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Effectiveness of High Flow Nasal Oxygen Therapy in Pneumonia with Acute Hypoxemic Respiratory Failure in Intensive Care Unit, DMCH, Dhaka, Bangladesh

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Abstract
Background: Acute hypoxemic respiratory failure is the major compilation of pneumonia. It is characterized by an impaired gas exchange between the lungs and the blood. It can be managed by administering oxygen via a nasal cannula or face mask, followed by positive pressure throughout the respiratory cycle (PEEP) in case of failure. Pressure support can be administered either through endotracheal intubation (mechanical ventilation) or a non-invasive interface Continous Positive airway pressure (CPAP) ventilation.
Aims: Purpose of this study was to determine the efficacy of high flow nasal oxygen therapy in pneumonic patient with acute hypoxemic respiratory failure in intensive care unit.
Methods: It is a prospective randomized control trial, carried out in the ICU at the Department of Anaesthesia, Analgesia, Palliative & Intensive Care Medicine, Dhaka Medical College Hospital, Dhaka. Study subject were pneumonic patients with Acute Hypoxemic Respiratory Failure admitted in Intensive Care Unit of Dhaka Medical College Hospital. Total 100 patients were recruited and allocated into two groups, Group-A: Patients assigned to receive High Flow Nasal Oxygen Therapy (HFNOT) and Group-B: the patients assigned to receive NIV. Then safety & effectiveness of both groups were evaluated and compared. Procedure details was recorded on specifically designed proforma.
Results: In this study mean ± SD age of the Group-A was 54.37±9.24 years with a range of 18-70 years and the mean ± SD age of the Group-B patients was 55.31±9.86 years with a range of 18-70 years. Gender distribution revealed, male: female ratio 2.8:1 in study group. Age and sex difference between two groups was statistically non-significant. Haemodynamic status and baseline laboratory parameters were similar in both groups. On evaluation of outcome, present study shows successful treatment was more achieved in group-A (76.0% vs. 70.0%), although difference was statistically non-significant (p=0.501). treatment failure rate was 24.0% patients in group-A and 30.0% patients in group-B. Among the patients with treatment failure, the intubation rate in the HFNC group was similar to that of the Continous Positive airway pressure (CPAP) ventilation group, and the treatment switch rate was higher than that in the NIV group (8.0% versus 14.0%). However, there were no significant differences between the two groups in intubation or treatment switch rate. Causes of treatment failure showed that the intolerance rate of Continous Positive airway pressure (CPAP) ventilation was significantly higher than that of the HFNC (P=0.038). However, there was no difference between the two groups regarding respiratory distress, hypoxemia and carbon dioxide retention. Duration ICU stay was almost similar in both groupa (192 hours vs. 187 hours in group-A & B respectively), the difference was statistically non-significant.
Conclusion: Present study concluded that High Flow Nasal Oxygen Therapy (HFNOT) was associated with better tolerance, less treatment failure rates and less incidence of complications compared to NIV.

Keywords: High flow nasal oxygen therapy (HFNOT), non-invasive ventilation (NIV), extubation of critical ill patients, non-invasive positive pressure ventilation (NPPV)

Introduction
Acute hypoxemic respiratory failure (AHRF) is the most common causes of critical illness, with a hospital mortality of approximately 33% to 42.7% [1, 2]. Pneumonia is an important cause of acute hypoxemic respiratory failure. Hypoxemic respiratory failure (type I) is characterized by an arterial oxygen tension (PaO_2) lower than 60 mm Hg with a normal or low arterial carbon dioxide tension ($PaCO_2$).

