine nursing. The patients were placed in a semi-recumbent position, and their oral cavity was cleaned with chlorhexidine solution. A catheter was placed at the glottis to drain the secretions. ICU environmental nursing was implemented through regular disinfection every day, maintenance of indoor temperature and humidity, regular replacement of sterile liquid of humidifiers and threaded tubes of ventilators, and timely cleaning of condensate water to avoid backflow. Nurses paid

attention to personal hygiene and protected themselves.

The experimental group received ICU nursing risk management combined with the cluster nursing model.

ICU nursing risk management: (I) nursing management teams were established, including ICU head nurses and specialist nurses with rich clinical experience and over 5 years of practice. As team leaders, head nurses carried out ICU nursing risk management training to improve the professional skills of other team members. (II) The patients were informed of VAP-related knowledge so that they could correctly understand VAP and eliminate negative emotions, improving treatment compliance (10). The vital signs of patients were closely monitored, and nursing for the prevention of infection was implemented through aseptic operation and disinfection. (III) Attention was paid to practical operation to ensure the standardization of clinical operation in nursing staff. A corresponding assessment mechanism was formulated to implement standardized operation, fundamentally reducing the incidence of VAP. (IV) The risk management awareness of nursing staff was strengthened through encouraging them to learn ICU nursing knowledge in their spare time to improve professional skills (11,12).

Cluster nursing model: (I) ward management was implemented through regular disinfection of ICU wards every day to keep the air fresh, strictly limiting the number of people and visits, and advising visitors to carry out disinfection of the whole body and wear insulated clothing when entering ICU wards. (II) Oral nursing, nasal feeding, and postural nursing were strengthened. The patients were placed in a semi-reclining position, and kept the same posture 30 minutes after the completion of nasal feeding to promote gastric emptying to avoid reflux and inhalation of gastric contents. As dental plaque is an important factor that induces VAP, oral nursing of patients was implemented 3–4 times every week after appropriate cleaning solution was selected according to the PH value of the patient's oral cavity. (III) For airway management, the nursing staff regularly turned over the patients' bodies every day, tapped the back to drain sputum, used a humidification system to humidify the sputum in their airway, and sucked sputum by flushing and negative pressure drainage, so as to reduce the damage to tracheal mucosa.

### *Evaluation indexes*

Efficacy evaluation (primary outcome): after nursing, the respiratory secretions of patients decreased greatly, and body

temperature and the number of leukocytes returned to normal levels compared with that before nursing, indicating that it was markedly effective. The clinical signs of patients did not change significantly or even worsened, which was ineffective. Total effective rate = markedly effective rate + effective rate.

The Acute Physiology and Chronic Health Evaluation (APACHE II) (13) was used to evaluate the severity of disease before and after nursing (second outcome). The scale included an acute physiology score, chronic health score, and age score, with a total score of 100 points. The higher the score was, the more serious the condition of the patients.

A total of 3 mL of fasting venous blood was collected from the two groups of patients before and after nursing (primary outcome). The enzyme-linked immunosorbent assay (ELISA) was used to measure the levels of interleukin-8 (IL-8), interleukin-6 (IL-6), and tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ). The kit was purchased from Suzhou Comin Biotechnology Co., Ltd. and measurements were performed strictly according to the kit instructions.

A pulmonary function detector (manufacturer: Jinan Laibao Medical Devices Co., Ltd.) was used to detect the vital capacity (VC), total lung capacity (TLC), forced expiratory volume 1 second (FEV<sub>1</sub>), and forced vital capacity (FVC) in the two groups of patients before and after nursing. Then, the FEV<sub>1</sub>/FVC was calculated (second outcome).

The MOS 36-item short form health survey (SF-36) (14) was used to evaluate the quality of life of patients in the two groups before and after intervention. The scale had 36 scoring items, with a total score of 100 points. The higher the score was, the higher the quality of life of the patients (second outcome).

