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Is high-flow nasal oxygen as effective as non-invasive ventilation in acute cardiogenic pulmonary Edema?

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ABSTRACT

Objective: Acute cardiogenic pulmonary edema (ACPE) is a significant cause of emergency department (ED) visits due to dyspnea. Non-invasive ventilation (NIV) is currently the recommended first-line treatment for respiratory failure secondary to ACPE. The aim of this study is to compare the effectiveness of high-flow nasal cannula (HFNC) and NIV in improving respiratory rate (RR) and other clinical outcomes in adult patients presenting to the ED with ACPE.

Methods: This study was conducted as a prospective, randomized, single-center, superiority trial with a 1:1 parallel-group allocation. All consecutive adult patients (≥18 years) who presented to our emergency department between July 2023 and April 2024 were screened for eligibility. Those meeting the inclusion and exclusion criteria were enrolled and randomly assigned in a 1:1 ratio to receive either high-flow nasal cannula (HFNC) or non-invasive ventilation (NIV) therapy. All analyses were performed according to the intention-to-treat (ITT) principle, with per-protocol (PP) analyses also presented for comparison.

Results: During the study period, 1376 patients were screened, and 178 were randomized. Baseline characteristics, including initial respiratory rates—34 (IQR, 30–38) breaths/min in the HFNC group and 33.5 (IQR, 30–37) in the NIV group—were similar between groups. In both intention-to-treat and per-protocol analyses, the change in respiratory rate at 120 min was similar across groups. No significant differences were observed in respiratory rates or their changes at 30, 60, and 120 min. Likewise, changes in other vital signs, arterial blood gas parameters, and dyspnea scores during follow-up did not differ significantly between the groups.

Conclusion: In this study, no difference was found between HFNC and NIV in reducing the symptoms and signs of respiratory failure with oxygen-ventilation support in patients with acute cardiogenic pulmonary edema. Considering that HFNC provides better patient tolerability and comfort, it may be considered a viable alternative to NIV in this specific patient population.

1. Introduction

Acute cardiogenic pulmonary edema (ACPE) is an important cause of emergency department (ED) visits for dyspnea [1-4]. The association of hypoxia and hypercarbia is common in these patients and significantly affects outcome [4,5]. Primary management includes correction of reversible causes, intravenous diuretics and nitrates, as well as oxygen and ventilatory support [1,6-8]. Conventional approaches to oxygen and ventilation therapy for these patients include nasal cannula or face mask oxygen, noninvasive ventilation, and intubation [8-10].

Non-invasive ventilation (NIV) is the recommended first-line treatment for respiratory failure caused by ACPE [1,2]. Positive pressure decreases alveolar edema and left ventricular afterload, improving cardiac output and reducing respiratory workload [6,11]. Additionally, pressure support enhances gas exchange, facilitating the removal of accumulated carbon dioxide (CO_2) [12-14]. This contributes to reduced intubation rates and improved in-hospital mortality [2,6,15,16]. However, NIV is poorly tolerated in some patients and may lead to treatment failure and poor outcome [6,17].

High-flow nasal cannula (HFNC) is an oxygen-ventilation therapy approach that delivers heated and humidified oxygenated air at up to 60 L/min [18]. It provides a fraction of inspired oxygen (FiO_2) support ranging from 21 % to 100 % [19]. Air flow levels both increase CO_2 clearance by washing dead spaces and support the decrease in

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respiratory workload caused by cardiogenic pulmonary edema with the positive air pressure it creates [4,9]. HFNC is more physiological and can be better tolerated by patients, as it allows patients to talk and eat [14,18].

The expected outcomes of these two treatments include improved oxygenation, normalization of blood gas parameters with ventilatory support, regression of respiratory distress symptoms, and a decrease in respiratory rate as a sign of clinical improvement [2,9]. Consequently, the respiratory rate (RR) emerges as a pertinent parameter for assessing the feasibility and efficacy of HFNC and NIV in the treatment of ACPE-related acute respiratory failure [20].

