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A Comparative Study between High Flow Nasal Cannula and The Standard Continuous Positive Airway Pressure Ventilation in Preventing Post-Extubation Respiratory Failure in Patients with Chronic Obstructive Pulmonary Disease Exacerbation

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Abstract:

Background: Chronic obstructive pulmonary disease (COPD) exacerbations often lead to respiratory failure, with post-extubation respiratory failure (PERF) being a major concern. Non-invasive ventilation methods such as high-flow nasal oxygen (HFNO) and continuous positive airway pressure (CPAP) improve oxygenation and reduce re-intubation risk, yet comparative research post-extubation in COPD is limited. **Aim:** To assess the effectiveness of HFNO and CPAP in preventing PERF and reintubation in COPD cases after mechanical ventilation (MV) weaning. Secondary goals included ICU and hospital stay duration and ICU mortality. **Methods:** This randomized controlled study was conducted at Benha University Hospitals' Critical Care Department from November 1st, 2022, to October 31st, 2023. It involved COPD exacerbation cases with respiratory failure weaned from MV. After meeting criteria and giving consent, patients were randomized into two groups: GROUP I (30 received HFNO for 24h post-extubation) and GROUP II (30 received CPAP for the same period). **Results:** The HFNO group showed greater effectiveness in preventing PERF, though mortality, reintubation rates, and ICU stay were similar between groups. PERF was lower in the HFNO group (8%) vs. CPAP group (11%). Reintubation rates: 20% for HFNO vs. 23.3% for CPAP. **Conclusion:** HFNO was linked to a reduced reintubation rate after extubation compared to CPAP. Patients managed with HFNO also had higher PaO_2 two hours post-extubation. Hospital stay and mortality were comparable. HFNO helped reduce reintubation in COPD patients with prior MV >72h. Those weaned with HFNO also showed improved PaO_2, lower respiratory rate, and higher mean blood pressure during the 24h observation.

Keywords: chronic obstructive pulmonary disease, continuous positive airway pressure, High flow nasal cannula, Respiratory failure.

Introduction

Chronic Obstructive Pulmonary Disease (COPD) exacerbations frequently necessitate mechanical ventilation (MV) for the management of acute respiratory failure (ARF). Following extubation, these cases are at an increased risk of respiratory deterioration, which may result in reintubation and heightened morbidity [(1)]. Conventionally, noninvasive ventilation (NIV), including Continuous Positive Airway Pressure (CPAP), has been employed to mitigate this risk [(2)]. However, High-Flow Nasal Cannula (HFNO) oxygen therapy has recently gained attention as a viable alternative [(3)].

HFNO is able to supply oxygen that is heated and humidified at increased flow rates, which improves oxygenation and reduces the amount of work required for respiration. In cases with COPD), its usage after extubation has increased, indicating that it has the potential to reduce the risk of reintubation and post-extubation respiratory failure (PERF). HFNO has been shown to offer results that are equivalent to those of NIV in term of avoiding reintubation and improving respiratory function, according to investigations [(4)].

Furthermore, HFNO has proven more effective than conventional oxygen therapy in reducing reintubation rates, with performance similar to NIV. Although mortality rates have remained comparable among HFNO, NIV, and conventional oxygen therapy, HFNO continues to be a promising therapeutic option [(5)].

This suggests that HFNO could serve as an effective option alongside NIV in reducing the risk of PERF in COPD cases. The effectiveness of HFNO compared to standard CPAP is still an area under investigation, and further research is needed to develop clear guidelines and improve case outcomes [(6)].

Therefore, this research was conducted to compare HFNO therapy with non-invasive ventilation using CPAP in preventing PERF and reintubation in cases with acute COPD exacerbation after weaning from MV. Secondary objectives included assessing the duration of intensive care unit (ICU) and hospital stays, along with ICU mortality in these cases.

Patients and methods

This prospective randomized controlled research was done in the Critical Care Department at Benha University Hospitals and included 60 patients admitted with acute exacerbation of COPD and ARF who were successfully weaned from invasive MV between November 1st, 2022, and October 31st, 2023. Only cases who met the inclusion criteria and provided consent were enrolled in the research. The inclusion criteria comprised individuals with acute exacerbation of COPD and ARF (PaO_2/FiO_2 ratio ≤ 300 or $PaCO_2 \geq 50$ mm Hg at intubation) who were successfully weaned from invasive MV according to the ICU weaning protocol, as determined by the treating physician. s less than 18 years of age, pregnancy, facial trauma or deformity, MV for less than 72 h, congestive heart failure, renal failure, hepatic failure, or neuromuscular diseases were excluded. The study received ethical clearance from the Scientific Research Ethics Committee (MD11-8-2022) at Benha University Hospitals.

