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Original Article

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Comparison of High-Flow Nasal Cannula (HFNC) Oxygen Therapy and Non-Invasive Ventilation (NIV) in Patients with COVID-19: A Randomized Clinical Trial

Maryam Sadat Mirenayat[1,2], Alieh Ghojoghi[1], Reyhaneh Zahiri[1,2], Mitra Lotfalipour[1] and Atefeh Fakharian[1,2]*

1. Chronic Respiratory Diseases Research Center (CRDRC), National Research Institute of Tuberculosis and Lung Diseases (NRITLD), Masih Daneshvari Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran
2. Pulmonary Rehabilitation Research Center (PRRC), National Research Institute of Tuberculosis and Lung Disease (NRITLD), Masih Daneshvari Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran

Abstract

Background: With the expansion of the COVID-19, the study of different oxygen therapy methods has yielded different results. In the current study, we compare the effects of non-invasive ventilation and oxygen therapy through the high-flow nasal cannula.

Methods: Non-intensive care unit-admitted COVID-19 patients were randomly divided into two groups. The first group received oxygen therapy with High Flow Nasal Cannula (HFNC) and the second group received Non-Invasive Ventilation (NIV). Clinical conditions and results obtained from laboratory tests were compared in two groups before oxygen therapy, and after 24 and 48 *hr*.

Results: The average age of the participants was 56.25. According to the results, after 24 *hr* of respiratory intervention, dyspnea was the most frequent in the NIV group with 83.33% and in the HFNC group with 90%. After 48 *hr*, in the NIV group, nasal flaring was observed with a frequency of 60%, and in the HFNC group, weakness and lethargy were the most common symptoms (56.66%). Comparison of clinical status and laboratory indices of the two groups of patients showed that most of the indices in patients in three time periods were not significantly different, while the results demonstrated that after 24 hours, the mean PaCo2 in the HFNC group was significantly lower than the NIV group (0.002) and the mean PH in the HFNC group was significantly higher than the other group (p=0.039).

Conclusion: The effectiveness of using HFNC compared to NIV is the same and shows no significant difference.

Keywords: Cannula, COVID-19, Dyspnea, Humans, Lethargy, Noninvasive ventilation

*** Corresponding author**

Atefeh Fakharian, MD
Chronic Respiratory Diseases Research Center (CRDRC), National Research Institute of Tuberculosis and Lung Diseases (NRITLD), Masih Daneshvari Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran
Pulmonary Rehabilitation Research Center (PRRC), National Research Institute of Tuberculosis and Lung Disease (NRITLD), Shahid Beheshti University of Medical Sciences, Tehran, Iran
Tel: +98 21 2610 9991
Fax: +98 21 2712 2009
Email: fakharian_2005@yahoo.com

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Introduction

Despite the decrease in the mortality rate of the COVID-19 pandemic, researchers are still trying to control and provide the best treatment line for these patients. The cause of this disease is a new infectious particle from the family of coronaviruses known as Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-COV-2). SARS-COV-2 is transmitted through respiratory droplets, contact with contaminated objects, and sometimes airborne through the transmission of contaminated aerosols (1,2). Since one of the main complications of COVID-19 is hypoxemic respiratory failure and widespread Acute Respiratory Distress Syndrome (ARDS), complementary oxygen delivery methods have been given much attention to maintaining proper respiratory function in patients (3). The use of oxygen delivery methods such as high-flow oxygen through the nasal cannula and non-invasive mechanical ventilation, if used with the necessary protective measures, can achieve more than the invasive methods (4).

In oxygen delivery through a High Flow Nasal Cannula (HFNC), oxygen is delivered to the patient during hot and humid air with high flow up to about 40 to 80 *L/min*. Oxygen transfer through cold and dry air causes burning and dryness of the patient's respiratory mucosa, thus using this method can provide favorable conditions for the patient to breathe satisfactorily (5,6) Also, the delicate and flexible cannula of this device has provided the possibility of using it while talking or eating. Besides, heat and humidity improve mucociliary function by maintaining hydration and motility of secretions. HFNC facilitates oxygen delivery by flushing the nasopharynx during exhalation. Nasopharyngeal and anatomical dead space flushing improve ventilation efficiency. This, along with a decrease in respiratory rate due to slow exhalation due to the inhaled gases, leads to a decrease in respiratory rate per minute (7). Expiratory impedance also causes positive expiratory pressure, which peaks during exhalation and reaches a flow of about 1 *cm* H_2O/10 *L/min*, and based on the available evidence can increase the pulmonary volume at the end of exhalation. Therefore, HFNC is beyond supplemental oxygen delivery and is a high-tolerance ventilation device that is easy and safe to use (8).

