scientific reports

OPEN

Relationship between difference in endotracheal tube cuff area and airway area with minimum cuff pressure for adequate airway sealing: a prospective observational study

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It is essential for clinicians to select the appropriate endotracheal tube to ensure effective airway management. However, an unmatched endotracheal tube cuff area to the airway area can lead to air or secretion leakage, even at the recommended cuff pressure of 20–30 cmH$_2$O. The present multicenter prospective observational study aimed to determine the relationship between the difference in cuff area and airway area with the minimum cuff pressure to avoid airway leakage. Adult patients who underwent mechanical ventilation were assigned into three groups, with a minimum cuff pressure of < 20, 20–30, and > 30 cmH$_2$O, respectively, in order to have adequate airway sealing. The primary outcome was the difference between the endotracheal tube cuff area and airway area (cuff-airway area difference) that was calculated for the three groups. A total of 284 patients were included, with the mean age of 65.19 (± 14.03) years old. There were 166, 63 and 55 patients who required a minimum cuff pressure of < 20, 20–30 and > 30 cmH$_2$O, respectively. The mean cuff-airway area difference was 236.00 ± 85.26, 149.70 ± 48.34 and − 12.29 ± 113.0 mm^2 in the < 20, 20–30, and > 30 cmH$_2$O groups, respectively. In addition, the simple linear regression analysis revealed a negative linear relationship between the cuff-airway area difference and minimum cuff pressure (Y = -0.1266 × X + 46.50, F = 571.40, *p* < 0.001). It can be concluded that a significant number of patients require a cuff pressure out of the recommended range (< 20 or > 30 mmH$_2$O) to have adequate airway sealing. Patients with a lower cuff-airway area difference require a higher minimum cuff pressure to seal the airway.

Keywords Cuff pressure, Air leakage, Endotracheal intubation, Mechanical ventilation

Endotracheal intubation for invasive mechanical ventilation (MV) is a treatment method to deliver air into the patient's lungs[1,2]. In general, a pressure of 20–30 cmH$_2$O inside the endotracheal tube cuff is recommended to create sufficient sealing between the cuff and patient airway[3–5]. However, studies conducted by the investigators and other research groups have revealed that some patients require a cuff pressure of > 30 cmH$_2$O to seal the airway during MV[6–15], while other patients require a cuff pressure of < 20 cmH$_2$O to seal the airway[7,16,17]. In clinic, physicians commonly select an endotracheal tube based on its diameter, without knowing the size and pressure in the cuff[18]. In addition, different brands of endotracheal tubes can have different cuff sizes, even

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when these have the same tube diameter[7]. Furthermore, the size of the patient airway is correlated to multiple factors, such as age, gender, height, and body mass index (BMI)[7,9,18–22]. All these factors can contribute to an unfitted endotracheal tube in the trachea, leading to leakage after intubation. The previous study conducted by the investigators revealed that gender, age, height, BMI, type of surgical operation, route of oral intubation, and the difference between the cuff inner diameter and tracheal area were the factors that contributed to airway leakage[9]. Among these factors, the surgical operation, route of oral intubation, and the difference between the cuff inner diameter and tracheal area were the primary causes. Thus, the present study performed an additional study to further investigate the relationship between the endotracheal tube size and patient airway, in order to facilitate the selection of an appropriate endotracheal tube for intubation, and ensure patient safety.

The present study aimed to investigate the area difference between the endotracheal tube cuff and patient airway when the airway is sealed, in order to provide a new strategy to select the appropriate endotracheal tube in clinical practice.

Methods

Study design and participant selection

The present multicenter prospective observational study was conducted in three intensive care units (ICUs) in two tertiary hospitals in Nantong, China, from March 2020 to July 2022. These three ICUs included two cardiothoracic ICUs and one respiratory ICU. The study protocol received the approval from the ethics committee at each hospital. Each study participant or healthcare proxy provided a signed informed consent.

The participant inclusion criteria were, as follows: (1) patients who received MV with nasal or oral endotracheal intubation; (2) patients who were ≥ 18 years old; (3) patients who had normal vital signs, with a urine output of ≥ 2 ml/kg/hr; (4) patients with chest computed tomography (CT) scan results in the previous three months. The participant exclusion criteria were, as follows: (1) patients with massive pleural effusion; (2) patients with pneumothorax; (3) patients with a peak airway pressure of ≥ 45 cmH_2O during MV.