Although the benefits of HFNC compared to conventional oxygen therapy in patients with acute heart failure (AHF) have been reported in the literature, there are limited studies comparing the effectiveness of HFNC and NIV in treating ACPE [8-10].

Therefore, the aim of this study is to compare the effectiveness of HFNC and NIV in improving RR and other clinical outcomes in adult patients presenting to the ED with ACPE.

2. Materials and methods

2.1. Design and setting

This was a prospective, randomized, single-center superiority trial with a 1:1 parallel-group design, conducted in an academic emergency department with an annual patient volume of 220,000. Approval was obtained from the local ethics committee, and the institutional review board (approval no. 09.2023.813, Marmara University Faculty of Medicine Clinical Research Ethics Committee).

2.2. Study population, eligibility, inclusion, and exclusion criteria

All consecutive adult patients (aged ≥18 years) presenting to our emergency department between July 2023 and April 2024 were screened for inclusion based on the following criteria. Patients were eligible if they met all of the following:

(i) Clinical suspicion of ACPE by the attending emergency physician at presentation, supported by: (a) Acute onset dyspnea without a history suggesting pulmonary aspiration or infection, (b) Bilateral rales on physical examination, (c) radiographic or sonographic evidence of pulmonary congestion, including pulmonary venous congestion, cardiomegaly, interstitial edema on chest radiography, and/or sonographic interstitial syndrome (multiple, bilateral, and homogeneously distributed B-lines on lung ultrasound) [21];

(ii) Requirement of ventilatory support with either NIV or HFNC, defined by all of the following: (a) respiratory rate (RR) >24 breaths/min, (b) pulse oximetry (SpO_2) <92 % on room air, (c) increased work of breathing (WOB; based on the use of accessory respiratory muscles or paradoxical abdominal breathing),

(iii) provision of informed consent by the patient, a relative, or a legal guardian.

Exclusion criteria were as follows: (i) Patients requiring immediate endotracheal intubation at presentation, (ii) Hemodynamically unstable patients, defined by a mean arterial pressure of 65 mmHg or below, or requiring vasopressor support, (iii) Patients with a Glasgow Coma Scale (GCS) of 13 or below, (iv) Patients with contraindications to use of NIV or HFNC [22], (v) Patients with ST elevation myocardial infarction, (vi) Patients with end-stage renal disease, (vii) Pregnant patients.

2.3. Randomization and allocation concealment

Patients who met the inclusion/exclusion criteria were enrolled and randomly assigned in a 1:1 ratio to receive either HFNC or NIV therapy. Randomization was performed using a computer-generated sequence with blocks of six to ensure a balanced allocation of groups. The allocation sequence of patients was concealed using consecutively numbered and sealed envelopes. Each patient received the assigned intervention for at least two hours.

2.4. Masking

Due to the nature of the intervention, blinding of the attending physician, nurses, investigators, and participants was not possible. However, outcome assessors and data analysts were masked to group allocation to minimize bias.

2.5. Data collection

All patients were evaluated by the attending emergency physicians at presentation to the ED for study inclusion and were then randomized to the study arms. Attending physicians and nurses recorded the baseline (0-min) and following (30-min, 60-min and 120-min) clinical parameters and vital signs of all patients in the hospital information system and study data collection charts. An arterial blood gas (ABG) sample was then obtained, and the assigned oxygenation strategy was initiated.

2.6. Interventions

HFNC was administered with large or medium bi-nasal tips using an Airvo2→ system (HFNC system/ Fisher&Paykel Healthcare). The flow was initially set to 60 L/min, the temperature to 31 °C, and FIO_2 was titrated to maintain a SpO_2 of at least 92 %. The flow, FIO_2 and temperature were adjusted according to the patient's tolerance and clinical response.

NIV was administered through an oronasal mask in continuous positive airway pressure (CPAP) mode using a specialized device (Astral 150/Resmed). Initial settings included a positive end-expiratory pressure (PEEP) of 5–10 cm H_2O, with FiO_2 titrated to maintain an $SpO_2 \geq 92$ %.