This is the most common form of respiratory failure, and it can be associated with virtually all acute diseases of the lung, which generally involve fluid filling or collapse of alveolar units. Continous Positive airway pressure (CPAP) ventilation is recommended as the gold-standard therapy for acute hypoxemic respiratory failure (Type-1 respiratory failure). Continous Positive airway pressure (CPAP) ventilation intolerance appears in more than 15% patients due to various reasons, which increases the risk of treatment failure and re-intubation. Multiple studies have shown that a sequential strategy with Continous Positive airway pressure (CPAP) ventilation using a pulmonary infection control (PIC) window as the switching point can reduce the duration of invasive ventilation in respiratory failure patients and significantly improve prognosis. The success of NIV is closely related to the experience and abilities of the treating medical staff, the level of education and compliance of patients, and the performance of the Continous Positive airway pressure (CPAP) ventilation device [3, 4]. Due primarily to poor patient tolerance, Continous Positive airway pressure (CPAP) ventilation fails in approximately 15 to 25% of patients, potentially leading to endotracheal intubation [5, 6]. High-flow nasal cannula (HFNC) oxygen therapy is an emerging respiratory support system, which is better tolerated than Continous Positive airway pressure (CPAP) ventilation [5]. High-flow nasal cannula (HFNC) oxygen therapy is a new type of respiratory support system which can supply high flow mixed gases through special nasal prongs at a sufficient temperature and humidity for patient comfort. Many studies have confirmed that the comfort and tolerance of HFNC is significantly higher than that of Continous Positive airway pressure (CPAP) ventilation [5, 6]. As an alternative to Continous Positive airway pressure (CPAP) ventilation, HFNC has been shown to be as efficacious as Continous Positive airway pressure (CPAP) ventilation in preventing respiratory failure or intubation in patients with hypoxemic respiratory failure [7, 8]. The number of airway care interventions and the incidence of nasofacial skin breakdown associated with HFNC were significantly lower than in Continous Positive airway pressure (CPAP) ventilation [6]. HFNC appears to be an effective means of respiratory support for pneumonic patients with acute hypoxemic respiratory failure. We hypothesized that HFNC is effective on pneumonic patients with acute hypoxemic respiratory failure compared with Continous Positive airway pressure (CPAP) ventilation.

Materials & Methods

Study design: Prospective randomized control trial.

Place of the study

The ICU at the Department of Anaesthesia, Analgesia, Palliative & Intensive Care Medicine, Dhaka Medical College Hospital, Dhaka, Bangladesh.

Study population

Pneumonic patients with Acute Hypoxemic Respiratory Failure admitted in Intensive Care Unit of Dhaka Medical College Hospital were included after careful history taking, examination and appropriate investigations fulfilling inclusion and exclusion criteria.

Duration of the study: September 2018- August 2020. Data were collected after approval of protocol by ethical review committee.

Sample Size (n): $\frac{(r+1)r(P)(1-P)(Z\beta+Z\alpha/2)2}{(p1-p2)2}$The sample size was calculated by using the following statistical formula:

Sample Size= In this study, 71 patients in each group were considered. So, the final sample size was 142. Due to covid pandemic situtaion total 100 patients will be included and assessed in this study.

Sampling method and Randomization: Pneumonic patients with acute hypoxemic respiratory failure were primarily included in the study. After fulfilling the inclusion and exclusion criteria, the nature and benefit of the study were explained to the patient's guardian in details. Purposive sampling was done. Before treatment patients randomly allocated to the computer generated sequence into two equal groups. The sequence generated as codes to which the study participants allotted to. In this study both the participants and the investigator are blind to the alloation of the participants in two groups, treated either HFNC (Group-A) or NIV (Group-B).

Inclusion criteria

Patients ≥18 years old having pneumonia with acute hypoxemic respiratory failure.

Exclusion criteria

1. $PaCO_2$ above 50 mm Hg,
2. Severe shock with ≥ two ionotropes.
3. Impaired consciousness with a Glasgow coma score ≤12.
4. Patients with urgent need for intubation, that is, respiratory or cardiac arrest, respiratory pauses with loss of consciousness or gasping for air.
5. Pregnant patient.
6. Trauma or surgery or blocked nasal passage.

