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Comparison of helmet versus face mask interface for noninvasive ventilation in patients with acute cardiogenic pulmonary oedema— A randomized controlled trial

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Abstract

Introduction: Non-invasive ventilation (NIV) is strongly recommended in patients with acute cardiogenic pulmonary oedema (ACPE). Recently, helmet has been introduced as an interface for NIV. This study was planned to compare helmet and face mask interface for administering NIV.

Methods: This was a prospective, randomized control trial conducted in patients with ACPE with respiratory failure treated with either face masks or helmet. Patients in Group H (Helmet) received minimum positive end expiratory pressure (PEEP) of 10, with a pressure support (PS) of 15. The cushion was inflated to 100 cm H_20 and pressurization/ rise time was kept 0.1 seconds. Group F (Facemask) patients received pressure support with expiratory positive airway pressure (EPAP) of 8 and inspiratory positive airway pressure (IPAP) of 16 cm H_20. EPAP & IPAP were adjusted according to tidal volume (TV) and respiratory rate (RR) respectively.

Results: Patients using helmet as the interface had less failure rate (0.0%) as compared to facemask 9 (22.5%), Odds Ratio (OR) [95% Confidence Interval (CI)]- 0.04 (0.0, 0.71) (p= 0.001) and less complications such as nasal and skin ulcers 3 (8.6%) in Group H as compared to 16 (45.7%) in Group F, OR (95% CI) o--0.11 (0.03,0.43) (p= 0.01).

Conclusion: Helmet was better than face mask in terms of reduced requirement of intubations, better patient tolerance and reduced complications.

Keywords: intubation; mask; non-invasive ventilation; ulcers

Introduction

Non-invasive ventilation (NIV) is the modality of choice for providing respiratory support in patients with acute cardiogenic pulmonary edema (ACPE). NIV provides dual benefit of reducing both right ventricular preload and left ventricular afterload, thereby, reducing pulmonary venous congestion and pulmonary edema [1]. Also, it avoids endotracheal intubation and reduces complications associated with endotracheal tube-like ventilator associated pneumonia, delirium, requirement of excessive sedation and intensive care (ICU) acquired weakness [2].

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ACPE is characterized by an excessive extravascular lung water, reduced respiratory system compliance and accumulation of excess fluid in pulmonary parenchyma [3]. It develops due to an imbalance between Starling's forces between pulmonary vasculature and alveoli. NIV is beneficial as it provides positive airway pressure and redistributes fluid back to pulmonary vasculature, improve oxygen delivery-consumption mismatch and enhance oxygenation. NIV is helpful in reducing both right ventricular preload and left ventricular afterload.

NIV delivered with the help of face mask is the most commonly utilized interface. However, face mask frequently leads to leaks and disturbed communication with the patient. Also, there is need for frequent interruptions due to mouth dryness and eye irritation. Face mask may also lead to pressure injuries on facial skin. Also, PEEP delivered via facemask is limited and higher PEEP levels are less often tolerated by patients. Often, these complications lead to facemask intolerance and thereby, failure of NIV.

On the other hand, helmet is a relatively new interface for administering NIV, which has recently gained popularity in management of covid-19 associated acute hypoxemic respiratory failure (AHRF) [4]. Helmet is advantageous in terms of better patient compliance, ability to deliver higher PS/ PEEP, uninterrupted ventilator support for longer time period, preventing patient induced self-inflicted lung injury (P-SILI), skin injury, lesser leaks and reduced aerosol generation [5]. Its widespread use is limited due to increased cost, bulky structure, lack of expertise, limited availability and risk of claustrophobia. However, its efficacy and safety is also largely limited due to lack of sufficient studies with this interface. An extensive search of literature has revealed no study of helmet NIV in patients with ACPE.

The primary objective of the study was to compare failure (intubation) rates of facemask and helmet NIV. Secondary objective was to compare partial pressure of oxygen (PaO_2) and carbon-dioxide ($PaCO_2$) in arterial blood gas (ABG) analysis. Also, any complications (nasal ulcers, claustrophobia, discomfort, etc) were noted in both the groups.