Successfully extubated cases were allocated to either Group I or Group II in a consecutive manner using random assignment. In Group I, there were thirty cases who were given HFNO treatment for a period of 24h after they had been extubated. The initial oxygen flow rate was set between 20- and 30-liters perm, followed by complete humidification at a temperature of 34 to 36 degrees Celsius. The inspired oxygen fraction was modified on a frequent basis in order to maintain a target SpO_2 level that was more than 92%. Immediately before to extubation, the treatment began with a HFNO flow rate of 10 L/min. This rate was gradually increased to 30 L/min, and then

modifications of 5 L/min were made depending on the case's tolerance. In order to maintain the oxygen saturation levels at the desired level, high-flow treatment was stopped after 24h, and cases were switched to conventional oxygen therapy if it was deemed essential.

Cases in Group II received CPAP via non-invasive ventilation for a period of 24h after extubation. Additionally, a silicone full-face mask, which was available in both medium and large sizes, was used in conjunction with a Dräger Savina ventilator. The head of the bed was raised to 45 degrees while the mask was carefully placed over the case's face in order to reduce the likelihood of the case aspirating anything.

Thereafter, the mask was secured and adjusted in order to guarantee the case's comfort and ensure that it was in sync with the ventilator. CPAP was provided in a mode that included a pressure support (PS) of 7-10 cmH2O, a positive end-expiratory pressure (PEEP) of 5-7 cmH2O, and a FiO2 beginning at 0.3. The FiO2 was adjusted to ensure that the SaO2 level remained more than 92% and the PaO2 level remained at or above 60 mmHg. In a ratio of two to four, oxygen was administered using nasal cannulas in alternating fashion for a period of 24h. In cases where hypoventilation was seen, namely when the PaCO2 level was equal to or greater than 50 mm Hg, the pressure was raised (up to a maximum of 18-20 cmH2O) until the hypoventilation improved. Cases who required non-invasive ventilation for more than 24h were not included in the research.

The subsequent data was collected for all cases: demographic information (including age and gender), duration of MV prior to extubation. Each case in both groups underwent clinical assessments at various time points (15m, 2 h, 6, 12, and 24 h post-extubation). Clinical data included heart rate (HR), mean arterial blood pressure (MAP), and arterial blood gases (ABG), which were assessed at each time point. The ABG parameters recorded included pH, SaO2, PaO2, PaCO2, and HCO3.

The primary outcome of this research was post-extubation failure, defined as the need for reintubation and resumption of invasive MV. Reintubation within 48 h of extubation was classified as weaning failure. The decision to reintubate was made by the ICU physician based on persistent presence of one or more of the following: systolic arterial pressure ≥180 mm Hg or ≤90 mm Hg, HR ≥140 bpm, life-threatening arrhythmias, decreased consciousness or severe agitation requiring sedation, respiratory rate ≥30 bpm, PaO2 ≤60 mm Hg or SaO2 ≤90% on FiO2 >50%, PaCO2 ≥50 mm Hg, pH <7.2, or difficulty clearing secretions. Secondary outcomes included ICU and hospital length of stay, and ICU mortality, monitored throughout the research.

Code Number: MD11-8-2022

Data and statistical analysis

The IBM SPSS Statistics program, version 25.0(IBM©, Armonk, NY, USA), was used in order to carry out the analysis of the data. The normality of the data was evaluated with the use of the Kolmogorov-Smirnov test. In the case of parametric data, descriptive statistics covered the mean and standard deviation, and in the case of non-parametric data, the median, range, and frequency were used to describe the information. When doing analytical statistics, the student's t-test was used to compare the means of two groups, the Mann-Whitney U test was utilized to analyze non-parametric variables, and the Kruskal-Wallis test was utilized to analyze more than two non-parametric variables concurrently. For the purpose of determining the nature of the correlations that exist between qualitative variables, the Chi-square and Fisher methods were used. A statistically significant p-value was deemed to be less than or equal to 0.05 [(7)].