### *Statistical methods*

The experimental data were statistically analyzed and processed by SPSS 20.0 software. GraphPad Prism 6 (GraphPad Software, San Diego, CA, USA) was used to construct the figures of the data. Count data were tested by the  $\chi^2$  test and expressed as n (%). Measurement data were assessed by the *t*-test and expressed as ( $\bar{x} \pm s$ ). Differences were statistically significant when  $P < 0.05$ .

## **Results**

### *Comparison of clinical data between the two groups of patients*

There were no significant differences in gender ratio, age,

**Table 1** Comparison of clinical data between the two groups of patients

Category	Experimental group (n=55)	Control group (n=55)	$\chi^2/t$	P
Gender, n (%)			0.147	0.702
Male	29 (52.73)	31 (56.36)		
Female	26 (47.27)	24 (43.64)		
Average age (years old)	53.63±4.28	53.67±4.32	0.049	0.961
BMI (kg/m <sup>2</sup> )	21.43±1.32	21.45±1.29	0.080	0.936
Smoking history, n (%)			0.146	0.703
No	27 (49.09)	29 (52.73)		
Yes	28 (50.91)	26 (47.27)		
Drinking history, n (%)			0.329	0.566
No	28 (50.91)	31 (56.36)		
Yes	27 (49.09)	24 (43.64)		
Marital status, n (%)			0.121	0.728
Unmarried	4 (7.27)	5 (9.09)		
Married	51 (92.73)	50 (90.91)		
Artificial airway modes, n (%)			0.157	0.692
Tracheotomy	36 (65.45)	34 (61.82)		
Tracheal intubation	19 (34.55)	21 (38.18)		
Residence, n (%)			0.147	0.702
Cities and towns	24 (43.64)	26 (47.27)		
Rural areas	31 (56.36)	29 (52.73)		

BMI, smoking history, drinking history, marital status, artificial airway modes, and residence between the two groups of patients ( $P>0.05$ ), indicating that they were comparable, as shown in *Table 1* and *Figure 1*.

#### ***Comparison of clinical efficacy between the two groups of patients***

The total clinical effective rate of patients in the experimental group was significantly higher than that of the control group ( $P<0.05$ ), as shown in *Table 2*.

#### ***Comparison of APACHE II scores between the two groups of patients before and after nursing***

The APACHE II scores of patients in both groups after nursing were significantly lower than those before nursing ( $P<0.05$ ), and the APACHE II score in the experimental

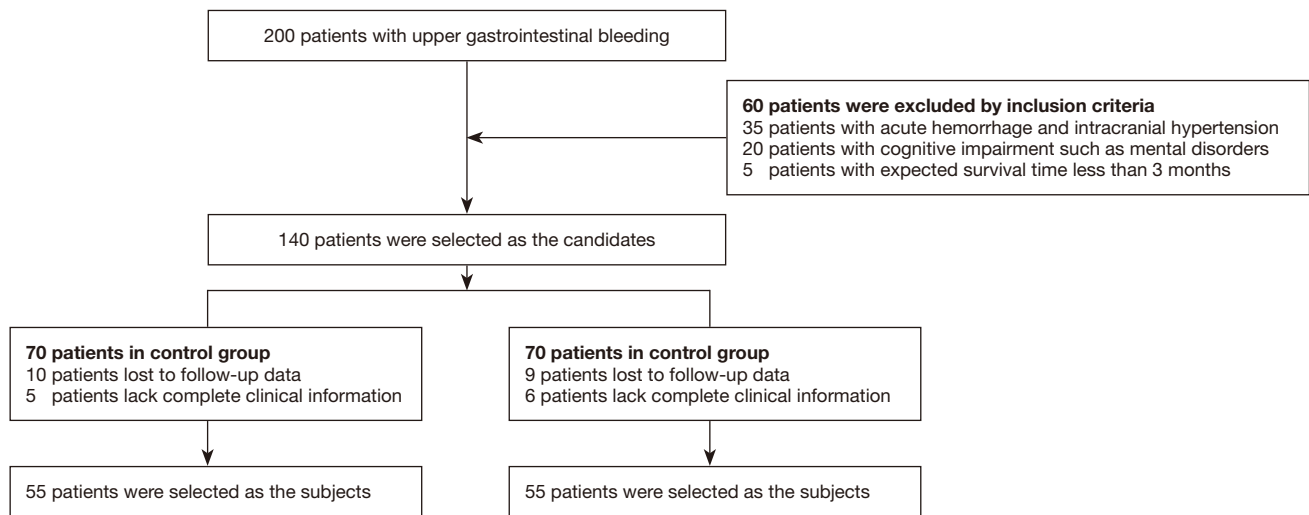
group after nursing was significantly lower than that in the control group ( $P<0.05$ ), as shown in *Figure 2*.