Materials

The following equipment and devices were used for the endotracheal intubation: reinforced endotracheal tube (Galanz Medical Equipment, China; Smith Medical Devices, China; Weili Medical Equipment, China), cuff pressure gauge (Ranran Trade, China), stethoscopes (Hausheng Technology and Trade, China), and retractable tube with a 1.5 m suction loop (Intesec Medical Devices, China).

Endotracheal intubation

The anesthesiologists were responsible for the oral and nasal endotracheal intubation of all study participants. In general, the tube size would range within 7.5–8.5 and 7.0–8.0 mm for male and female patients, respectively, during oral endotracheal intubation, and range within 7.0-7.5 and 6.5–7.0 mm for male and female patients, respectively, during nasal endotracheal intubation[23,24]. However, the anesthesiologists had the flexibility to select the endotracheal tube with the appropriate size, according to experience and clinical judgment. After the successful intubation, the anesthesiologists decided on the MV mode.

Data collection

The patient demographics, height, weight, and surgical vs. non-surgical issues were recorded. Information on the inner diameter (ID, 3.0–9.0) of the endotracheal tube was documented. The cross-sectional cuff area of the tracheal tube was calculated, as follows: cross-sectional cuff area = $\pi \times r^2$[25], with r = L/2. The cuff diameter (L) was obtained from the manufacturer's manual.

The correct position of the endotracheal tube was confirmed by bedside chest X-ray. The patient airway cross-sectional area was calculated in the transverse CT image at the slide that corresponded to the level of the endotracheal tube cuff in the airway in the hospital picture archiving and communication system. The difference between the endotracheal tube cuff area and airway area (cuff-airway area difference) was calculated, as follows: cuff-airway area difference = cross-sectional cuff area - cross-sectional airway area.

Minimum cuff pressure measurement

Within 24 h after endotracheal tube placement, the minimal occlusive volume technique was applied to determine the lowest endotracheal tube cuff pressure, and prevent air leakage, as previously described[26]. Briefly, the patient was placed in the 30-degree semi-recumbent position. After cleaning the patient airway and nasal cavity, the endotracheal tube cuff was slowly deflated. Once the air leakage was heard, as determined by the auscultation at the trachea using a stethoscope, the cuff was slowly re-inflated. When the air leakage sound disappeared, the value displayed on the balloon pressure gauge (VBM, Germany) was documented as the minimum cuff pressure to prevent air leakage. This measurement was separately performed twice by two anesthesiologists. The average of two measurements was used for the data analysis.

Sample size determination

The present study was a prospective observational study designed to explore the relationship between the difference in cuff area and airway area with the minimum cuff pressure. Due to the exploratory nature of the study and lack of relevant previous data, a formal sample size calculation was not conducted. All eligible cases during the study period were collected to explore the research question.

Statistical analysis

All enrolled patients were assigned into two groups based on the minimum cuff pressure to prevent air leakage (≤ 30 cmH_2O and > 30 cmH_2O groups). The normal distribution and logarithmic econometric data were presented in mean ± standard deviation or median with interquartile range, and compared by *t*-test or Mann-Whitney test, depending on the normality test results. The categorical data were presented in numbers with percentages, and compared by Chi-square test. Simple linear regression analysis was used to evaluate the relationship between the cuff-airway area difference and minimum cuff pressure. All statistical analyses were performed using SPSS (version 25.0; IBM, USA). The figures were created using Prism 8 (GraphPad, USA). A p-value of < 0.05 was considered statistically significant.

Results

Participant characteristics

A total of 457 patients, who underwent MV during the study period, were screened. Among these patients, 284 patients were included for the present study, which comprised of 209 (73.6%) male and 75 (26.4%) female patients. The mean age of these patients was 65.19 (± 14.03) years old. A total of 166, 63 and 55 patients had a minimum cuff pressure of < 20, 20–30, and > 30 cmH_2O, respectively. The characteristics of these patients are listed in Table 1.

Negative linear relationship between cuff-airway area difference and minimum cuff pressure by regression analysis

As shown in Fig. 1, there was a strong linear relationship between the independent variable "cuff inner area minus tracheal area" and dependent variable "minimum cuff pressure when the airway is closed", with $p < 0.001$, indicating that the independent variable had a pronounced effect on the dependent variable.

The mean cuff-airway area difference was 236.00 ± 85.26, 149.70 ± 48.34, and − 12.29 ± 113.0 mm^2 in the < 20, 20–30 and > 30 cmH_2O groups, respectively. This indicates that patients with a lower cuff-airway area difference required a higher minimum cuff pressure to seal the airway (Fig. 2).

