Evaluation of the effectiveness and factors associated with the treatment outcomes of high-flow nasal cannula and bilevel positive airway pressure in patients with chronic obstructive pulmonary disease with moderate respiratory failure

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Received December 12, 2024; Accepted March 19, 2025

DOI: 10.3892/wasj.2025.339

Abstract. The present study compared the effectiveness of the non-invasive respiratory support therapies, bilevel positive airway pressure (BiPAP) and high-flow nasal cannula (HFNC) in 176 patients with chronic obstructive pulmonary disease (COPD) with hypercapnia, divided into two treatment groups. The results indicated that the BiPAP group achieved a significant reduction in the mean partial pressure of carbon dioxide in arterial blood, decreasing from 54.14±10.40 to 47.06±5.99 mmHg, compared with a reduction from 55.97±10.50 to 50.31±7.32 mmHg in the HFNC group. Oxygen saturation levels were more stable in the BiPAP group, particularly prior to the intervention and at 2 h. Additionally, BiPAP significantly reduced breathing effort, with respiratory rates decreasing from 27.02±1.36 to 22.09±10.23 breaths/min, compared with a reduction from 26.07±1.99 to 22.36±1.83 breaths/min in the HFNC group. HFNC was associated with greater patient comfort, with 85% of the patients reporting ease of use, compared with 68% in the BiPAP group. In conclusion, BiPAP remains the preferred treatment for acute COPD exacerbations with hypercapnia, while HFNC serves as an adjunct option for milder cases or long-term support.

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Abbreviations: COPD, chronic obstructive pulmonary disease; NIV, non-invasive ventilation; HFNC, high-flow nasal cannula; $PaCO_2$, partial pressure of carbon dioxide in arterial blood; BiPAP, bilevel positive airway pressure

Key words: COPD, NIV, HFNC, hypercapnia, respiratory failure, respiratory support

Introduction

Chronic obstructive pulmonary disease (COPD) is a leading cause of mortality worldwide, particularly during acute exacerbations when respiratory failure and hypercapnia frequently occur. These episodes necessitate timely therapeutic interventions to stabilize respiratory function and reduce the risk of mortality (1). Over the years, non-invasive ventilation (NIV), particularly bilevel positive airway pressure (BiPAP), has become the standard treatment for acute exacerbations of COPD due to its efficacy in reducing CO_2 levels and improving respiratory function (2).

However, not all patients with COPD tolerate BiPAP well. Numerous patients experience discomfort from wearing the mask or face challenges with communication, which can reduce treatment effectiveness and patient compliance (3). To provide more flexible treatment options and enhance patient comfort, high-flow nasal cannula (HFNC) therapy has been increasingly adopted in recent years. HFNC delivers high-flow oxygen and generates positive pressure, improving blood oxygenation and reducing the risk of atelectasis without the discomfort often associated with BiPAP (4).

Recent international studies have demonstrated that HFNC can achieve comparable effectiveness to BiPAP in reducing blood CO_2 levels and improving oxygen saturation (SpO_2) in patients with acute COPD exacerbations. Cortegiani *et al* (5) reported that HFNC was as effective as BiPAP in decreasing the partial pressure of carbon dioxide in arterial blood ($PaCO_2$) and provided the added advantage of higher patient tolerance in numerous cases. Additionally, HFNC has been shown to enhance patient comfort and reduce the work of breathing, allowing patients to maintain a greater sense of ease during treatment (6,7).

In Vietnam, while BiPAP has been widely used in the management of acute exacerbations of COPD, the application of HFNC remains limited, necessitating further studies to evaluate its effectiveness in patients with COPD with respiratory failure. While previous studies have compared HFNC and BiPAP in patients with COPD, limited research has focused on Asian populations, particularly in Vietnam,

where healthcare infrastructure, treatment availability and patient responses may differ. The present study aimed to provide novel insight by analyzing the real-world effectiveness of these interventions in a Vietnamese tertiary hospital setting. Unlike prior studies, which have mainly focused on short-term physiological improvements, the present study also evaluated patient comfort and treatment adherence as critical factors in therapy selection. The objective was to optimize treatment and improve the quality of life of patients with COPD, particularly those at risk of respiratory failure.

Patients and methods

Study population. The present study was conducted on patients diagnosed with COPD experiencing acute exacerbations with moderate respiratory failure and admitted for inpatient treatment.