HFNC and NIV were continued for at least two hours unless clinical deterioration required earlier additional intervention, such as intubation. The protocol was to switch to a nasal cannula if clinical treatment endpoints were achieved (RR < 24 breaths/min, SpO_2 > 92 % and decreased WOB); however, all patients completed the 2-h treatment duration. If patients could not tolerate or clinically benefit from the assigned treatment with evidence of persistent or worsening respiratory symptoms (e.g., increased respiratory rate, elevated CO_2 levels, decreased SpO_2), a switch to alternative oxygen-ventilation methods was allowed. All patients received standard medical treatment for ACPE, including intravenous diuretics and nitrate derivatives according to established guidelines.

Modified Borg Dyspnea Scale (MBDS) was used to measure patients' dyspnea levels. MBDS is a scale ranging from 0 to 10 that can provide quick and simple information about patients' subjective state of shortness of breath [23]. It has also been found to have a strong positive correlation with other clinical parameters and dyspnea scales (Numerical Rating Scale and Dyspnea-12) [24]. A score change of one or more on the MBDS is considered to be clinically significant [23,24]. The attending physicians and nurses asked and charted the patients' MBDS ratings at baseline and at 120 min. No masking was also possible for the 2nd hour evaluation of the patients.

2.7. Outcomes

The primary outcome of our study was the comparison of the change in RR after 120 min of treatment, which was accepted as a surrogate endpoint of improvement in respiratory failure. The secondary outcomes included changes in vital signs (RR, SpO_2, SBP, DBP), blood gas parameters (pH, PCO_2, lactate), and MBDS within 120 min. All outcomes were assessed and reported using both per-protocol and intent-to-treat approaches.

2.8. Sample size estimation

At the time of study planning, no published studies had directly compared HFNC and NIV in the ED for the management of ACPE. Therefore, the sample size calculation was based on data derived from a previous study, which compared the efficacy of helmet-type NIV and HFNC in a similar clinical context [2]. To estimate the required sample size, we assumed a clinically meaningful difference in the primary outcome (change in RR at 2 h) between the two groups. Specifically, we hypothesized a mean RR reduction of 12 breaths/min in one group versus 10 breaths/min in the other, with a common standard deviation (SD) of 3.5 breaths/min. Based on these assumptions, considering loss to follow-ups and difference in the interventions, we estimated that a sample size of 90 patients per group (180 in total) would provide 90 % power to detect this difference using a two-sided test with a type I error rate (α) of 0.05. Sample size calculations were performed using the G*Power statistical software (Universität Düsseldorf, Germany) [25].

2.9. Statistical analysis

Analyses were conducted on an intention-to-treat (ITT) basis; per-protocol (PP) results were also reported for comparison. No data was missing for the primary outcome. The last observation carried forward (LOCF) approach was used for missing data in consecutive measurements. For the PP approach, patients who had been switched were evaluated in the group where they had been treated for a longer period. Baseline continuous variables were presented as mean (SD) or median (IQR), and categorical variables as n (%). The between-groups differences were calculated using the change of each group and reported as mean or median differences with 95 % confidence intervals (CI). We considered differences statistically significant if the 95 % CI did not cross zero. Effect sizes of differences and ratios were reported with their 95 % CI. The accepted Type 1 error in this study was 5 %. Graphs were produced using GraphPad Prism 10.4.1 (GraphPad Software Inc., San Diego, California). Statistical analyses were performed using Jamovi version 2.3.26 (The Jamovi Project, Australia).

3. Results

3.1. Characteristics of study subjects

During the recruitment period, we screened 1376 patients and randomized 178 patients in the study (see CONSORT flow diagram, Fig. 1).

Baseline characteristics were similar among the study groups (Table 1).

Twenty-nine patients had a treatment switch, with sixteen moved from HFNC to NIV and thirteen from NIV to HFNC. HFNC was switched to NIV at the discretion of the physician due to lack of efficacy in eleven patients and clinical impairment in five patients, while NIV was switched to HFNC due to discomfort in eight patients, lack of efficacy in four patients, and clinical impairment in one patient. Intubation occurred in two patients from the HFNC group and one patient from the NIV group.