Discussion

The present study investigated the relationship between the cross-sectional area of the cuff and cross-sectional area of the patient's airway. It was found that a significant number of patients required < 20 or > 30 mmH_2O cuff pressure to have adequate airway sealing. In addition, there was a negative linear relationship between the cuff-airway area difference and minimum cuff pressure. That is, a small cuff area could have airway leakage even at a cuff pressure > 30 cmH_2O, while a large cuff area could cause the cuff wall to wrinkle, and allow airway secretions to flow into the airway. Therefore, clinicians should consider the cuff-airway area difference when selecting the appropriate endotracheal tube.

The recommended cuff pressure during tracheal intubation is 20–30 cmH_2O, but air leakage during endotracheal intubation has been frequently reported in clinic[27]. The present study revealed that a significant number of patients (55 patients, 19.37%) required a cuff pressure of > 30 cmH_2O to achieve adequate sealing. Therefore, it is important to identify a way to help clinicians select the appropriate endotracheal tube and cuff pressure, in order to provide adequate airway sealing during MV. Furthermore, the present study provided clinical evidence that patients with a low cuff-airway area difference were more likely to require a higher minimum cuff pressure for adequate sealing in the airway. This finding can help clinicians select the appropriate endotracheal tube, and decide on the cuff pressure during MV.

		Minimum cuff pressure to seal airway, cmH_2O			
Characteristics	**Total (n = 284)**	**< 20 (n = 166)**	**20–30 (n = 63)**	**> 30 (n = 55)**	***p***
Age (year), M ± SD	65.19 ± 14.03	62.86 ± 14.08	65.92 ± 13.79	71.38 ± 12.32	< 0.001
Weight (kg), M ± SD	64.81 ± 11.35	65.21 ± 11.89	64.72 ± 10.26	63.69 ± 10.97	0.689
Height (cm), M ± SD	166.60 ± 7.09	165.60 ± 7.14	167.00 ± 7.31	169.00 ± 6.06	0.006
Body mass index (kg/m^2), M ± SD	23.34 ± 3.66	23.74 ± 3.74	23.23 ± 3.57	22.24 ± 22.24	0.030
Sex, n (%)					< 0.001
Male	209 (73.60)	106 (63.90)	51 (81.00)	52 (94.50)	
Female	75 (26.40)	60 (36.10)	12 (19.00)	3 (5.50)	
Surgical operation, n (%)					< 0.001
Y	221 (77.80)	146 (88.00)	41 (65.10)	34 (61.80)	
N	63 (22.20)	20 (12.00)	22 (34.90)	21 (38.20)	
Oral intubation route, n (%)					< 0.001
Y	259 (91.20)	160 (96.40)	57 (90.50)	42 (76.40)	
N	25 (8.80)	6 (3.60)	6 (9.50)	13 (23.60)	
Peak inspiratory pressure (cmH_2O), M ± SD	20.87 ± 4.49	20.42 ± 3.97	21.13 ± 4.62	21.93 ± 5.58	0.084
Tidal volume (ml), M ± SD	557.40 ± 102.30	565.50 ± 91.12	547.70 ± 119.70	550.00 ± 90.73	0.366
Cuff area (mm^2), M ± SD	497.1 ± 107.4	518.60 ± 93.43	493.50 ± 117.10	436.50 ± 113.50	< 0.001
Patient airway area (mm^2), M ± SD	328.30 ± 120.70	282.60 ± 83.70	343.80 ± 103.20	448.80 ± 145.80	< 0.001

Table 1. Patient characteristics.