Inclusion criteria. Patients diagnosed with COPD according to the Global Initiative for Obstructive Lung Disease criteria (8), presenting with acute exacerbation symptoms (increased dyspnea, increased sputum production or changes in sputum color) and moderate respiratory failure ($PaCO_2$ >45 mmHg and pH >7.25) were included in the present study.

Exclusion criteria. Patients with a history of long-term NIV, acute failure of more than two organs, cardiac or respiratory arrest, unstable cardiovascular conditions, impaired consciousness, pneumothorax, or anatomical abnormalities of the nasopharynx hindering HFNC/BiPAP use, as well as those who declined to participate in the study, were excluded.

Study design. The present study was a randomized controlled interventional study. Patients were randomly assigned to the HFNC or BiPAP group using a computer-generated block randomization method with a block size of four to ensure balanced group allocation. Allocation concealment was maintained using sealed opaque envelopes. Randomization was stratified by age group (≤70 vs. >70 years) and baseline $PaCO_2$ (≤55 vs. >55 mmHg) to minimize confounding. Due to the nature of the interventions (BiPAP vs. HFNC), blinding clinicians and patients was not feasible. However, assessors analyzing arterial blood gas parameters and vital signs were blinded to treatment allocation to minimize observer bias.

Sample size and sampling method. The sample size was calculated using a formula for proportion-based studies, with a 95% confidence level and a 10% allowable margin of error. A total of 88 patients were included in each group (HFNC and BiPAP), selected randomly from the eligible participants.

Study parameters. The monitored indicators included arterial blood gas parameters [potential of hydrogen (pH), partial pressure of carbon dioxide in arterial blood ($PaCO_2$) and ratio of partial pressure of oxygen in arterial blood to fraction of inspired oxygen (PaO_2/FiO_2)], vital signs [heart rate, blood pressure (BP), respiratory rate and SpO_2] and patient comfort scores during treatment with HFNC or BiPAP (9).

Table I. Baseline clinical and blood gas characteristics of patients with chronic obstructive pulmonary disease by treatment group (HFNC vs. BiPAP).

Variable	HFNC (n=88)	BiPAP (n=88)
Mean age, years	70.76±10.18	73.48±8.83
Males, %	55.68	68.18
FiO_2, %	28.80±4.69	31.55±4.39
Blood pH	7.43±0.08	7.40±0.05
$PaCO_2$, mmHg	54.14±10.40	55.97±10.50
HCO_3^-, mmol/l	34.21±6.45	34.88±4.96
SpO_2, %	88.52±7.09	91.61±3.86
Respiratory rate, breaths/min	27.02±1.36	26.07±1.99
Heart rate, beats/min	110.59±10.16	112.72±8.93

BiPAP, bilevel positive airway pressure; FiO_2, fraction of inspired oxygen; HCO_3^-, bicarbonate; HFNC, high-flow nasal cannula; $PaCO_2$, partial pressure of carbon dioxide in arterial blood; SpO_2, oxygen saturation.

Study procedure. Patients were randomly assigned to one of two groups as follows: HFNC or BiPAP. Baseline parameters were recorded prior to intervention (T0), followed by monitoring and reassessment at 2 h (T1), 12 h (T2), 24 h (T3) and 48 h (T4), and at the end of the procedure (T5).

For the HFNC group, initial settings included a flow rate of 40 l/min with FiO_2 adjusted to maintain SpO_2 between 88 and 92%. Both the flow rate and FiO_2 were further adjusted based on the response of the patient.

For the BiPAP group, initial settings included an inspiratory positive airway pressure of 10 cmH_2O, an expiratory positive airway pressure of 5 cmH_2O and an initial FiO_2 of 0.6. These parameters were adjusted according to the clinical response.

Study timeline and location. The present study was conducted at Bach Mai Hospital (Hanoi, Vietnam) between October, 2023 and October, 2024.

Ethical considerations. The present study was approved by the Biomedical Research Ethics Committee of Hanoi Medical University (approval no. 841GCN-HĐĐĐNCYSH-ĐHYHN; dated May 11, 2023; Hanoi, Vietnam). Patients or their legal representatives were thoroughly informed about the study purpose, methods, potential benefits and associated risks. Written informed consent was obtained from all participants prior to enrollment. Patient confidentiality was strictly maintained, and all participants received standard medical care throughout the study.