Patients whose treatments switched were analyzed based on which treatment they received for a longer duration in PP. Therefore, six patients were assigned to the HFNC group and one patient to the NIV group in the PP analysis.

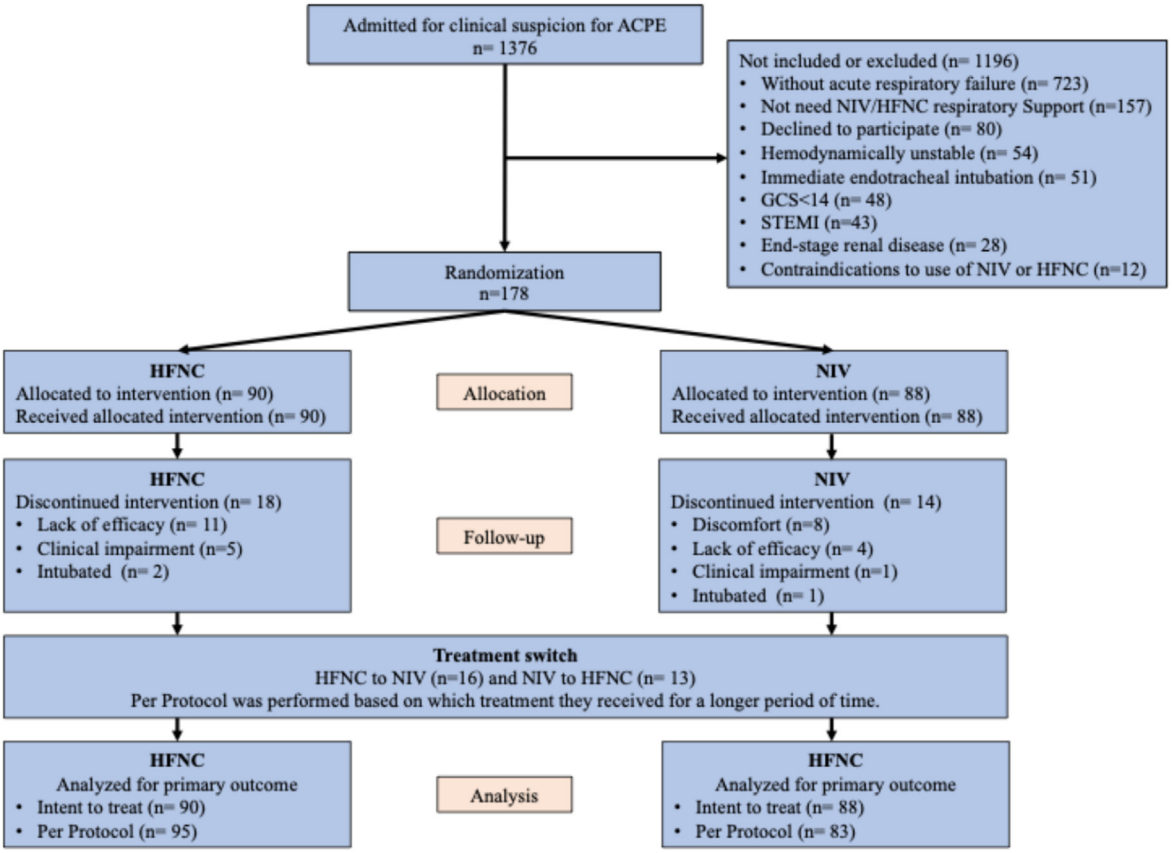

Fig. 1. Patient flowchart.

Table 1
Baseline Demographics and Clinical Characteristic.