Study procedure: Both male and female fulfilling the inclusion and exclusion criteria were included in the study. Informed written consent was obtained from the attendant of patient. Both male and female fulfilling the inclusion and exclusion criteria were enrolled in the study. Patients eligible for study were randomized after they meet inclusion criteria, and assigned to one of the two following groups: Group-A: Patients assigned to receive High Flow Nasal Oxygen Therapy (HFNOT) and Group-B: the patients assigned to receive Continous Positive airway pressure (CPAP) ventilation. Immediately after randomization, patients of Group-A continuously treated by HFNOT with a flow of 70 L/min and FiO_2 adjusted to obtain adequate oxygenation (SpO_2 ≥94%) through a heated humidifier set to the 'intubation' position. For patients experiencing HFNOT intolerance due to high flow levels despite reinsurance, flow will be decreased to the maximal tolerated level. In Group-B, Continous Positive airway pressure (CPAP) ventilation was initiated with a first session of at least 4 hours until clinical improvement (assessed by the attending physician) and then applied by sessions of at least 1 hour for a minimal duration of at least 12 hours a day. Non rebreather bag mask ventilation was used to maintain SpO_2 ≥ 94% in between Continous Positive airway pressure (CPAP) ventilation. In Continous Positive airway pressure (CPAP) ventilation PEEP level of at least 8 cm H2O and

FiO_2 adjusted to obtain adequate oxygenation ($SpO_2 \geq 92\%$). For patients experiencing Continous Positive airway pressure (CPAP) ventilation intolerance despite reinsurance, physicians were encouraged to modify Continous Positive airway pressure (CPAP) ventilation settings to improve Continous Positive airway pressure (CPAP) ventilation tolerance.

Duration of treatment: Grpoup A HFNC and Group Continous Positive airway pressure (CPAP) ventilation was applied for a minimal duration of 48 hours with continuous. Observation was done up to ICU discharge or death. After that, continuation of the treatment was decided according to patient respiratory status.

Statistical analysis: Following collection of the data, all data were edited and encoded into a statistical software named 'statistical program Statistical Package for Social Science' (SPSS) version 22.0. Data was entered into the software (termed as variable) according to the prior analysis plan. In this study, continuous data was displayed as frequency, mean ± Standard deviation. Data were collected from the patients and recorded in structured data collection sheet. Clinical examination and relevant investigation were done meticulously.

Results

A total 100 patients were selected for study and allocated in two groups, Group-A (Patients assigned to receive High Flow Nasal Oxygen Therapy), Group-B (patients assigned to receive NIV). During the treatment 8 patients was died. So, finally 92 cases enrolled for primary analysis. All patient in both arm completed treatment and follow-up. The result and observations are given below.

Table 1: Characteristic of the study subjects (n=100).

Age (Years)	Group A (n=50) n (%)	Group B (n=50) n (%)	p-value
Mean ± SD	54.37±9.24	55.31±9.86	0.916^{ns}
Range	25-70	25-70	
Male	39 (78.0)	35 (70.0)	0.984
Female	11 (22.0)	15 (30.0)	

Group A: Patients who received HFNO
Group B: Patients who received NIV

Values are express as Mean ± SD and within parenthesis percentage (%) over the column in total. *Chi-square test (χ^2) was performed to copmpare between two groups. Student t-test was performed to compare the mean age of both groups. There had no significant difference in the age (p=0.916) and gender distribution as (p=0.984).

Table 2: Distribution of the patients according to co-morbidity (n=100)

Coexisting disease	Group A (n=50) n (%)	Group B (n=50) n (%)	p-value
Hypertension	18 (36.0)	15 (30.0)	0.758^{ns}
Diabetes	13 (26.0)	12 (24.0)	0.982^{ns}
HTN & DM	4 (8.0)	7 (14.0)	0.098^{ns}
CAD	9 (18.0)	12 (24.0)	0.124^{ns}
CVD	5 (10.0)	8 (16.0)	0.075^{ns}

No significant differences were observed in regard to risk factors. Table-2 shows the coexisting disease of the study subjects, in group-A patients 36.0% had hypertension, 26.0% had Diabetes, 18.0% had CAD and 10.0% had H/O CVD. In group-B patients 30.0% had hypertension, 24.0% had Diabetes, 14.0% had CAD and 16.0% had H/O CVD. Difference of coexisting disease between two groups was not statistically significant.