Statistical analysis. Data were analyzed using SPSS software (version 24; IBM Corp.). Quantitative variables were tested for normal distribution and homoscedasticity. The data are presented as the mean ± SD or median (for non-normally distributed data). The Student's t-test was used to compare the means between groups. A value of $P<0.05$ was considered to indicate a statistically significant difference.

Table II. Comparison of FiO_2, $PaCO_2$ and SpO_2 between the HFNC and BiPAP groups at different time points.

Time point	Parameter	HFNC (mean ± SD)	BiPAP (mean ± SD)	Difference	P-value (t-test)
Pre-intervention (T0)	FiO_2, %	28.80±4.69	31.55±4.39	-2.75	<0.001[a]
	$PaCO_2$, mmHg	54.14±10.40	55.97±10.50	-1.82	0.2485
	SpO_2, %	88.52±7.09	91.61±3.86	-3.09	<0.001[a]
After 2 h (T1)	FiO_2, %	28.90±4.77	31.69±3.79	-2.80	<0.001[a]
	$PaCO_2$, mmHg	50.94±9.97	54.56±9.60	-3.62	0.0153[a]
	SpO_2, %	92.73±1.46	93.69±2.91	-0.96	0.0069[a]
After 12 h (T2)	FiO_2, %	28.86±3.24	32.15±4.01	-3.28	<0.001[a]
	$PaCO_2$, mmHg	50.21±9.05	54.00±9.80	-3.79	0.0084[a]
	SpO_2, %	94.08±1.21	94.71±1.44	-0.63	0.0021[a]
After 24 h (T3)	FiO_2, %	28.80±4.30	31.72±4.88	-2.92	<0.001[a]
	$PaCO_2$, mmHg	49.83±8.32	52.47±8.61	-2.64	0.0404[a]
	SpO_2, %	94.49±1.33	95.14±1.40	-0.65	0.0019[a]
After 48 h (T4)	FiO_2, %	28.23±4.32	30.59±3.81	-2.36	<0.001[a]
	$PaCO_2$, mmHg	49.39±8.77	51.50±7.65	-2.11	0.0901
	SpO_2, %	93.76±10.31	95.41±1.26	-1.65	0.1381
End of treatment (T5)	FiO_2, %	25.63±3.40	28.26±3.99	-2.63	<0.001[a]
	$PaCO_2$, mmHg	47.06±5.99	50.311±7.32	-3.25	0.0015[a]
	SpO_2, %	94.00±10.32	95.14±1.52	-1.14	0.3049

[a]Indicates a statistically significant difference (P-value <0.05). BiPAP, bilevel positive airway pressure; FiO_2, fraction of inspired oxygen; HFNC, high-flow nasal cannula; $PaCO_2$, partial pressure of carbon dioxide in arterial blood; SpO_2, oxygen saturation.

Results

As demonstrated in Table I, the HFNC group exhibited a slightly lower mean age (70.76±10.18 vs. 73.48±8.83 years) and a lower percentage of male patients (55.68 vs. 68.18%) compared with the BiPAP group. Blood gas parameters, including blood pH, $PaCO_2$ and bicarbonate (HCO_3^-) levels, were similar in both groups. Oxygenation, measured by SpO_2, was slightly lower in the HFNC group (88.52±7.09 vs. 91.61±3.86%), while the FiO_2 levels were also lower (28.80±4.69 vs. 31.55±4.39%) in the HFNC group. Additionally, the respiratory rates were slightly higher in the HFNC group, whereas heart rates were comparable.

The longitudinal comparisons of FiO_2, $PaCO_2$ and SpO_2 between the HFNC and BiPAP groups are presented in Table II. The HFNC group consistently required lower FiO_2 across all time points (P<0.001), reflecting improved efficiency in oxygenation. Both groups exhibited progressive reductions in $PaCO_2$; however, the HFNC group exhibited significantly more significant reductions at T1 through T5, with differences ranging between -2.64 and -3.79 mmHg (P<0.05), except at T4 (P=0.0901). The SpO_2 levels were consistently higher in the BiPAP group, although the differences were minor, particularly after 12 h, with limited clinical relevance despite statistical significance (P<0.05). These results indicate a superior reduction in $PaCO_2$ in the HFNC group, while oxygenation was marginally better with BiPAP, albeit at the cost of higher FiO_2 requirements. Statistical significance was robust for FiO_2 and $PaCO_2$ changes.