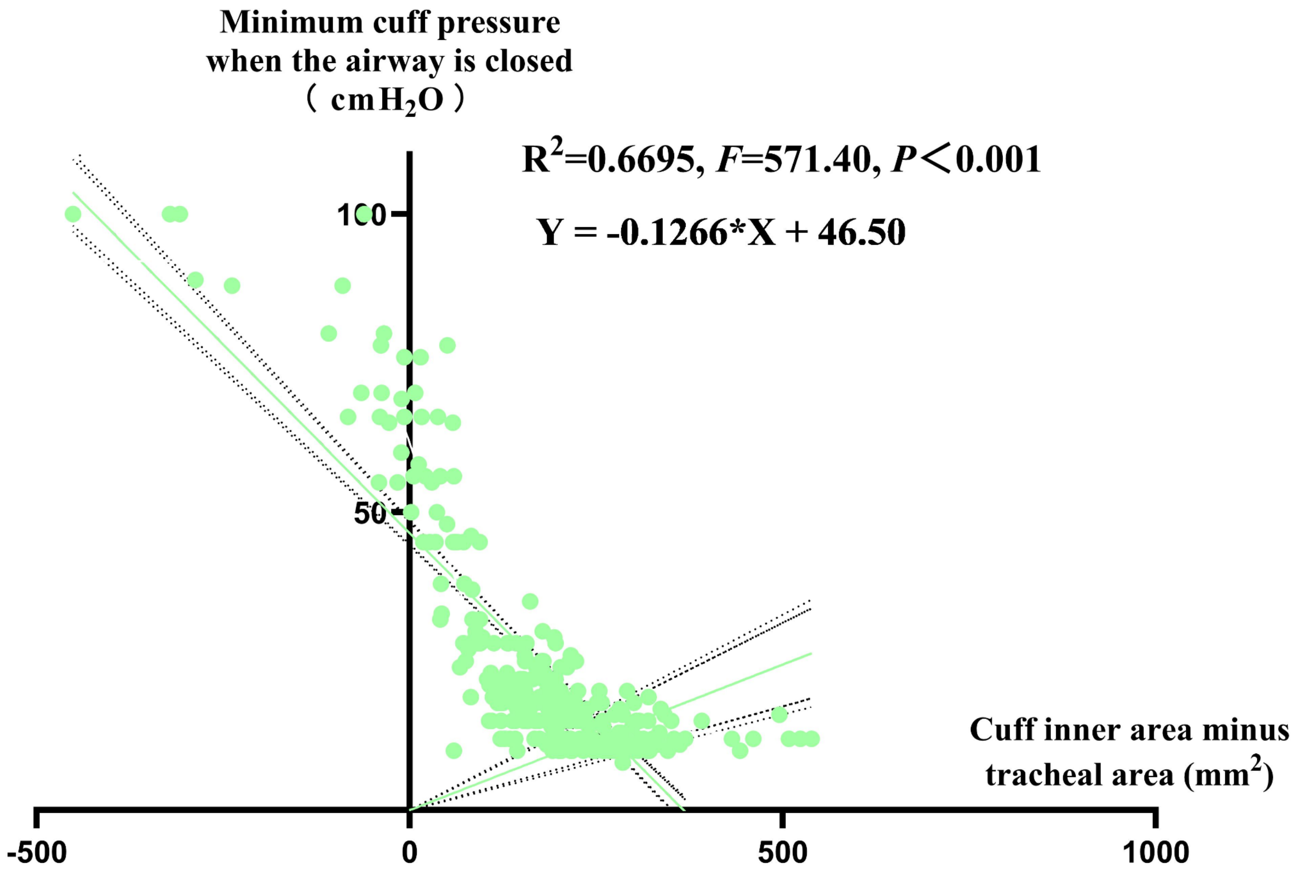

Fig. 1. Comparison of cuff-airway area differences (differences in endotracheal tube cuff area and airway area) under different cuff pressures.