Another approach that is on the agenda of many medical centers in the delivery of supplemental oxygen to these patients is the use of Non-Invasive Ventilation (NIV). According to the clinical guideline provided by the ERS/ATS, this method can be used in Acute Respiratory Failure (ARF) and ARDS without severe organ failure (9). In patients with ARF undergoing NIV, high expiratory tidal volume (VTE) is produced in pressure-controlled states by ventilator pressure and respiratory muscles. Therefore, monitoring VTE and unwanted leaks is very important (10).

Frat *et al* found that the use of HFNC during NIV sessions in patients with PaO_2/FiO_2 <300 and ARDS could reduce the need for intubation by up to 36% (11). In 2003, at the same time as the Severe Acute Respiratory Syndrome (SARS) outbreak, the use of NIV in patients with an initial mean PaO_2/FiO_2 of 137 was evaluated in Hong Kong (12). The results indicated that in 70% of the cases, endotracheal intubation was prevented and none of the medical personnel who met the requirements of personal protection were infected with this disease. The use of non-invasive ventilation in influenza A H1N1 was also evaluated and was 15 to 25% successful (13,14). In the Middle East Respiratory Syndrome (MERS) epidemic, researchers also found that NIV could be a useful first-line treatment (15). Using HFNC in the treatment of MERS has also been reported to be successful in various studies (16).

Due to the differences of opinion regarding the use of these two methods in the treatment line of patients with COVID-19, in the present study, we compared the results of nasal cannula oxygen delivery with non-invasive ventilation in these patients.

Materials and Methods

Study design

The present study was performed as a clinical trial with IRCT code: IRCT20160516027929N8 from May 2020 to February 2021. Patients with criteria including age over 18, moderate to severe COVID-19, and patients who had no contraindications of NIV were included in the study by signing a written consent form. Also, patients who did not have the tolerance and desire to use non-invasive ventilation were excluded from the study. All the participants

were admitted to the ward dedicated to COVID-19 and were treated according to the national guidelines for COVID-19. Sixty hospitalized patients with moderate to severe COVID-19 who required respiratory support were studied. The patients were divided into two groups (30 patients in each group) based on a simple randomization method. In one group, patients underwent non-invasive ventilation with a BiPAP ST device, which was adjusted daily based on the patient's condition, and in the second group, patients received the required oxygen for 48 *hr* through nasal high-flow therapy (Fisher & Paykel).

Using a pre-designed questionnaire under the direct supervision of a specialist physician and treatment team, the patients' clinical condition at the time of admission, 24 and 48 *hr* after oxygen therapy with HFNC and NIV were recorded and evaluated. The flowchart of the study process is shown in figure 1.

Statistical analysis

Mean was utilized to describe quantitative variables according to the conditions, and frequency report was used for qualitative variables. Independent t-test or Mann-Whitney U test was used to compare quantitative outcomes between the two groups. An independent t-test or Wilcoxon test was used to compare the results before and after the intervention within each group. Statistical analyses were performed with SPSS 16 (SPSS Inc, Chicago, USA) software package. Probability (p) values of <0·05 were considered significant.

Results

A total of 71 participants responded to the survey from May 2020 to February, 2021, with 60 individuals with an average age of 56.25 years, providing complete data on the variables in the present analyses. According to table 1, 36 (60.00%) of all individuals were male, and 24 (40.00%) were female (Table 1).