Table 3: Haemodynamic & Laboratory status of the study subjects (n=100)

Variables	Group A (n=50) n (%)	Group B (n=50) n (%)	p-value
Vital signs			
Temperature (C)	37.63±1.27	37.72±1.02	1.025^{ns}
Heart rate (b/pm)	98.43±19.34	95.53±15.13	0.985^{ns}
Respiratory rate (breath/min)	25.23±7.23	26.17±8.21	0.812^{ns}
Mean arterial BP (mmHg)	92.50±28.43	91.82±25.70	1.027^{ns}
ABGs (Arterial Blood Gases)			
pH	7.38±0.17	7.36±0.22	0.157^{ns}
PaO_2/FiO_2	138±6.3	140±6.5	0.703^{ns}
$PaCO_2$ (mmHg)	45.01±5.32	42.32±5.94	0.894^{ns}
PO_2 (mmHg)	92.13±7.85	89.45±10.02	0.513^{ns}
HCO_3 (mEq/l)	24.86±2.52	25.29±2.49	1.108^{ns}

Continuous variables are expressed as mean and standard deviation. HR indicates heart rate; RR indicates respiratory rate; MABP indicates mean arterial blood pressure
Table-3 showed the baseline haemodynamic status analysis. The difference of all parmeters were similar in both groups. No significant difference observed.

Table 4: Distribution of the study subjects according to primary outcome (n=100)

Outcome	Group A (n=50) n (%)	Group B (n=50) n (%)	p-value
Successful treatment	38 (76.0)	35 (70.0)	
Treatment failure	12 (24.0)	15 (30.0)	0.501^{ns}

Table-4 shows the outcome between groups. Successful treatment was more achieved in group-A (76.0% vs. 70.0%), although difference was statistically non-significant (p=0.501). treatment failure was 24.0% patients in group-A and 30.0% patients in group-B. Among the patients with treatment failure, the intubation rate in the HFNC group was similar to that of the NIV group, and the treatment switch rate was higher than that in the NIV group (8.0% versus 14.0%). However, there were no significant differences between the two groups in intubation or treatment switch rate.

Table 5: Analysis of treatment failure between groups (n=27)

Analysis of treatment failure	Group A (n=12) n (%)	Group B (n=15) n (%)	p-value
Treatment intolerance	0	7 (46.7)	0.038^{s}
Aggravation of respiratory distress	6 (50.0)	3 (20.0)	0.106^{ns}
Aggravation of hypoxemia	2 (16.7)	1 (6.7)	0.420^{ns}
Aggravation of carbon dioxide retention	4 (33.3)	4 (26.7)	0.714^{ns}

Analysis of the reasons of treatment failure in the two groups showed that the intolerance rate of NIV was significantly higher than that of the HFNC (P=0.038). However, there was no difference between the two groups regarding respiratory distress, hypoxemia and carbon dioxide retention.

Table 6: Comparison of complications between groups (n=100)

Complications	Group A (n=50) n (%)	Group B (n=50) n (%)	p-value
Haemodynamic changes	7 (14.0)	7 (14.0)	1.00^{ns}
Respiratory changes			
SPO_2 <90	12 (24.0)	15 (30.0)	0.501^{ns}
Tachypnoea	4 (8.0%)	12 (24.0%)	0.029^{s}
Bradypnoea	0	2(4.0%)	0.155^{ns}
Death	4 (8.0)	4 (8.0)	1.00^{ns}

Table-6 shows different complications between groups. Study revealed that except tachypnoea, all other complications were non-significant. SPO_2 <90% changes was 24.0% patients in group-A & 30.0% in group-B, Haemodynamic changes was 14.0% patients in group-A & 14.0% patients in group-B and bradypnoea was 4.0% patients in group-B. Mortality rate was 8.0% patients in group-A & 8.0% in group-B.