Materials and methods

This was a prospective, randomized controlled trial conducted in a district teaching hospital in Delhi from July 2019 to June 2021. The study protocol was approved by Institutional Ethical committee. Written informed consent was taken from all the patients. All adult patients between 18 to 80 years of age with a diagnosis of ACPE with respiratory failure were recruited to participate in this study. Patients with chronic obstructive pulmonary disease (COPD), Acute respiratory distress syndrome (ARDS), bronchial asthma, community acquired pneumonia (CAP), hospital acquired pneumonia (HAP), drowsiness, unconsciousness, uncooperative patients were excluded from participation in the study.

All patients underwent a complete workup of the illness, associated comorbidities and underwent a general physical examination. All routine haematological and biochemical investigations along with ABG analysis was performed. Patients presenting tachypnea (respiratory rate >30 breaths/min), desaturation (SpO_2 < 85%), bilateral crepitations on chest radiograph, presence of B-lines on lung ultrasound in more than two lung zones were assessed. If two out of four of these criteria were present, a diagnosis of acute cardiogenic pulmonary edema was made. Patients were randomly allocated, using a computer-generated random number table into two groups. The sealed envelopes were opened on the day of admission to ICU, just before the administration of NIV. Patients were then randomly allocated into two groups of 35 each. Patients were either administered facemask or helmet NIV as per the random number allocated to them (Figure 1). GROUP H- Patients were treated with helmet NIV. GROUP F- Patients were treated with facemask NIV. Continuous monitoring included 12 lead ECG, non-invasive blood pressure (NIBP), SpO_2, end tidal carbon-dioxide ($EtCO_2$), RR, temperature and urine output.

Patients with ACPE were treated with NIV either by face mask or helmet in addition to IV antibiotics, intermittent nebulisation and diuretics in patients showing features of congestive heart failure. Patients in Group H were administered Helmet (Starmed) NIV via ventilator in pressure support (PS) / positive end expiratory pressure (PEEP) mode. The minimum PEEP applied to all patients was 10, with a pressure support of 15. The circuit length was limited to 65 cm, and the cushion was inflated to 100 cm H_20. The pressurization/ rise time was kept minimum of 0.1 seconds. Patients in Group F received NIV via face mask connected to a standard single limb ventilator (Philips Respironics V 60) and were treated with EPAP of 8 and IPAP of 16 cm H_20. Ramp was 2cm H_20 and Ramp time was 10 min. Rise time was 0.1sec. EPAP & IPAP was set according to PaO_2 & $PaCO_2$ respectively. Maximum limit set for IPAP was 25 cm H20 and EPAP was 10 cm H_20. The duration of study period was 72 hours. PaO_2 and $PaCO_2$ of both groups were compared before and after 72 hours of NIV. Heart rate, acidosis, consciousness, oxygenation and respiratory rate (HACOR score)--- was used to predict NIV failure. Those with a score of >/= 6 for more than 2 hours of maximal NIV support in both group , were considered as NIV failure and were placed on mechanical ventilation.

Statistical analysis

Keeping alpha error of 0.05, power of 0.85, 26 patients were required in each group. Keeping in mind natural drop outs, 35 patients in each group was considered optimal. The patients were randomly assigned to receive treatment in one of the two groups using a computer generated random number in opaque slips. The data was entered into the computer through Epilnfo Version 3.3.2 to create a database of the study and was analysed to assess the outcome of the study. Statistical comparison was made between groups by applying chi-square test to a contingency table and two ANOVA was applied. The statistical analysis was done using SPSS version 20.0. The values were represented in Number, proportion (%) and Mean ± SD.

Results

Demographic profile of both the groups was similar. This is shown with the help of table 1. Respiratory and haemodynamic parameters in both the groups are shown in tables 2 and 3. Nine patients in Group F (22.5%) required endotracheal intubation whereas in Group H, no patient (0.0%) required endotracheal intubation, Odds ratio (95%Confidence Interval) = 0.04 (0.0,0.71), (p=0.001). Complications (face ulcers, nose/neck ulcers, claustrophobia) were only 3 (8.6%) in Group H as compared to 16 in Group F (45.7%) (p=0.01).

Length of time on NIV was significantly lesser in Group H (39.83 ± 16.48) as compared to Group F (58.54 ± 11.01) (p<0.001). Mortality after 28 days of ICU stay was 0

Table 1: Demographic profile of two groups.