Examination of the clinical condition and underlying diseases of the patients in the two groups showed that the patients of the two groups were not significantly

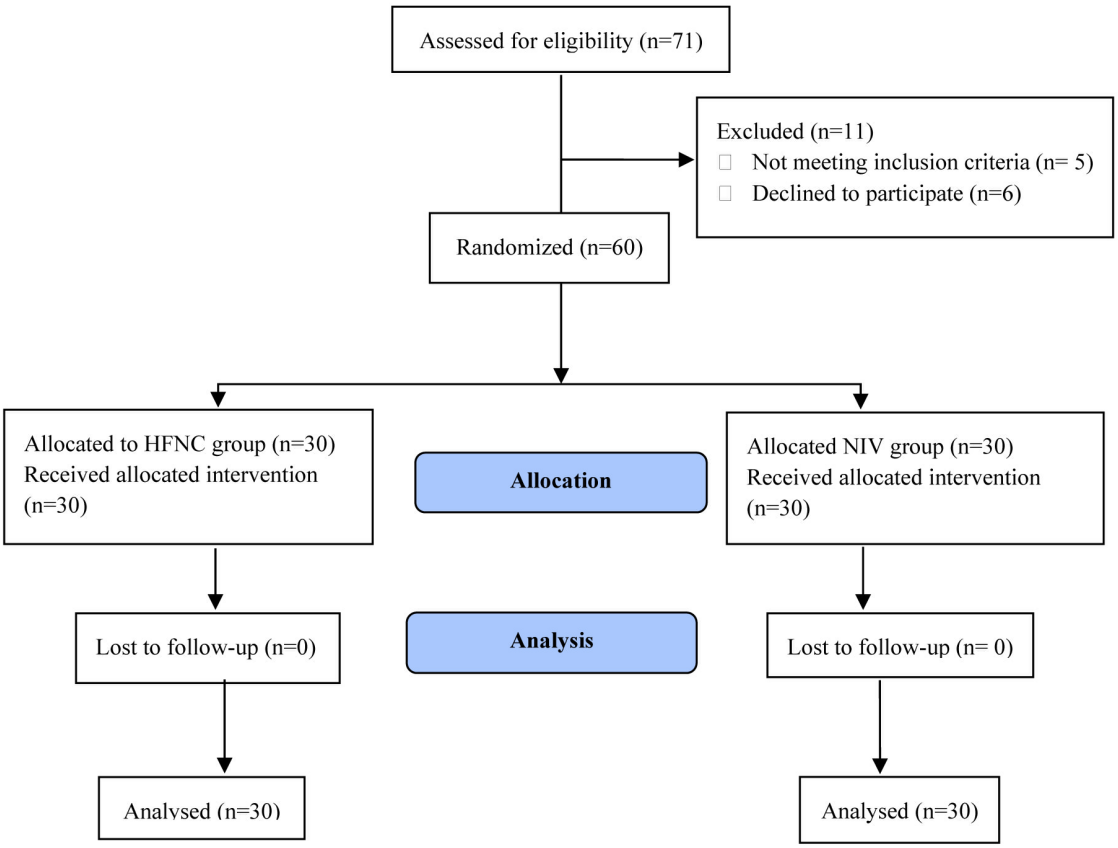

Figure 1. Flow diagram of patients with COVID-19 participated and excluded. No harmful complications were reported in the two groups.

Table 1. Demographic data of patients in two groups

Indexes		NIV group	HFNC group
Age (M±SD)		55.6±15.58	56.9±15.03
Gender (Male)		0.56	0.63
High (M±SD) *cm*		168.23±7.44	169.51±7.152
Weight (M±SD) *kg*		77.36±9.43	79.55±9.10
BMI (M±SD)		27.27±2.34	27.60±2.01
Blood group	O^+	8	3
	O^-	1	0
	A^+	3	7
	A^-	2	0
	B^+	4	4
	B^-	0	0
	AB^+	2	2
	AB^-	0	0

BMI: Body Mass Index.

different in terms of clinical symptoms and underlying diseases. However, hypertension with 16 (26.67%) cases and diabetes with 26 (43.34%) were the following most common underlying diseases. However, there was no significant difference between the two groups (Table 2).