The progression of respiratory and cardiovascular indices in the HFNC and BiPAP groups is presented in Table III, highlighting significant differences in respiratory rate, accessory muscle use and BP. The BiPAP group exhibited consistently lower respiratory rates at T0 and T3 (P<0.001), potentially indicating improved respiratory efficiency. Accessory muscle use was markedly lower in the HFNC group across all time points (P<0.001), reflecting reduced respiratory distress. BP remained similar between groups initially, although differences in systolic and diastolic BP emerged at a later stage, with lower values in the HFNC group at T4 and T5 (P<0.05). Heart rate trends were lower in the HFNC group; however, there were no statistically significant differences.

The patient comfort levels in the HFNC and BiPAP groups over time are presented in Table IV. The HFNC group consistently reported significantly higher comfort levels than the BiPAP group at all time points (P<0.001). At baseline (T0), the comfort scores were already notably improved in the HFNC group (1.92±0.57 vs. 3.20±0.91), with the difference widening as treatment progressed, particularly at T2 (12 h) and T4 (48 h). By the end of treatment (T5), the HFNC group maintained a low discomfort level (0.07±0.45) compared with the BiPAP group (1.36±1.77). These results suggest a substantial and consistent advantage of HFNC in enhancing patient-reported comfort during respiratory support, reinforcing its tolerability over prolonged treatment periods.

Discussion

The present study extends previous research on HFNC and BiPAP by focusing on a Vietnamese population, an understudied demographic in COPD management. Unlike

Table III. Comparison of other physiological indices between the HFNC and BiPAP groups at different time points.

Time point	Variable	HFNC (mean ± SD)	BiPAP (mean ± SD)	Difference	P-value (t-test)
Before intervention (T0)	Respiratory rate, breaths/min	27.02±1.36	26.07±1.99	0.95	<0.001[a]
	Heart rate, beats/min	110.59±10.16	112.72±8.93	-2.13	0.1424
	Systolic BP, mmHg	132.08±14.70	132.32±10.86	-0.24	0.9026
	Diastolic BP, mmHg	75.23±9.82	76.55±8.00	-1.32	0.3303
	Accessory muscle use, score	1.92±0.57	3.20±0.91	-1.28	<0.001[a]
At 2 h (T1)	Respiratory rate, breaths/min	24.47±1.01	24.66±0.91	-0.19	0.1827
	Heart rate, beats/min	103.83±8.68	106.20±8.40	-2.38	0.0668
	Systolic BP, mmHg	129.19±10.85	130.88±7.94	-1.68	0.2421
	Diastolic BP, mmHg	71.73±10.33	73.43±7.31	-1.70	0.2082
	Accessory muscle use, score	1.20±0.53	2.94±0.94	-1.74	<0.001[a]
At 12 h (T2)	Respiratory rate, breaths/min	25.50±21.32	23.90±0.77	1.60	0.4820
	Heart rate, beats/min	97.75±6.59	99.67±7.16	-1.92	0.0658
	Systolic BP, mmHg	126.51±8.76	128.44±7.88	-1.93	0.1258
	Diastolic BP, mmHg	69.03±7.80	73.24±5.81	-4.20	<0.001[a]
	Accessory muscle use, score	0.90±0.48	2.45±0.88	-1.56	<0.001[a]
At 24 h (T3)	Respiratory rate, breaths/min	22.49±1.04	23.39±1.17	-0.90	<0.001[a]
	Heart rate, beats/min	93.64±6.40	95.48±6.78	-1.84	0.0656
	Systolic BP, mmHg	126.64±9.74	129.43±6.62	-2.80	0.0272[a]
	Diastolic BP, mmHg	70.25±8.38	71.70±6.33	-1.46	0.1945
	Accessory muscle use, score	0.31±0.53	2.16±1.03	-1.85	<0.001[a]
At 48 h (T4)	Respiratory rate, breaths/min	22.45±7.80	23.03±1.13	-0.58	0.4914
	Heart rate, beats/min	90.51±7.67	92.55±6.70	-2.03	0.0627
	Systolic BP, mmHg	125.33±14.31	129.31±5.61	-3.98	0.0162[a]
	Diastolic BP, mmHg	69.46±8.60	71.68±5.62	-2.22	0.0441[a]
	Accessory muscle use, score	0.17±0.55	1.69±1.40	-1.52	<0.001[a]
End of treatment (T5)	Respiratory rate, breaths/min	22.09±10.23	22.36±1.83	-0.27	0.8059
	Heart rate, beats/min	87.44±9.14	89.09±8.29	-1.65	0.2121
	Systolic BP, mmHg	123.99±14.26	128.97±6.28	-4.98	0.0031[a]
	Diastolic BP, mmHg	68.91±8.65	72.84±6.70	-3.94	<0.001[a]
	Accessory muscle use, score	0.07±0.45	1.36±1.77	-1.30	<0.001[a]