#### ***Comparison of inflammatory factor levels between the two groups of patients before and after nursing***

The IL-8, IL-6, and TNF- $\alpha$  levels of patients in both groups after nursing were significantly lower than those before nursing ( $P<0.05$ ), and the levels in the experimental group after nursing were significantly lower than those in the control group ( $P<0.05$ ), as shown in *Table 3*.

#### ***Comparison of pulmonary function indexes between the two groups of patients before and after nursing***

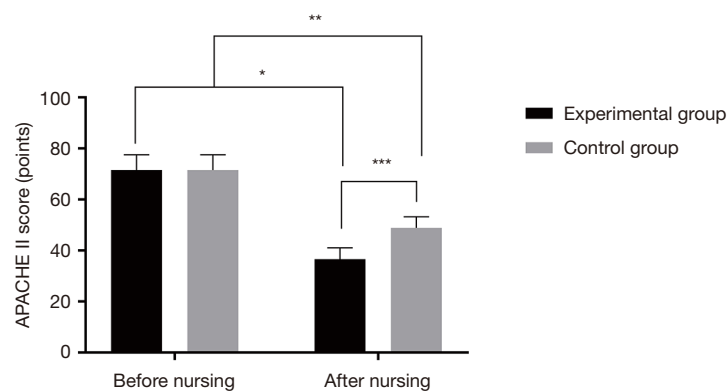
The VC, TLC, and FEV<sub>1</sub>/FVC levels of patients in both groups after nursing were significantly higher than those before nursing ( $P<0.05$ ), and the levels in the experimental



**Figure 1** Study profile.

**Table 2** Comparison of clinical efficacy between the two groups of patients [n (%)]

Group	N	Markedly effective	Effective	Ineffective	Total effective rate
Experimental group	55	26 (47.27)	26 (47.27)	3 (5.45)	53 (94.55)
Control group	55	21 (38.18)	24 (43.64)	10 (18.18)	45 (81.82)
$\chi^2$					4.274
P					0.039



**Figure 2** Comparison of APACHE II scores between the two groups of patients before and after nursing ( $\bar{x} \pm s$ ). The abscissa represents before nursing and after nursing, and the ordinate represents the APACHE II score (points). The APACHE II score of patients in the experimental group was  $67.24 \pm 8.56$  points before nursing and  $33.49 \pm 6.24$  points after nursing. The APACHE II score of patients in the control group was  $67.28 \pm 8.53$  points before nursing and  $45.73 \pm 6.21$  points after nursing. \* indicated that there was a significant difference in APACHE II scores of patients in the experimental group before and after nursing ( $t=23.629$ ,  $P=0.000$ ); \*\* indicated that there was a significant difference in APACHE II scores of patients in the control group before and after nursing ( $t=15.147$ ,  $P=0.000$ ); \*\*\* indicated that there was a significant difference in APACHE II scores between the two groups of patients after nursing ( $t=10.311$ ,  $P=0.000$ ). APACHE II, Acute Physiology and Chronic Health Evaluation.