Baseline Variables	Treatment Groups (ITT)		
	HFNC (n = 90)	NIV (*n* = 88)	Difference (95 % CI)
Age (years), median (IQR)	70.5 (64; 78)	68 (60; 75)	3 (−1–6)
Female sex, n (%)	49 (54.4)	51 (57.9)	0.04 (−0.11 to 0.18)
CPD, n (%)	35 (38.8)	36 (49.0)	0.02 (−0.13 to 0.17)
HT, n (%)	86 (95.5)	79 (89.7)	−0.21 (−0.48 to 0.05)
DM, n (%)	53 (58.8)	45 (51.1)	−0.08 (−0.23 to 0.07)
Active Cancer, (%)	13 (14.4)	9 (10.2)	−0.01 (−0.33 to 0.12)
RR, bpm, median (IQR)	34 (30; 38)	33.5 (30; 37)	0 (−0 to 2)
MAP, mmHg, median (IQR)	138 (122; 150)	143 (130; 156)	−5 (−11 to 1)
SaO_2, %, median (IQR)	89 (85; 91)	90 (85; 92)	−1 (−2 to 0)
MBDS, median (IQR)	7 (6; 9)	7 (6; 9)	0 (−0 to 1)
pH, median (IQR)	7.3 (7.27; 7.31)	7.29 (7.27; 7.31)	0 (−0.01 to 0.01)
*PCO_2, median (IQR)	54 (50; 61)	54 (47; 60)	2 (−2 to 5)
*Lactate, mmol/L, median (IQR)	3.2 (2.6; 4)	3.1 (2.4; 3.8)	0.1 (−0.2 to 0.5)
Creatinine, mg/dL, median (IQR)	1.2 (0.8; 1.5)	1.14 (0.8; 1.4)	0.09 (−0.07 to 0.2)
Troponin, ng/L, median (IQR)	19 (13; 41)	17.5 (11; 24)	2.63 (−0 to 6)

CPD, chronic pulmonary disease; DM, diabetes mellitus; HFNC, high-flow nasal cannula; HT, hypertension; IQR, interquartile range; ITT, Intent-to-Treat; MAP; mean arterial pressure; MBDS, modified borg dyspnea scale; NIV, non-invasive ventilation; PCO_2, partial carbon dioxide; RR, respiratory rate; SaO_2, oxygen saturation.
* Analyzed in 75 patients from both groups with interpretable arterial blood gas data.

3.2. Main results

The baseline respiratory rate in the HFNC and NIV groups was 34 (IQR, 30; 38) and 33.5 (IQR, 30; 37) breaths/min, respectively. In ITT and PP analyses, the mean changes at 120 min were similar for both groups (Table 2). There was no difference between respiratory rates and mean changes at the 30th, 60th, and 120th minutes (Fig. 2 and supplementary table 1).

In addition, changes in other vital and blood gas parameters recorded during the follow-up period and improvements in patients' dyspnea levels did not show any statistically significant differences between the groups (Table 2 and supplementary fig. 1).

4. Discussion

In this randomized study of patients presenting to the ED with ACPE, we compared NIV and HFNC with respect to improvement in respiratory distress symptoms and arterial blood gas parameters. At the end of the two-hour treatment period, there was no statistically significant difference between the NIV and HFNC groups in terms of respiratory rate reduction, the primary outcome. Similarly, dyspnea scores, assessed using a validated scale, did not differ between the two interventions.

There are several studies in the literature comparing HFNC and NIV in patients with acute hypoxemic or hypercapnic respiratory failure. These studies generally used in-hospital mortality, intubation rates, or blood gas parameters as endpoints [12,15,16]. The meta-analysis by Chaudhuri et al., published in 2023, evaluated 9 studies and found that HFNC and NIV may be similarly effective in reducing the need for intubation in patients with acute hypoxemic respiratory failure. However, it was emphasized that an effective evaluation according to the specific causes of the etiology of hypoxemic respiratory failure was not possible due to the small number of patients and data and the clinical and statistical heterogeneity of the studies included in the meta-analysis [15]. In the meta-analysis by Ovtcharenko et al. comparing these two ventilation methods in patients with hypercarbic respiratory failure, it was

Table 2
Comparison of outcomes in treated patients with NIV and HFNC.