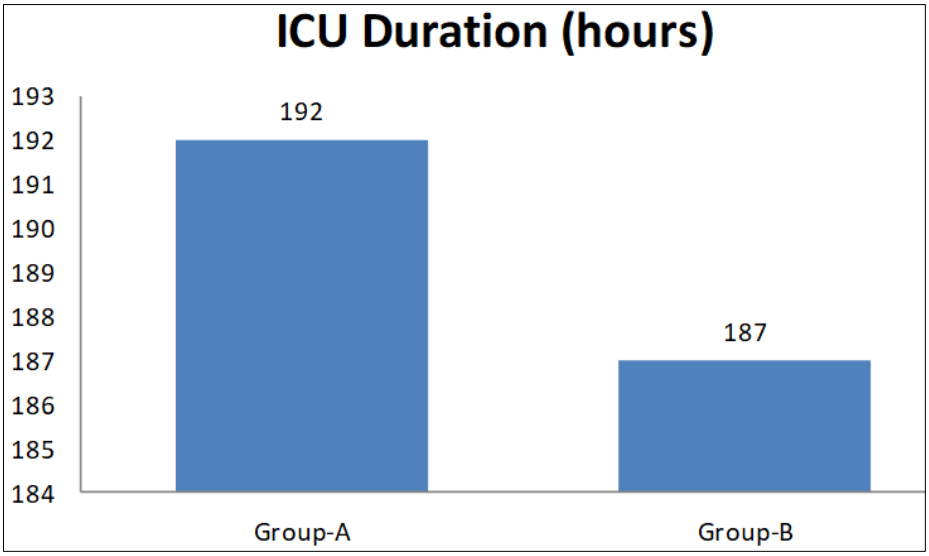

Fig 1: Length of ICU stay (n=100)

Figure shows the ICU length of stay. Duration ICU stay was almost similar in both groupa (192 hours vs. 187 hours in group-A & B respectively), the difference was statistically non-significant.

Discussion

This study was conducted to assess the effectiveness of High flow nasal Oxygen therapy for the patients with pneumonia with acute hypoxemic respiratory failure. In this study mean± SD age of the Group-A was 54.37±9.24 years and the mean± SD age of the Group-B patients was 55.31±9.86. Gender distribution revealed, male: female ratio 2.8:1 in study group. Distribution of age and sex difference between two groups was statistically non-significant as p - value >.05. This finding is consistent with the finding of Sun *et al.* [5] also Tan *et al.* [6]. The lower mean age and sex distribution ratio maybe due to geographical variations, racial, ethnic differences, and genetic causes. Regarding co-morbid diseases high number of patients had HTN (36.0% of HFNC group and 30% of NIV group of patients) followed by DM (26% of HFNC group and 24% of NIV group of patients) without any statistically significant difference. It also observed that, in group a 18.0% had H/O CAD and 10.0% had H/O CVD, in group-B 14.0% had H/O CAD and 16.0% had H/O CVD. This difference also came out to be statistically not significant. This study reveals co-morbidity like HTN and DM contributes to a large number with pneumonic patient of ICU referral. Regarding the ABG parameters the HFNC therapy and NIV therapy showed similar result of PaO_2, PaO_2/FiO_2 ratio. In group A patients PaO_2/FiO_2 ratio was 138±6.3 and PaO_2 was 92.13±7.85 vs group B patients PaO_2/FiO_2 ratio was 140±6.5 and PaO_2 was 89.45±10.02. With a high-flow system the ventilatory demand of the patients is completely by the gas flow delivered by the device. In this study HFNC reduce in better oxygenation for the same set of FLO_2. Several mechanism could explain this effect. First, by delivering the gas at flow rates that exceed the patient's peak inspiratory flow rate. HFNC provides a content $F1O_2$. As a result, the final concentration of oxygen truly delivered to the patient is evaluated to the FIO_2 (SET). Several authors have shown that the delivered $F1O_2$ is greater with high-flow oxygenation devices that with the standard system supplying low gas flow rates. With these later devices, the delivered $F1O_2$ can decrease considerably when the patient's inspiratory flow is high as its opten the case critically ill patients. Morever the high gas flow can without the upper airways dead space and may create an oxygen reservoir within the upper airways. Finally, the high gas flow generates a positive airway pressure of 2-5 can H2O, which is proportional to gas flow and may recruit the atelectasis lung. Similar findings were observed where the HFNC significantly improved the PaO_2 and SPO_2 after use. In this study haemodynamic status were similar in both groups. No significant difference was observed between groups. significant. Tan *et al.* [6] demonstrated that there were also no significant differences in respiratory parameters, and vital signs between the two groups at the time of enrollment. The stable FiO_2 after extubation in the HFNC group was 0.32 (0.28-0.38), which was not significantly different from