Results

Clinical and socio-demographic features of the participants:

The research enrolled 60 ICU cases who required MV (orotracheal intubation) for over 72 h during the one-year period. The HFNO and NIV groups were comparable regarding age, sex, comorbidities, or MV duration**. (Table 1).**

Arterial blood gases among research groups:

The mean PH levels exhibited no significant variation between the groups at 15m, 6 h, and 24 h after extubation. However, a notable decline was detected in the NIV group than in the HFNO at the 2-hour and 12-hour marks. **(Table 2).**

Vital signs among research groups

BP remained comparable between the groups at 15m, and 2, 6, and 24 h post-extubation, but at the 12-hour mark, the mean BP was significantly lower in the NIV group than in HFNO. HR exhibited no noticeable variation between the groups across all measured time points. Respiratory rate (RR) was also similar at 15m, 2 h, 6 h, and 12 h post-extubation; however, at 24 h, it was significantly elevated in the NIV group compared to HFNO. **(Table 3).**

Reintubation in both research groups:

In our research, weaning failure and reintubation with the resumption of invasive MV were considered the primary outcomes. Reintubation was primarily attributed to cardiorespiratory arrest, agitation, inability to clear secretions, hemodynamic impairment and persistent PERF.

The reintubation rate was comparable between the HFNO group (20%) and the NIV group (23.3%).

Post-extubation Respiratory failure

Following extubation, the HFNO group exhibited a significant lower incidence of respiratory failure (8) compared to the NIV group (11) **(Table 4).**

Table 1: General characteristics of the enrolled cases

	Measure	**GroupI (**HFNO) **(N=30)**	**Group II (**NIV) **(N=30)**	P
Age (years)	**Mean±SD**	54. 2±6. 1	54. 5±5. 0	0.130
Sex	**Male**	21 (65. 0%)	20 (62. 5%)	0.645
	Feamle	9 (35. 0%)	10 (37. 5%)	
Comorbidities	**Smoking**	18 (60. 0%)	20 (62. 5%)	1.0
	DM	21 (70. 0%)	25 (85. 0%)	0.824
	HTN	19 (65. 0%)	21 (70. 0%)	0.696
	IHD	20(67. 5%)	22.5 (75. 0%)	1.0
	CLD	1 (2. 5%)	2 (5. 0%)	0.703
MV Duration (days)	**Mean±SD**	4. 7±0. 9	4. 5±0. 7	0.224

DM: Diabetes mellitus, HTN: Hypertension, CLD: Chronic liver disease, IHD: Ischemic Heart Disease, MV: mechanical ventilation, Mean ± SD= Mean ± standard Deviation.

Table 2: Comparison between the two groups as regard Mean Arterial PO2

Time	**Mean PH**		
	G1 HFNO	**G2 NIV**	**P**
Pre	7.46 ± 0.05	7.44 ± 0.66	0.130
15 min post ext.	7.46 ± 0.04	7.45 ± 0.03	0.106
2 hrs post ext.	7.45 ± 0.05	7.42 ± 0.06	0.03*
6 hrs post ext.	7.45 ± 0.05	7.43 ± 0.08	0.251
12 hrs post ext.	7.46 ± 0.03	7.42 ± 0.05	0.02*
24 hrs post ext.	7.43 ± 0.07	7.41 ± 0.06	0.189

*p> 0.05 Mean significant. Mean arterial PCO2 levels remained similar between the groups at 15m, 2, 6, 12, and 24 h post-extubation. Likewise, mean arterial PO2 exhibited no notable variation at 15m, 6, 12, and 24 h, though a significant decline was detected in the NIV group compared to HFNO at 2 h. For mean arterial SpO2, values were comparable at 15m, and 2, and 6 h, but a significant decrease occurred in the NIV group relative to HFNO at 12 and 24 h post-extubation.

Table 3: Comparison between the two groups as regard Mean RR

Time	Mean RR		
	G1 HFNO	**G2 NIV**	**P**
15 min post	20. 10±2. 05	19. 55±1. 15	0.42
2 hrs post	19. 65±2. 93	19. 65±2. 52	0.85
6 hrs post	18. 85±2. 49	20. 15±3. 08	0.52
12 hrs post	19. 05±2. 96	20. 60±3. 42	0.40
24 hrs post	18. 05±1. 67	24. 10±3. 97	0. 001*

Table 4: Post-extubation Respiratory failure causes of the enrolled cases:

	Group I (N=30)	**Group II (N=30)**	**I/II P**
Respiratory failure causes	8(26. 6%)	11 (36.6%)	0.028*
Respiratory acidosis	1 (3. 3%)	2 (6. 6%)	0.93
Hypoxia	1 (3. 3%)	2 (6. 6%)	0.93
Unbearable dyspnea	3 (6. 6%)	3 (10%)	0.69
Decreased level of consciousness	1 (3. 3%)	1(3. 3%)	0.85
Inability to clear Secretions	2 (6. 6%)	3 (13. 3%)	0.90

The values were non significantly different in both groups regarding duration ICU stay.