Outcomes	Intent-to-Treat Analyses			Per-Protocol Analyses		
	HFNC (*n* = 90)	NIV (*n* = 88)	Difference (95 % CI)	HFNC (*n* = 95)	NIV (*n* = 83)	Difference (95 % CI)
Change in the respiratory rate (breaths/min)						
0th - 120th min, mean (±SD)	8 (4)	7.7 (3.3)	0.37 (−0.71 to 1.46)	8 (4)	7.8 (3.2)	0.21 (−0.88 to 1.30)
Change in the MAP (mmHg)						
0th - 120th min, mean (±SD)	34.8 (17.4)	38.4 (22.1)	−3.58 (−9.46 to 2.30)	34.6 (17.1)	38.9 (22.6)	−4.38 (−10.37 to 1.61)
Change in the SaO_2 (%)						
0th - 120th min, mean (±SD)	−8.1 (3.7)	−7.6 (5.4)	−0.46 (1.84 to 0.91)	−8.1 (3.7)	−7.6 (5.5)	−0.53 (−1.90 to 0.85)
Change in pH						
0th - 120th min, mean (±SD)	−0.04 (0.03)	−0.04 (0.03)	0 (−0.01 to 0.01)	−0.04 (0.03)	−0.04 (0.03)	0 (−0.01 to 0.01)
Change in PCO_2 (mmHg)						
0th - 120th min, mean (±SD)	[a]9.3 (6.2)	[a]9.3 (5.8)	−0.01 (−1.94 to 1.91)	[b]8.9 (6.6)	[c]9.7 (5.2)	−0.79 (−2.72 to 1.13)
Change in the Lactate (mmol/L)						
0th - 120th min, mean (±SD)	[a]1.1 (0.8)	[a]1 (1)	0.14 (−0.14 to 0.42)	[b]1.1 (0.8)	[c]1 (0.9)	0.09 (−0.19 to 0.37)
Change in the MBDS						
0th - 120th min, mean (±SD)	[a]3.1 (1.7)	[a]3.2 (1.3)	−0.13 (−0.59 to 0.33)	[b]3.1 (1.7)	[c]3.3 (1.3)	−0.19 (−0.65 to 0.27)
Hospitalization, n (%)	71 (78.8)	72 (81.8)	0.05 (−0.14 to 0.23)	76 (80.0)	67 (80.7)	0.01 (−0.17 to 0.20)

SD, standard deviation; CI, confidence interval; HFNC, high-flow nasal cannula; IQR, interquartile range; MAP, mean arterial pressure; MBDS, modified Borg dyspnea scale; NIV, non-invasive ventilation; PCO_2, partial carbon dioxide; SaO_2, oxygen saturation.
[a] Analyzed in 75 patients with interpretable arterial blood gas data.
[b] Analyzed in 79 patients with interpretable arterial blood gas data.
[c] Analyzed in 71 patients with interpretable arterial blood gas data.