Clinical symptoms of patients in 3 periods before oxygen therapy with HFNC and NIV, after 24 *hr*, and after 48 *hr* were compared in two groups. The results showed that among the patients in the HFNC group, 14 patients (46.66%) had body pain after 24 *hr*. In the NIV group, only 9 patients (30%) had body pain. Also, before the intervention, 20 patients (66.66%) in the HFNC group and 13 patients (43.33%) in the NIV group had headaches, and after 24 *hr*, there was no difference in the number of patients with headaches in the HFNC group [19 patients (63.33%) in the HFNC group and 9 patients (30%) in the NIV group]. Among the patients in the HFNC group, 17 (56.66%)

Table 2. Clinical characteristics of the enrolled patients in two groups under study

Groups	Variables	NIV group (M±SD)	HFNC group (M±SD)	p-value
BP (*mmHg*)		131.51±15.08	136.76±13.19	0.124
Temperature (°*C*)		38.90±1.21	38.95±1.23	0.868
HR (*beats/min*)		110.26±11.12	106.4±11.50	0.19
RR (*breaths/min*)		19.13±1.90	18.7±1.71	0.330
Duration of hospitalization		14.71±7.23	9.4±6.75	0.134
Underlying diseases	Diabetes	12 (40.00%)	14 (46.66%)	0.281
	HTN	9 (30.00%)	7 (23.33%)	0.234
	MI	0 (0.00%)	0 (0.00%)	0.00
	CVA	0 (0.00%)	1 (3.00%)	0.837
	COPD	0 (0.00%)	5 (16.66%)	0.071
	Kidney dysfunction	0 (0.00%)	1 (3.00%)	0.837
	Liver dysfunction	4 (13.33%)	3 (10.00%)	0.837
	Smoker	9 (30.00%)	13 (43.33%)	0.195
	Opium	1 (3.00%)	6 (20.00%)	0.186
	Alcohol	0 (0.00%)	2 (6.67%)	0.271
	Cancer	0 (0.00%)	0 (0.00%)	0.00
	Infection	6 (20.00%)	4 (13.33%)	0.271
PCR positive		30 (100%)	30 (100%)	0.999

HFNC: High Flow Nasal Cannula, NIV: Noninvasive Ventilation, BP: Blood Pressure, HR: Heart Rate, RR: Respiratory Rate, HTN: Hypertension, MI: Acute Myocardial Infarction, CVA: Cerebrovascular Accident, COPD: Chronic Obstructive Pulmonary Disease.

had weakness and lethargy after 48 *hr*. While in the NIV group, only 11 people (36.66%) were weak and lethargic. Olfactory and taste disorders were also higher in patients in the HFNC group than in the NIV group. Contrary to the mentioned clinical signs, nasal flaring was observed more in the NIV group in all three time periods than in the HFNC group. But after 48 hours, the number of patients in the NIV group with nasal flare-up decreased from 21 to 18 (Table 3). Evaluation and comparison of clinical status and laboratory indexes of the two groups of patients demonstrated most of the indices in patients in three time periods (before, 24, and 48 *hr* later) were not significantly different, while the mean of PH in patients in the HFNC group after 24 *hr* were significantly more than patients in the NIV group (p=0.039). Also, $PaCo_2$ changes in the HFNC group were significantly less than NIV group (0.002) (Table 4).

Table 3. Clinical symptoms of patients in 3 time periods

Groups	Indexes	NIV group (N=30)	HFNC group (N=30)
Fever			
	Before	22 (73.33%)	22 (73.33%)
	24 *hr* later	19 (63.36%)	20 (66.66%)
	48 *hr* later	6 (20%)	10 (33.33%)
Dyspnea			
	Before	28 (93.33%)	29 (96.66%)
	24 *hr* later	25 (83.33%)	27 (90%)
	48 *hr* later	16 (53.33%)	15 (50%)
Cough			
	Before	14 (46.66%)	15 (50%)
	24 *hr* later	12 (40%)	14 (46.66%)
	48 *hr* later	10 (33.33%)	7 (23.33%)
Sore throat			
	Before	1 (3.33%)	2 (6.66%)
	24 *hr* later	0 (0%)	2 (6.66%)
	48 *hr* later	0 (0%)	2 (6.66%)
Body pain			
	Before	12 (40%)	16 (53.33%)
	24 *hr* later	9 (30%)	14 (46.66%)
	48 *hr* later	6 (20%)	5 (16.66%)
Abdominal pain			
	Before	2 (6.66%)	1 (3.33%)
	24 *hr* later	2 (6.66%)	1 (3.33%)
	48*hr*later	1 (3.33%)	1 (3.33%)
Headache			
	Before	13 (43.33%)	20 (66.66%)
	24 *hr* later	9 (30%)	19 (63.33%)
	48 *hr* later	2 (6.66%)	6 (20%)

Contd. table 3.