0.35 (0.30-0.40) in the NIV group. Sun *et al*. [5] reported that, initial respiratory rate was 27.5±3.5 breaths/min. The initial FiO_2 in the HFNC group was 0.3 (0.2-0.4), and the gas flow rate was 50 (40-50) L/min. While the initial FiO_2 in the NIV group was 0.4 (0.3-0.6), inspiratory airway pressure was 10 (8-12) cmH2O, and expiratory airway pressure was 4 (4-5) cmH_2O.On evaluation of outcome, present study shows successful treatment was more achieved in group-A (76.0% vs. 70.0%), although difference was statistically non-significant (p=0.501). treatment failure was 24.0% patients in group-A and 30.0% patients in group-B. Among the patients with treatment failure, the intubation rate in the HFNC group was similar to that of the NIV group. However, there were no significant differences between the two groups in successful treatment and treatment failure. Sun *et al*. [5] shows that overall treatment failure rate was 34.1% (28 of 82 patients), and total mortality at day 28 was 14.6% (12 of 82 patients). Treatment failed in 11 of 39 patients with HFNC, in which eight cases received invasive ventilation and three cases switched to NIV. 17 of 43 patients in the NIV group had treatment failure, in which nine cases received invasive ventilation and eight cases later received HFNC. The HFNC group had a treatment failure rate of 28.2%, which was lower than that of the NIV group (39.5%). However, result is similar between this study and Sun *et al*. [5] regarding successful treatment and treatment failure. In this study causes of treatment failure showed that the intolerance rate of NIV was significantly higher than that of the HFNC (P=0.038). However, there was no difference between the two groups regarding respiratory distress, hypoxemia and carbon dioxide retention. Sun *et al*. [5] shows that intolerance rate of NIV was significantly higher than that of the HFNC. However, there was no difference between the two groups regarding respiratory distress, hypoxemia and carbon dioxide retention. One patient's intolerance in the HFNC group was due to "too strong airflow". Tan *et al*. [6] showed that treatment intolerance was significantly lower in the HFNC group than in the NIV group, with a risk difference of − 50.0% (95% CI, − 74.6 to−12.9%, p = 0.015). There was no significant difference between the two groups in exacerbated respiratory distress, hypoxemia, or carbon dioxide retention. The causes for six intolerances in the NIV group were feelings of claustrophobia (n = 2), excessive air flow or pressure (n = 2), breathlessness (n = 1), and headache (n = 1). Duration of ICU stay was noticed in group A patients and group B patients were similar as p value >.05. This finding is similar to the study of Riker and his collogues [9]. This may due to both group patients had same rate of treatment success rate. However, NIV intolerance is a frequent occurance and increases NIV failure rates, intubation rates and overall mortality [10]. HFNC is a novel means of oxygen therapy with a favourable tolerance profile. In theory, HFNC is suitable for acute respiratory failure patients, because it can provide high airflow but at relatively lower FiO_2 levels, which can create a small positive mean airway pressure, relieve respiratory distress and reduce work of breathing [11]. This study reveals that despite some treatment failure in both group patients had similar outcome in treatment success rate with good tolerance in HFNC group patients. There was no difference in intubation rates, ABG parameter like pH, PaO_2 and $PaCO_2$ after treatment between HFNC and CPAP ventilation were also similar. So HFNC can significantly improve hypoxemia, with good efficacy and safety.

Conclusion

This study showed that HFNC was not inferior to NIV in the means of treatment failure and re-intubation for pneumonia patients with hypoxemic respiratory failure. Compared with NIV, HFNC was better tolerated. The number of airway care interventions and the incidence of complications associated with HFNC were significantly lower than in NIV. HFNC appears to be an effective means of respiratory support for pneumonic patients with severe hypoxemic respiratory failure.

Limitation

- Certain limitations of this work must be recognized. Due to covid pandemic situation data collection was not possible up to the sample size.
- Single centre study.

Recommendation

The following recommendation are proposed:
High flow nasal oxygen therapy can be used in Pneumonic patient with acute hypoxemic respiratory failure instead of NIV therapy.

Conflict of Interest

Not available.

Financial Support

Not available.

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