**Table 3** Comparison of inflammatory factor levels between the two groups of patients before and after nursing ( $\bar{x} \pm s$ , pg/mL)

Group	N	Time	TNF- $\alpha$	IL-8	IL-6
Experimental group	55	Before nursing	84.32 $\pm$ 4.54	89.41 $\pm$ 7.31	65.23 $\pm$ 4.29
		After nursing	33.28 $\pm$ 4.19	35.52 $\pm$ 6.21	28.41 $\pm$ 3.56
Control group	55	Before nursing	84.35 $\pm$ 4.52	89.39 $\pm$ 7.32	65.26 $\pm$ 4.31
		After nursing	54.21 $\pm$ 4.23*	54.72 $\pm$ 6.19*	41.58 $\pm$ 3.47*

The inflammatory factor levels of patients in both groups after nursing were significantly lower than those before nursing. \* indicated the comparison between the experimental group and the control group ( $P < 0.001$ ). TNF- $\alpha$ , tumor necrosis factor- $\alpha$ ; IL-8, interleukin-8; IL-6, interleukin-6.

**Table 4** Comparison of pulmonary function indexes between the two groups of patients before and after nursing ( $\bar{x} \pm s$ , %)

Group	N	Time	VC	TLC	FEV <sub>1</sub> /FVC
Experimental group	55	Before nursing	80.26 $\pm$ 4.21	76.42 $\pm$ 4.21	84.64 $\pm$ 3.26
		After nursing	89.54 $\pm$ 4.17	89.03 $\pm$ 3.18	94.21 $\pm$ 3.17
Control group	55	Before nursing	80.25 $\pm$ 4.23	76.39 $\pm$ 4.19	84.67 $\pm$ 3.24
		After nursing	83.79 $\pm$ 4.19*	86.41 $\pm$ 3.22*	90.13 $\pm$ 3.32*

The pulmonary function indexes of patients in both groups after nursing were significantly higher than those before nursing. \* indicated the comparison between the experimental group and the control group ( $P < 0.001$ ). VC, vital capacity; TLC, total lung capacity; FEV<sub>1</sub>, forced expiratory volume 1 second; FVC, forced vital capacity.

group after nursing were significantly higher than those in the control group ( $P < 0.05$ ), as shown in *Table 4*.

#### *Comparison of SF-36 scores between the two groups of patients before and after nursing*

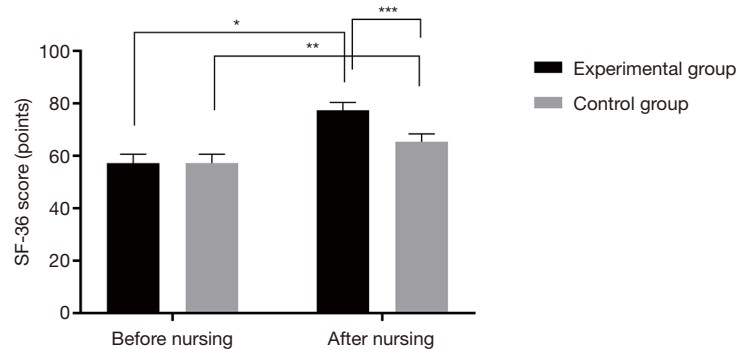
The SF-36 scores of patients in both groups after nursing were significantly higher than those before nursing ( $P < 0.05$ ), and the SF-36 score in the experimental group after nursing was higher than that in the control group ( $P < 0.05$ ), as shown in *Figure 3*.

#### **Discussion**

Mechanical ventilation can effectively improve the ventilation conditions of ARDS patients, prevent the body from hypoxia, and create conditions for disease treatment (15). Studies have found that endotracheal intubation can bring normal bacterial flora of the upper airway into the lower airway, leading to respiratory tract infection. In addition, unclean hands and sputum suction tubes amongst other factors can also lead to flora into the respiratory tract of patients which induces infection (16-18). VAP is a common respiratory tract infectious disease in

ARDS patients, with a high incidence and mortality. The pathogenic risk of VAP is related to a variety of factors, such as the nutritional status of patients, complications, ward environment, and health standards of medical staff, amongst others. VAP can cause difficult weaning from mechanical ventilation in patients and prolong the ICU treatment time, resulting in increased treatment costs and threatening the lives and safety of patients. Therefore, effective nursing measures for inpatients with ARDS have important clinical significance in reducing the incidence of VAP and improving the prognosis of the disease.