Mortality rates were compared between the two research groups to assess whether HFNO was effective in reducing mortality, as it was a key outcome in the research. In the research, deaths were primarily caused by multiorgan failure (50%) and other factors, including cardiac arrhythmias and ARDS. Post-extubation, there were no significant variations in mortality rates across the groups that were under investigation.

Discussion

The main observations in the present investigation were that HFNO was as effective as NIV in weaning COPD cases from invasive ventilation, as assessed by vital signs and ABG measurements. PaCO2 levels remained comparable between both groups throughout the research, though PaO2 declined in the NIV group at 2 h post-extubation. This aligns with findings from a subgroup analysis of hypercapnic cases in a retrospective comparison of HFNC and NIV for post-extubation management [(8)].

Our findings are supported by the findings of a prospective research that exhibited no significant variations in ABG values between the HFNC and NIV groups after 6 and 24 h in COPD cases with mild hypercapnic ARF. This finding is in line with our findings [(9)]. In addition, a crossover trial conducted on cases with stable hypercapnic COPD exhibited that HFNC led to a decrease in PaCO2 from 53.7 to 45.5 mmHg. This reduction was then sustained at 46.4 mmHg with the use of NIV. Furthermore, it was shown that much greater flow rates (30 L/min) were more successful in reducing PaCO2 than lower flow rates (20 L/min) [(10)].

With respect to RR, a significant increase was noted in the NIV group compared to the HFNO group at 24 h post-extubation, aligning with previous investigations that demonstrated HFNC effectively reduces RR in stable hypercapnic COPD cases [(11)].

Concerning BP, a notable decline was detected in the NIV group at 12 h post-extubation, whereas no substantial change occurred in the HFNO group. This disparity may be linked to variations in mean airway pressure between the two modalities. An interventional clinical research exhibited that NIV generated a significantly elevated mean airway pressure (7.46 ± 1.77 cmH2O) compared to HFNO (3.01 ± 1.03 cmH2O), indicating that NIV may exert a greater influence on

venous return, potentially explaining the BP reduction seen in our research [12].

In a previous research, mean airway pressures were measured at 3.01 ± 1.03 cmH2O for HFNC with a flow rate of 50 L/min and 7.46 ± 1.77 cmH2O for NIV set at PS 6-14 cmH2O. This indicates that HFNC has a lesser effect on venous return compared to NIV [10]. In our research, the NIV pressure setting was between PS 7-10 cmH2O.

In term of reintubation, the HFNO group had a reintubation rate of 20%, which was much lower than the NIV group's reintubation rate of 23.3%. This finding demonstrates that high-flow conditioned oxygen treatment was superior to NIV in eliminating the need for reintubation. There was no discernible change seen in the overall reintubation rates, especially when non-respiratory factors were excluded.

The reintubation causes were similar in both groups; however, consistent with the Hernandez trial involving a low-risk population using HFNO [12], secretion clearance issues were less frequent in the HFNO group. Similarly, in this trial, cases with respiratory failure experienced fewer secretion management difficulties with HFNO. The potential advantage of improved secretion clearance with HFNO had already been suggested in previous investigations [13].

In our investigation, there was a similarity between the rates of reintubation and PERF that were seen in prior research on cases who were getting standard oxygen treatment. (14-15). Although, the rate of reintubation in the NIV group was somewhat greater than the 11%-16% that was exhibited in these trials. The 24h protocol that was employed in this investigation may have resulted in a relatively restricted use of both NIV and high-flow conditioned oxygen therapy in comparison to more lengthy treatment techniques [12-13].

Inability to administer sedatives in order to improve tolerance to NIV may have contributed to a reduction in the total amount of time required for NIV therapy. Furthermore, the cases who participated in this research have been shown to have hypercapnia, which is a recognized risk factor for the need for reintubation.