Weakness and lethargy			
	Before	22 (73.33%)	26 (86.66%)
	24 *hr* later	21 (70%)	23 (76.66%)
	48 *hr* later	11 (36.66%)	17 (56.66%)
Diarrhea			
	Before	1 (3.33%)	1 (3.33%)
	24 *hr* later	2 (6.66%)	1 (3.33%)
	48 *hr* later	0 (0%)	1 (3.33%)
Nausea			
	Before	4 (13.33%)	3 (10%)
	24 *hr* later	3 (10%)	3 (10%)
	48 *hr* later	1 (3.33%)	3 (10%)
Olfactory disorder			
	Before	2 (6.66%)	9 (30%)
	24 *hr* later	2 (6.66%)	9 (30%)
	48 *hr* later	1 (3.33%)	4 (13.33%)
Taste disorder			
	Before	1 (3.33%)	7 (23.33%)
	24 *hr* later	1 (3.33%)	7 (23.33%)
	48 *hr* later	1 (3.33%)	4 (13.33%)
Urinary disorders			
	Before	0 (0%)	0 (0%)
	24 *hr* later	0 (0%)	0 (0%)
	48 *hr* later	0 (0%)	0 (0%)
Use of respiratory sub-muscles			
	Before	2 (6.66%)	2 (6.66%)
	24 *hr* later	1 (3.33%)	2 (6.66%)
	48 *hr* later	1 (3.33%)	1 (3.33%)
Nasal flaring			
	Before	21 (70%)	12 (40%)
	24 *hr* later	21 (70%)	12 (40%)
	48 *hr* later	18 (60%)	12 (40%)
Intubation	48 *hr* later	1 (3.33%)	2 (6.66%)
Cortone	48 *hr* later	21 (70%)	24 (80%)
IVIG	48 *hr* later	2 (6.66%)	6 (20%)
Dialysis	48 *hr* later	0 (0%)	2 (6.66%)

HFNC = High Flow Nasal Cannula, NIV = Noninvasive Ventilation

Table 4. Comparison of clinical status differences and laboratory tests of the patients in HFNC and NIV groups in three time periods of before, after 24 *hr*, and 48 *hr* after oxygen therapy

Groups	Variable	NIV group (Mean±SD)	HFNC group (Mean±SD)	p-value
Glasgow coma scale score				
	Before	15±0	15±0	-
	24 *hr* later	15±0	15±0	-
	48 *hr* later	15±0	14.53±1.80	0.321
APACHE II score				
	Before	15.56±4.68	16.8±7.00	0.499
	24 *hr* later	15.1±4.47	14.75±4.38	0.767
	48 *hr* later	15.26±4.51	15±4.53	0.822
PH				
	Before	7.41±0.07	7.41±0.06	0.701
	24 *hr* later	7.41±0.05	7.44±0.04	0.039
	48 *hr* later	7.42±0.02	7.42±0.02	0.474
LDH (*L/U*)				
	Before	745.16±424.07	643.08±360.58	0.321
	24 *hr* later	750.87±396.05	699±289.09	0.717
	48 *hr* later	621.33±24.00	605.57±161.92	0.897
SaO_2 (%)				
	Before	54.82±22.12	53.52±21.62	0.818
	24 *hr* later	73.97±13.69	70.85±14.62	0.412
	48 *hr* later	86.90±6.91	86.43±8.54	0.834
$PaCo_2$ (*mmHg*)				
	Before	47.80±16.43	43.17±12.73	0.160
	24 *hr* later	46.75±11.02	39.60±9.28	0.002
	48 *hr* later	55.55±53.66	41.61±38.15	0.162
Creatinine (*µmol/L*)				
	Before	1.34±1.11	1.53±1.02	0.486
	24 *hr* later	1.47±1.60	1.47±1.32	0.992
	48 *hr* later	1.28±1.18	1.45±1.07	0.527
Sodium (*mmol/L*)				
	Before	136.9±3.24	137.13±3.30	0.786
	24 *hr* later	136.83±3.71	136.5±3.82	0.739
	48 *hr* later	136.3±3.66	136.66±3.67	0.702
Potassium (*mmol/L*)				
	Before	3.95±0.89	4.04±0.72	0.660
	24 *hr* later	4.15±0.46	4.17±0.53	0.866
	48 *hr* later	4.07±0.45	4.15±0.54	0.555
HCL				
	Before	38.69±7.10	39.73±8.93	0.657
	24 *hr* later	38.67±6.66	38.70±8.26	0.987
	48 *hr* later	38.13±6.41	37.39±9.38	0.762

Contd. table 4.