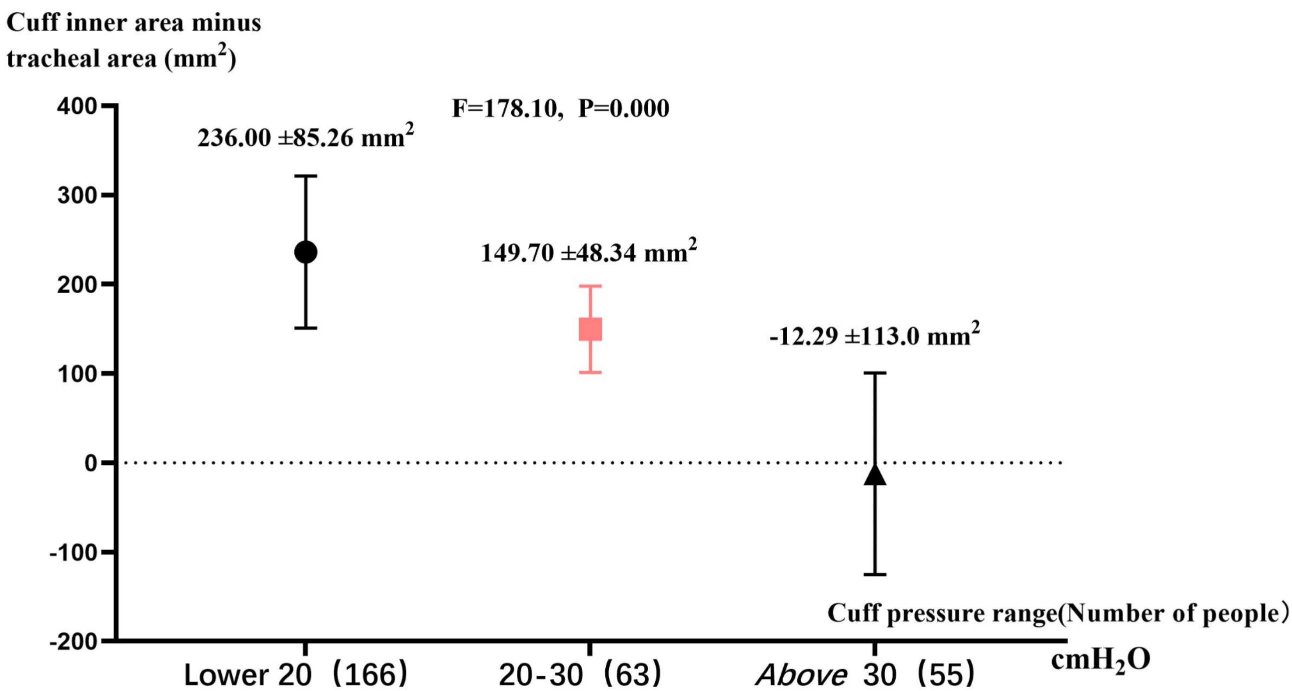

Fig. 2. Comparison of the difference between the area of the cuff and area of the airway, when the airway was closed, at different stages of the minimum pressure of the cuff.

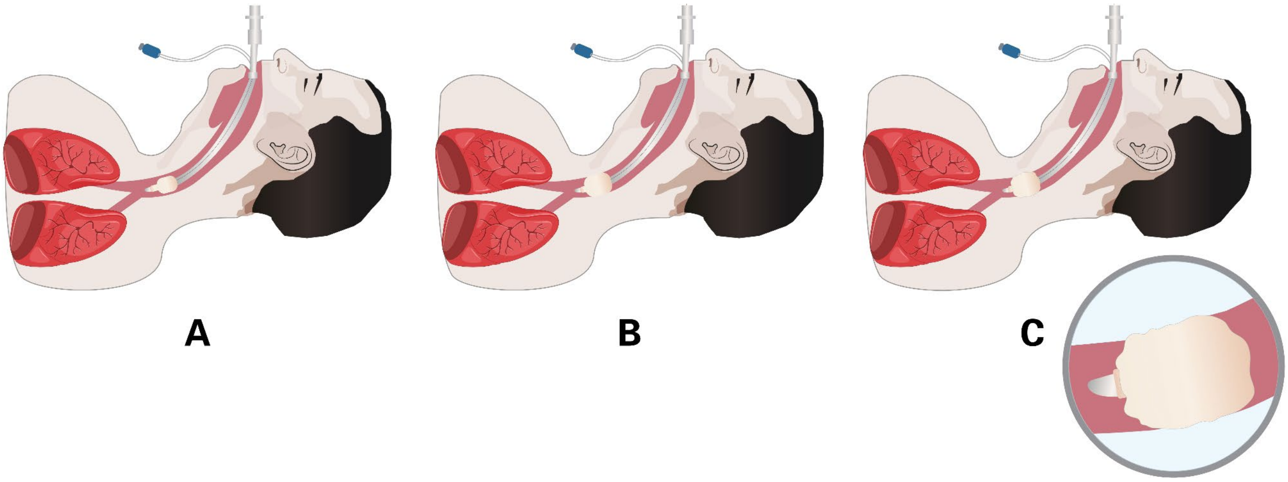

Fig. 3. Illustrations of the relationship between the endotracheal tube cuff area and airway area. (**A**) The cuff area was smaller than the airway area; (**B**) The cuff area was similar to the airway area; (**C**) The cuff area was larger than the airway area.

In the present study, it was found that there is a negative linear relationship between the cuff-airway area difference and minimum cuff pressure. That is, as the cuff-airway area difference decreased, the minimum cuff pressure required to seal the airway increased. This suggests that a smaller difference between the cuff and airway area would carry a higher risk to have airway leakage, and require a higher cuff pressure to have adequate airway sealing.