The FLORALI trial, French multicenter research involving 310 cases with acute hypoxemic respiratory failure but without hypercapnia, randomized participants to receive HFNO, standard oxygen therapy, or NIV. The intubation rates, which served as the primary outcome, were 38% for the HFNO group, 47% for those receiving standard oxygen, and 50% in the NIV group (P=0.18) (16). Similarly, cases were randomly allocated to either a Venturi mask (n=52) or HFNO (n=53) for a period of 48 h in randomized controlled research that included 105 cases who had a PaO2/FiO2 that was less than 300 mm Hg prior to extubation before the procedure. Both the need for any type of ventilatory assistance (7% vs 35%; P<0.001) and the need for reintubation were considerably reduced in the HFNO group (4% versus 21%; P=0.01), indicating a significant difference in the need for reintubation [13].

In multicenter research that included 527 cases who were considered to be at low risk for reintubation after extubation, the cases were randomly assigned to either HFNO (n=264) or conventional oxygen treatment (n=263). The results exhibited that the HFNO group had a decreased incidence of reintubation after 72 h (4.9% vs 12.2%; P=0.004) [12].

Similarly, the incidence of PERF was much lower in the HFNO group compared to the NIV group in our investigation of critically ill COPD cases. This was due to the fact that the number of episodes that occurred was significantly lower. A significant portion of this result may be ascribed to the increased secretion clearance that is linked with HFNO.

A previous RCT that was conducted across many centers and included 406 cases who had been receiving MV for more than 48 h and had successfully completed a

spontaneous breathing experiment allocated them to either NIV (n=202) or standard medical therapy (n=204). Both groups exhibited comparable baseline characteristics, with no significant differences in extubation failure rates (control: 13.2% vs. NIV: 14.9%). In the NIV group, the most common reason for unsuccessful extubation was excessive secretions, which accounted for 35.1% of the cases [(17)]. One more multicenter experiment included the random assignment of 527 cases who were at a low risk for reintubation to either HFNO (n=264) or conventional oxygen treatment (n=263). Only 8.3 percent of cases in the HFNO group had PERF, compared to 14.4 percent in the control group (P = 0.03). There were no side events noted [(12)].

BiPAP was compared against HFNO in the BiPOP experiment, which was multicenter randomized research that included 830 cardiothoracic surgery cases who were at risk for PERF. HFNO was shown to be non-inferior to BiPAP, with treatment failure rates of 21.0% (87/414) in the HFNO group and 21.9% (91/416) in the BiPAP group (P=0.00). This information was obtained by a statistical analysis [(18)].

Regarding ICU length of stay and mortalities, our research exhibited no notable differences between both groups. In a similar manner, a multicenter RCT that included 406 cases who had been mechanically ventilated for more than 48 h and had successfully completed a spontaneous breathing experiment allocated them to either NIV (n=202) or standarad medical therapy(n=204). The research exhibited comparable ICU and hospital mortality between the groups [(17)].

In the FLORALI experiment, cases were assigned to receive either HFNO, normal oxygen therapy, or NIV treatment. In comparison to both normal oxygen treatment (hazard ratio: 2.01; 95% CI, 1.01–3.99; P=0.046) and NIV (hazard ratio: 2.50; 95% CI, 1.31–4.78; P=0.006), the mortality rate was considerably reduced with HFNO at 90 days [(16)]. A similar comparison was made between HFNO and BiPAP in the BiPOP experiment, which was multicenter randomized research that included 830 cardiothoracic surgeries cases who were at risk for respiratory failure after becoming extubated. In the critical care unit, neither of the two groups exhibited any statistically significant differences in the rate of mortality (BiPAP: 5.5% vs. HFNO: 6.8%; P=0.66; absolute difference: 1.2%; 95% confidence range, -2.3% to 4.8%) as compared to the other group [(18)].

The results of our research may not be able to be generalized due to a number of limitations, including the fact that it was conducted at a single location and that the sample size was relatively small. Conducting a larger, multicenter RCT would help generate more robust evidence. Furthermore, the absence of recent pulmonary function tests in most cases limited our ability to assess the relationship between baseline lung function and HFNO success in weaning. Future research should address this gap and investigate how baseline pulmonary function influences HFNO outcomes in COPD cases.

Conclusion

Compared to NIV alone, HFNO was linked to lower reintubation rates when initiated immediately after planned extubation. Cases weaned with HFNO exhibited elevated PaO2 levels two h post-extubation. However, the length of hospital stay and mortality were comparable between the groups. In COPD cases with respiratory failure who had been receiving MV for more than 72 h, the administration of HFNO immediately after extubation was significantly associated with a decline in the reintubations rates. Additionally, those managed with HFNO exhibited improved PaO2, a lower respiratory rate, and elevated MAP compared to those receiving CPAP-based NIV during the 24h observation period.

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