WBC ($\times 10^9/L$)				
	Before	9.36±4.12	9.42±6.17	0.971
	24 *hr* later	10.25±7.27	10.71±7.09	0.807
	48 *hr* later	9.58±2.78	10.71±5.53	0.431

HFNC = high flow nasal cannula, NIV = noninvasive ventilation, APACHE II= acute physiology and chronic health evaluation II, LDH= Lactate Dehydrogenase, SaO2= arterial oxygen saturation, PaCo2= partial pressure of carbon dioxide, HCL= Hydrogen chloride, WBC= White blood cell counts

Discussion

With the outbreak of the new coronavirus since late 2019, optimizing oxygen delivery to patients with this infection has always been one of the most important challenges for medical teams around the world (4,17). The main finding of our study is that HFNC in the management of patients with COVID-19 has been similar to the use of NIV. When compared to non-invasive ventilation, there was no significant difference in the rate endotracheal intubation or the mortality rate, and the duration of therapy was not significantly different between the two groups. The role of humidified high flow nasal oxygen in the management of hypoxemia associated with respiratory distress is described in previous studies (4). Our results are in accordance with the results of another study which showed an average rate of endotracheal intubation for COVID-19 patients treated with HFNC of 17%, and 15% for those treated with NIV; the average duration of therapy in this study was 5.1 days for HFNCO and 6.8 days for NIV (18).

Two meta-analyses of HFNC in hypoxemic respiratory failure patients found no added benefit to usual treatment, while another recent meta-analysis found a beneficial effect of HFNCO with significant reduction of the rate of endotracheal intubation, and the benefits were comparable to NIV in terms of outcome and mortality rate (19,20). In our study, HFNC proved to be successful in managing patients with COVID-19 and acute hypoxemic respiratory failure; the rate of failure and the need to escalate the respiratory support were very low. Comparing the results of HFNC with NIV, there was no statistically significant difference in terms of outcomes.

In our study, patients' clinical symptoms such as dyspnea, cough, body pains, headaches, *etc*. were generally reduced after 48 *hr* of receiving HFNC and NIV. Also, the levels of SaO_2, pH, and other laboratory variables that are effective in the inflammatory response of COVID-19 patients have improved. Although the comparison of the parameters of the two groups was not statistically significant, the trend of reducing the severity of symptoms indicates the effective performance of supportive therapies used and therefore both HFNC and NIV methods have been effective in the treatment of patients with COVID-19. Furthermore, among the 60 patients studied, only one in the NIV group and two in the HFNC group required intubation. Therefore, the rate of intubation and death was very low in both groups. These findings are in accordance with the findings reported in another study comparing HFNC to NIV in hypoxemic respiratory failure patients, and they also reported similar improvement in patients receiving either HFNC or NIV, with no difference in the rate of endotracheal intubation or mortality rate (21).

A previous study has evaluated alternating HFNC with NIV in patients with hypoxemic respiratory failure, and they found beneficial effects of HFNC given in between the sessions of NIV; it helped to avoid major drops in oxygenation levels (22). It has been previously demonstrated that NIV can improve gas exchange, decrease the rate of endotracheal intubation, and reduce the mortality in patients with respiratory failure. Compared with NIV, HFNCO may have some advantages, such as greater patient comfort, easier clearance of secretions, and lower costs, in addition to lower incidence of different adverse events that may lead to poorer outcomes (23). Our study had some limitations. This was a single-center study that examined patients over a three-day period. Using a larger sample size and comparing the data of different medical centers in a longer follow-up period can help in obtaining more reliable results.

Conclusion

The effectiveness of using High Flow nasal cannula oxygen (HFNCO) compared to NIV is the same and does not show a significant difference. However, the use of any of these methods is applicable according to the clinical condition of patients and the diagnosis of the physician.

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Conflict of Interest

There is no conflict of interest in this study.

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