As shown in Fig. 3A, the cuff of the endotracheal intubation was too small during MV. A tracheal tube with a small-sized cuff area would be more prone to have airway leakage in clinical practice[8,9,28]. Several guidelines have recommended to maintain a cuff pressure of 20–30 cmH_2O[29–31]. Therefore, clinical nurses focus more attention to the guidelines that require them to manage a cuff pressure of 20–30 cmH_2O during tracheal intubation, while overlooking the role of the cuff, in effectively sealing the patient's airway[6,8,9,32]. The cuff in the endotracheal tube maintains adequate sealing in the airway, and prevents leakage[33,34]. When the cuff area is smaller than the patient's airway area, the cuff cannot seal the airway even when the cuff pressure reaches 30 cmH_2O. If the pressure inside the cuff is greater than 30 cmH_2O, the pressure inside the cuff may not be equal to the pressure on the lining of the airway mucosa. Oral and nasal secretions can leak into the airways, and cause complications, such as ventilator-associated pneumonia. This situation might be more frequently encountered during nasotracheal intubation. Due to the small diameter of the patient's nasal cavity, and in order to improve the success rate of the nasotracheal intubation, some anesthesiologists might choose an endotracheal tube with a narrow diameter, which could result in a small difference between the cuff area and airway area (a small cuff-airway area difference). As shown in the present study, a small cuff-airway area difference commonly required a higher minimum cuff pressure to completely seal the airway.

As shown in Fig. 3B, when the tracheal intubation cuff pressure was between 20 and 30 cmH_2O, the cuff could seal the patient's airway. The average cuff-airway area difference was 149.70 ± 48.34 mm^2.

As shown in Fig. 3C, the cuff of the tracheal intubation tube was too large during MV. A large-sized cuff can lead to tube folding in the airway[35]. For the 284 patients surveyed for MV, it is noteworthy that the proportion of patients with an excessive cuff area was relatively large (58.5%, 166/284). As a result, the cuff of most patients that underwent tracheal intubation may wrinkle, and airway secretions may flow into the airways.

A previous study reported a significant difference in the cuff area provided by different manufacturers, even when the endotracheal tube was labeled as the same size[36]. Therefore, the investigators suggest that clinicians should pay attention to this during endotracheal intubation.

Strengths and limitations

The strengths of the present study include its multi-center design, and the relatively large sample size. The present study had several limitations. First, the study was performed for Chinese patients. Thus, the results might not be generalized to patients in other countries. Second, most of the patients were male patients with oral endotracheal intubation, which might introduce selection bias into the present study. Third, although all eligible cases were collected during the study period, a robust statistical calculation was not performed, which might have resulted in small sample bias, and inadequate power to reveal the difference. Finally, the patients were not followed up to determine the clinical outcomes. Future studies would address these issues.

Conclusion

Even when the recommended cuff pressure is 20–30 cmH_2O, a number of patients require a pressure of >30 mmH_2O or <20 mmH_2O to have adequate airway sealing. The negative association between the cuff-airway area difference and minimum cuff pressure for adequate sealing suggests that patients with a lower cuff-airway area difference require a higher minimum cuff pressure to seal the airway. Clinicians should consider the cuff-airway area difference when selecting the appropriate endotracheal tube for MV.

Data availability

The supporting data for the study findings are available from the corresponding author upon request.

Received: 26 July 2024; Accepted: 2 January 2025
Published online: 18 February 2025

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Acknowledgements
We would like to thank our colleagues at the Cardiothoracic Intensive Care Unit and Respiratory Medical Care Unit of the Affiliated Hospital of Nantong University, and the Cardiothoracic Intensive Care Unit of Nantong Third People's Hospital for their significant contributions.

Author contributions
HLW, MJL and YHW: patient recruitment, data collection, and manuscript draft; JHS: data analysis and study design; YHX and LD: patient recruitment, data collection, and informed consent process; HWS, JHS, YPZ and WQS: study design, patient recruitment, and manuscript proofreading.

Funding
The study was funded by the 2021 Jiangsu Province Postgraduate Research & Practice Innovation Program in China (Grant number: SJCX21_1479), the 2021 Nantong Health Commission Research Initiative (Grant number: 2021006), and grants from Jiangsu Provincial Research Hospital (Grant number: YJXYY202204-YSB19).

Declarations

Competing interests
The authors declare no competing interests.

Ethics statement
The study was approved by the ethics committee of The Affiliated Hospital of Nantong University, and Nantong Third People's Hospital (No. 2021-K062-01). A written informed consent was obtained from all individual participants or their healthcare proxy. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

Additional information
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