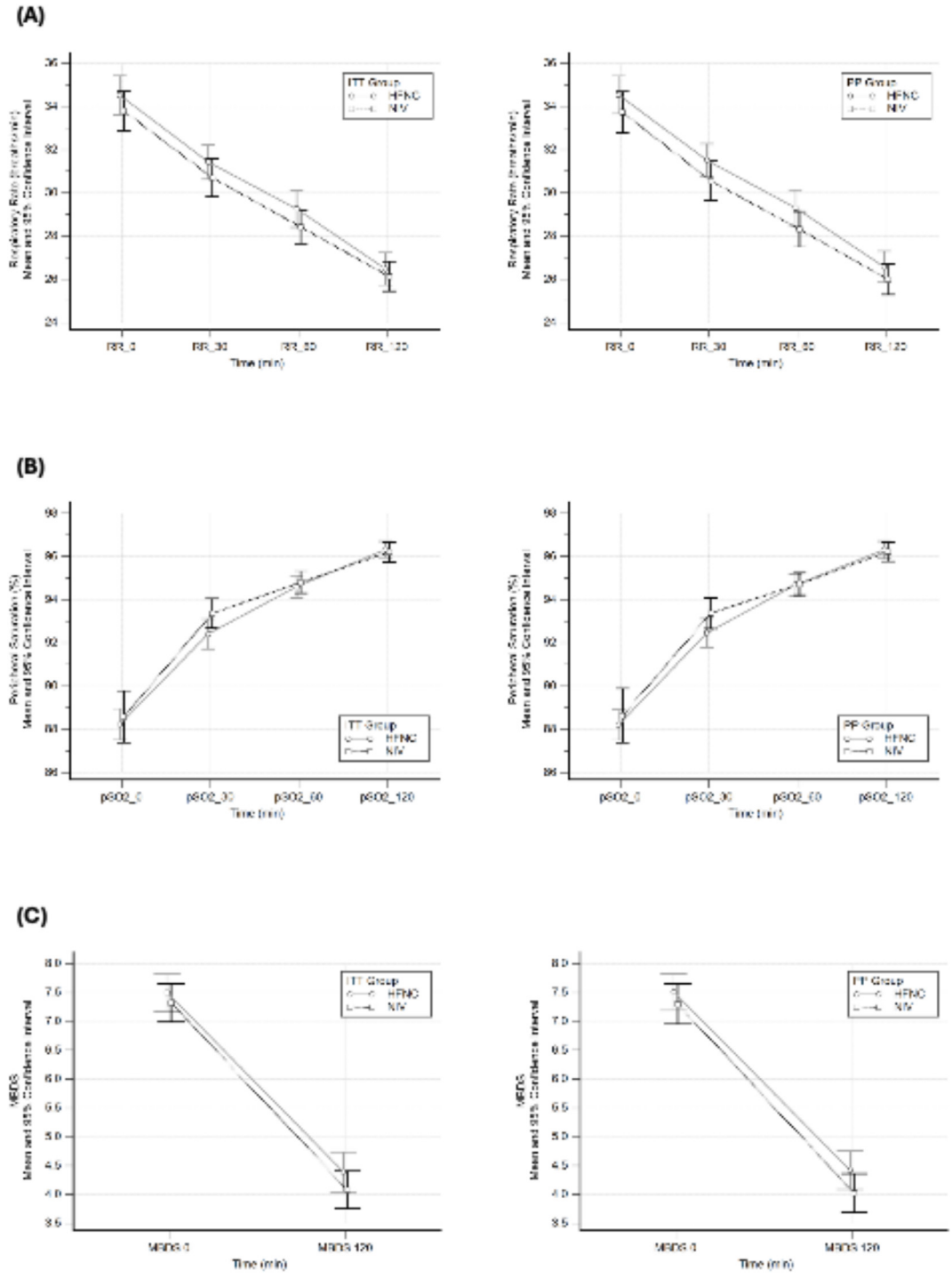

Fig. 2. Respiratory rate at time points within 120th minutes after initiation of oxygen-ventilation support.

mentioned that the evidence was insufficient to determine whether HFNC could be an alternative to NIV, and again the heterogeneity of the study populations was mentioned [12].

Two similar studies comparing HFNC and NIV in patients with ACPE reported contradictory results. In the study conducted by Osman et al., NIV performed better than HFNC in terms of changes in respiratory rate and improvement on the dyspnea scale; in contrast, in the study by Marjanovic et al., no statistically significant difference was observed between the groups regarding these parameters, and HFNC provided better comfort than NIV in this patient group [2,9]. This may be due to the helmet-type CPAP utilized by Osman et al. in their study, which results in reduced air leakage, not affected by facial features and is more comfortable compared to oro-nasal CPAP. However, it should be kept in mind that helmet-type CPAP also has disadvantages, and ora-nasal CPAP is still used in many EDs [17]. In our study, we found that HFNC and NIV provided similar benefits in improving these two parameters in patients with ACPE. In addition, there was no significant difference in blood gas pH and lactate levels between HFNC and NIV-treated patients at baseline and after treatment. These results suggest that HFNC improves both oxygenation and ventilation at least as well as NIV.