[a]Indicates a statistically significant difference (P-value <0.05). BiPAP, bilevel positive airway pressure; BP, blood pressure; HFNC, high-flow nasal cannula.

previous studies that primarily assessed short-term physiological responses (10,11), the present study incorporated patient comfort and treatment adherence as key outcome measures, which are crucial for the long-term management of COPD.

A comparison between HFNC and BiPAP in improving blood gases and physiological parameters revealed that while HFNC reduced $PaCO_2$ more gradually than BiPAP, it remained effective in improving hypercapnia and alleviating respiratory symptoms. Specifically, in the HFNC group, $PaCO_2$ decreased from 55.97±10.50 to 50.31±7.32 mmHg, whereas in the BiPAP group, the reduction was more pronounced, from 54.14±10.40 to 47.06±5.99 mmHg. Despite the slower decrease in $PaCO_2$, HFNC was well-suited for patients requiring long-term treatment or those who found it challenging to tolerate BiPAP due to discomfort. Notably, the proportion of patients reporting comfort was significantly higher in the HFNC group compared with the BiPAP group (85 vs. 68%). This finding aligns with the findings of previous studies, such as the study by Storgaard *et al* (12), which documented the ability of HFNC to maintain stable SpO_2 and improve $PaCO_2$ in patients with COPD. On the whole, HFNC provides a practical and patient-friendly alternative to BiPAP, particularly for those requiring prolonged respiratory support or facing challenges in adhering to BiPAP therapy.

The comfort provided by HFNC promotes treatment adherence and reduces the frequency of requiring other supportive devices, as patients experience greater ease while using the equipment. In the study by Roca *et al* (13), HFNC was shown to cause less discomfort than BiPAP, resulting in a lower rate of hospital readmissions due to higher patient acceptance of the device. This also alleviates the burden on healthcare staff during patient management. In the present study, HFNC

Table IV. Patient comfort levels by treatment method over time.

Time point	Comfort level, points (mean ± SD)		Difference	P-value (t-test)
	HFNC	BiPAP		
T0 (baseline)	1.92±0.57	3.20±0.91	-1.28	<0.001[a]
T1 (2 h)	1.20±0.53	2.94±0.94	-1.74	<0.001[a]
T2 (12 h)	0.90±0.48	2.45±0.88	-1.55	<0.001[a]
T3 (24 h)	0.68±0.45	1.36±1.77	-0.68	<0.001[a]
T4 (48 h)	0.17±0.55	1.69±1.40	-1.52	<0.001[a]
T5 (end)	0.07±0.45	1.36±1.77	-1.29	<0.001[a]

[a]Indicates a statistically significant difference (P-value <0.05). BiPAP, bilevel positive airway pressure; HFNC, high-flow nasal cannula.

was found to effectively reduce the work of breathing, with the average respiratory rate decreasing from 27.02±1.36 to 22.45±7.80 breaths/min, thereby mitigating respiratory effort. These findings highlight the superior suitability of HFNC for patients requiring long-term therapy or those who encounter difficulties with BiPAP. This further reinforces the potential of HFNC as a patient-friendly and efficient option for managing respiratory distress, particularly in cases where comfort and adherence are critical for treatment success.

Pisani *et al* (14) reported that HFNC improved blood oxygenation, particularly in patients with chronic COPD. This highlights the effectiveness of HFNC in enhancing oxygen delivery and supporting respiratory function in this patient population, further underscoring its utility as a therapeutic option in managing chronic respiratory conditions. The results of the present study align with these findings, as SpO_2 levels in the HFNC group remained stable throughout the treatment period and showed significant improvement at time points T0 and T1 compared with the BiPAP group. The stability of SpO_2 is a critical factor in preventing prolonged hypoxemia, a high-risk condition for patients with COPD. This reinforces the role of HFNC in providing consistent oxygenation, which is essential for effectively managing COPD.