Cluster nursing provides comprehensive and systematic nursing services for patients with severe diseases. Compared with traditional nursing, this nursing model pays more attention to the personal feelings of patients, which is more scientific, effectively improving the prognosis of ARDS patients with VAP and shortening the hospitalization time. ICU nursing risk management can significantly reduce the incidence of clinical risk events and nurse-patient disputes, and reduce the incidence of VAP (19,20). Before implementing ICU nursing risk management, the nursing staff should firstly identify the various risk factors of patients during hospitalization, strive to improve professional knowledge, and enhance nursing skills to



**Figure 3** Comparison of SF-36 scores between the two groups of patients before and after nursing ( $\bar{x} \pm s$ ). The abscissa represents before nursing and after nursing, and the ordinate represents the SF-36 score (points). The SF-36 score of patients in the experimental group was  $54.74 \pm 4.87$  points before nursing and  $75.23 \pm 4.28$  points after nursing. The SF-36 score of patients in the control group was  $54.78 \pm 4.85$  points before nursing and  $63.16 \pm 4.35$  points after nursing. \* indicated that there was a significant difference in SF-36 scores of patients in the experimental group before and after nursing ( $t=23.438$ ,  $P=0.000$ ); \*\* indicated that there was a significant difference in SF-36 scores of patients in the control group before and after nursing ( $t=9.539$ ,  $P=0.000$ ); \*\*\* indicated that there was a significant difference in SF-36 scores between the two groups of patients after nursing ( $t=14.668$ ,  $P=0.000$ ). SF-36, the MOS 36-item short form health survey.

implement standardized nursing operation and improve clinical efficacy. The APACHE II score is an important indicator that reflects the degree of acute physiological abnormalities in patients (21,22). This study found that the APACHE II score in the experimental group after nursing was significantly lower than that in the control group ( $P<0.05$ ), suggesting that the combined nursing model can significantly improve the condition of ARDS patients with VAP and improve the treatment effect. In addition, this study found that the SF-36 score in the experimental group after nursing was significantly higher than that in the control group ( $P<0.05$ ). The reasons for this are firstly, before clinical nursing for ARDS patients with VAP, the nursing staff received training of professional knowledge to improve the level of nursing operation and enhance service awareness. Secondly, the risk management awareness of nursing staff was strengthened, and aseptic operation was strictly followed to reduce the occurrence of clinical infection events. In addition, since some patients were prone to anxiety due to a lack of understanding of their own disease, they were informed of VAP-related knowledge to correctly understand the disease and establish confidence in treatment. Makris *et al.* (23) pointed out in their study that after ICU nursing risk management combined with cluster nursing was adopted for patients with severe respiratory failure and VAP, the SF-36 score after nursing ( $74.86 \pm 4.24$ ) was significantly higher than ( $63.28 \pm 4.27$ ) of the reference group, indicating that the combined nursing model can

significantly improve the quality of life of patients with mechanical ventilation, which is beneficial to treatment.

In conclusion, ICU nursing risk management combined with the cluster nursing model can effectively and significantly improve pulmonary function, reduce inflammatory reactions, enhance quality of life, and improve the prognosis of ARDS patients with VAP, making it worthy of promotion and application.

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## Footnote

*Reporting Checklist:* The authors have completed the CONSORT reporting checklist. Available at <https://dx.doi.org/10.21037/apm-21-1192>

*Trial Protocol:* Available at <https://dx.doi.org/10.21037/apm-21-1192>

*Data Sharing Statement:* Available at <https://dx.doi.org/10.21037/apm-21-1192>

*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at <https://dx.doi.org/10.21037/apm-21-1192>). The authors have no conflicts

of interest to declare.

**Ethical Statement:** The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by ethics board of Wuhan Jinyintan Hospital (No. 2018051207) and the patients and their families knew the purpose and process of this experimental study, and signed the informed consent.

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