A recent meta-analysis by Marjanovic et al. compared HFNC and NIV for treatment failure in patients treated for respiratory failure due to acute heart failure and showed that HFNC was not associated with a higher risk of treatment failure in the initial management of patients

[10]. In our own study, we observed more patients to have treatment switches in the HFNC group, but this did not result in a statistical difference in either ITT or PP analysis between the two groups. Especially in patients treated with HFNC, it is necessary to keep the mouth closed during treatment in order to generate effective PEEP with airflow and to wash the dead spaces of CO_2. Furthermore, even when applied correctly, HFNC cannot generate the same level of PEEP as NIV [15]. This may explain the lack of efficacy and clinical deterioration observed in the HFNC group. Nonetheless, there are also some challenges associated with the use of NIV. As in the patients in our study, tolerance is more difficult, and anatomical differences on the face and mask selections can cause air leaks. This situation reduces the effectiveness of NIV.

4.1. Limitations

This study was conducted at a single tertiary care center in Turkey, which may limit the generalizability of the findings to other populations or practice settings. Future multicenter trials involving diverse geographic and demographic populations are warranted to account for potential ethnic, genetic, or sociocultural differences that may influence the response to noninvasive respiratory support in acute cardiogenic pulmonary edema (ACPE).

Second, although both study arms followed a standardized treatment protocol, there may have been variability in the use and timing of adjunctive therapies such as diuretics and vasodilators (e.g., nitrates), which could have impacted the resolution of pulmonary edema and confounded the observed effects of the respiratory support modalities. Third, due to the nature of the interventions, blinding of treating clinicians, patients, and bedside staff was not feasible, which introduces a risk of performance and detection bias. However, outcome assessors remained blinded to group allocation until the completion of data entry and analysis to reduce potential bias in outcome assessment. Nevertheless, awareness of being observed in a clinical trial (Hawthorne effect) may have influenced provider behavior or patient adherence, potentially improving care beyond routine standards and limiting external validity.

Fourth, the primary outcome was assessed at two hours; this short observation window may not fully capture the trajectory of clinical improvement or deterioration. It is possible that additional changes in respiratory status or escalation of care occurred after the follow-up period, including intubation, ICU admission, hospital length of stay, or mortality -none of which were assessed in this study.

Fifth, we did not collect long-term outcome data such as rehospitalization, need for mechanical ventilation, or 30-day mortality. Future studies should incorporate these endpoints to better evaluate the sustained impact of HFNC and NIV in the management of ACPE.

Finally, the last two participants appointed to receive NIV per the randomization list were excluded from the study due to the depletion of ventilator sets necessary for NIV administration in our hospital. As a result, the NIV group was included in the analysis with two missing patients.

5. Conclusion

In conclusion, despite a more severe patient population compared to patients in previous studies, no difference was found between HFNC and NIV in reducing the symptoms and signs of respiratory failure, with oxygen-ventilation support in patients with acute cardiogenic pulmonary edema. Considering that HFNC provides better patient tolerability and comfort, it can be considered as an alternative to NIV in this specific patient population.

CRediT authorship contribution statement

Erhan Altunbas: Writing – review & editing, Writing – original draft, Validation, Resources, Project administration, Methodology, Investigation, Data curation, Conceptualization. **Nurseli Bayram:** Writing – review & editing, Writing – original draft, Validation, Supervision, Software, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. **Emir Unal:** Writing – review & editing, Software, Methodology, Formal analysis, Data curation, Conceptualization. **Cigdem Ozpolat:** Writing – review & editing, Software, Methodology, Formal analysis, Data curation. **Sinan Karacabey:** Writing – review & editing, Validation, Supervision, Project administration, Methodology, Conceptualization. **Haldun Akoglu:** Formal analysis, Methodology, Software, Supervision, Visualization, Writing – review & editing. **Arzu Denizbasi:** Writing – review & editing, Validation, Supervision, Project administration, Methodology, Conceptualization.

Ethical approval

Marmara University Faculty of Medicine Clinical Research Ethics Committee approved on 02.08.2023 with protocol code 09.2023.813.

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Declaration of competing interest

None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ajem.2025.08.023.

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