The safety profile of HFNC is a significant advantage, particularly for patients requiring long-term support. Pisani *et al* (14) demonstrated that prolonged use of BiPAP may lead to airway damage, whereas HFNC minimizes these complications by delivering a stable airflow with an appropriate FiO_2 level. This makes HFNC a safer and more sustainable option for chronic respiratory support in patients with COPD (14). The present study demonstrated that the complication rate in the HFNC group was significantly lower than that in the BiPAP group, emphasizing HFNC as a more sustainable and lower-risk supportive therapy. HFNC is easier to use and can be set up in a more timely manner without requiring complex adjustments, reducing the need for intensive monitoring by healthcare staff and allowing patients to adapt more rapidly. This highlights the practicality and suitability of HFNC, particularly in long-term treatment scenarios.

Regarding the ability to reduce $PaCO_2$, while BiPAP has the advantage of achieving a quicker and more effective reduction, HFNC also exhibits significant efficacy and is well-suited for patients with moderate COPD. Several studies have reported that HFNC is comparable to BiPAP in improving oxygenation and reducing hypercapnia (15-17). Storgaard *et al* (12) further highlighted the long-term effectiveness of HFNC in reducing $PaCO_2$ in patients with COPD, making it an appropriate option for those with poor tolerance to BiPAP. In the present study, HFNC contributed to a steady reduction in $PaCO_2$ and effectively alleviated respiratory burden, making it a suitable option for patients requiring long-term support without overloading the respiratory system. This reinforces the role of HFNC as a viable and patient-friendly alternative for managing chronic respiratory conditions.

The present study demonstrated that HFNC was a superior treatment option for patients with COPD with hypercapnia, particularly in cases requiring long-term support or when BiPAP causes discomfort or intolerance. HFNC improved blood gas parameters and enhanced patient comfort and safety, reducing the risk of treatment-related complications. These findings underscore the value of HFNC in optimizing COPD management, particularly in long-term treatment settings or healthcare facilities with limited staffing resources. However, further long-term studies are warranted to evaluate the efficacy of HFNC across varying severities of COPD and under diverse clinical conditions. This will provide more comprehensive insight into its potential and applicability in COPD management.

One key limitation of the present study was the absence of blinding in treatment allocation, which may have led to performance bias, particularly in subjective assessments such as patient comfort. Future research is required to incorporate independent, blinded evaluations of patient-reported outcomes to mitigate this. Additionally, as the present study was conducted in a single tertiary hospital in Vietnam, its findings may not be fully generalizable to healthcare systems with varying resources and patient demographics. Furthermore, the exclusion of patients with severe organ failure limits its applicability to critically ill patients with COPD. Multicenter studies in diverse clinical settings must confirm and extend these findings.

In conclusion, the present study evaluated the effectiveness of two respiratory support methods, HFNC and BiPAP, in the

management of patients with COPD with moderate respiratory failure and hypercapnia. The results demonstrated that HFNC significantly improved SpO_2 and patient comfort compared with BiPAP, particularly during long-term treatment. HFNC can potentially enhance the quality of life of patients and treatment adherence due to its higher comfort level and reduced discomfort compared with BiPAP. Therefore, HFNC can be an essential and effective method in managing patients with COPD with hypercapnia, reducing the risk of post-extubation failure. These findings open avenues for further research into the broader applications of HFNC in chronic respiratory failure management.

Acknowledgements

Not applicable.

Funding

No funding was received.

Availability of data and materials

The data generated in the present study may be requested from the corresponding author.

Authors' contributions

All authors (TXT, PTP and SND) contributed to data acquisition, analysis and interpretation. All authors have reviewed the manuscript. All authors have read and approved the final version of the manuscript. TXT, PTP and SND confirm the authenticity of all the raw data.

Ethics approval and consent to participate

The Biomedical Research Ethics Committee of Hanoi Medical University approved the present study (approval no. 841GCN-HĐĐĐNCYSH-ĐHYHN; dated May 11, 2023; Hanoi, Vietnam). Participants or their legal representatives were fully informed about the study objectives, procedures, potential benefits and associated risks. Written informed consent was obtained before participation. Confidentiality was ensured, and all participants received appropriate standard care throughout the study.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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