Variable	*Group H (n=35)*	*Group F (n=35)*	*p value*
Age (years)	26.32 (6.39)	26.47 (7.59)	0.986
Gender (male: female)	21:14	20:15	0.808
Body Mass Index (kg/m^2)	23.77 (2.66)	22.76 (1.76)	0.562
SOFA Score	6.31 (4-8)	7.8 (4-9)	0.122

Abbreviations: n= number of patients, H=Helmet, F= Face mask

Table 2: Haemodynamic parameters of Group F and Group H.

Variable	*Group H (n=35)*	*Group F (n=35)*	*p-value*
Respiratory rate (CPM)	34.51 ± 2.95	36.54 ± 3.27	1.000
Systolic BP (mmHg)	179.66 ± 11.02	171.26 ± 14.87	0.09
Diastolic BP (mmHg)	93.89 ± 5.86	95.23 ± 6.89	0.326
Hco_3	20.09 ± 2.72	18.66 ± 3.14	0.084
SPO_2	86.23 ± 3.29	86.23 ± 2.56	0.756
G1 (Liters)	0.95 ± 0.17	1.01 ± 0.20	0.187
Lactate (Day 1)	4.83 ± 0.48	4.86 ± 1.66	0.365
PaO_2/FiO_2 (Baseline)	172.94 ± 15.59	161.06 ± 25.98	0.167
PaO_2/FiO_2 (Post-Intervention)	330.60 ± 438.99	237.74 ± 31.99	0.074

Abbreviations: n= number of patients, H=Helmet, F= Face mask

Table 3: Haemodynamic parameters of Group F and Group H.

Variable	*Group H*	*Group F*	*p-value*
PaO_2 (Baseline)	69.18 ± 6.24	64.40 ± 10.43	0.167
PaO_2 (Post-Intervention)	102.90 ± 6.32	95.01 ± 12.75	0.063
pCO_2 (Baseline)	60.97 ± 7.48	58.83± 8.02	0.44
pCO_2 (Post-Intervention)	39.91 ± 5.47	39.37 ± 23.59	0.104
pH (Baseline)	7.28 ± 0.05	7.25 ± 0.05	0.20
pH (Post-Intervention)	7.40 ± 0.04	7.34 ± 0.11	0.02
NIV Timing	39.83 ± 16.48	58.54 ± 11.01	<0.001

Abbreviations: n= number of patients, H=Helmet, F= Face mask

(0.0%) in Group H as compared to 3 (8.6%) in Group F (p=0.239), but it was not statistically significant (Table 4). Kaplan Meier survival curves were analysed for NIV timing in the two groups. Partial pressure of oxygen in arterial blood showed improvement from baseline after intervention in both the groups. However, P/F ratio in both the groups was similar in both the groups. This is shown in table 2.

Table 4: Primary and secondary outcomes of study.

Primary outcome	*Group H (n=35)*	*Group F (n=35)*	*Odds Ratio (95% CI)*	*pvalue*
No. (%) of endotracheal intubation	0 (0.0%)	9 (22.5%)	0.04 (0.0, 0.71)	0.001
Secondary outcome				
Adverse events (Face ulcers, claustrophobia, nose/neck ulcers)	3 (8.6%)	16 (45.7%)	0.11 (0.03, 0.43)	0.01
Length of time on NIV	39.83 ± 16.48	58.54 ± 11.01		<0.001
28- day mortality	0(0.0%)	3 (8.6%)	0.13 (0.01, 2.63)	0.239

Abbreviations: n= number of patients, H=Helmet, F= Face mask

Discussion

NIV has been widely used for the management of patients with ACPE. It confers the dual advantage of preserving patient's consciousness and simultaneously, maintaining the ability to protect airways. The present study compared both the interfaces for management of patients with ACPE.

Failure of NIV and number of intubations was significantly less in Group H as compared to Group F. Helmet NIV had the unique ability to deliver higher pressure support continuously for a longer period of time. Since helmet NIV improved patient comfort, it could provide pressure support uninterrupted and reduced number of intubation. In a similar study by Foti et al, all ACPE patients were applied CPAP with helmet. The authors reported a significant improvement in oxygenation parameters and patient tolerance (p<0.01) [6].

Optimal settings of NIV were revealed in another study by Mojoli et al [7], high PEEP (10 cm H_2O), neck cushion inflation (120-150 cm H_2O) and fast pressurization time was considered optimal. Similar settings were used in our study too to achieve best results. Claustrophobia is yet another concern with helmet NIV. In the present study, none of the patients experienced this complication as compared to face mask.

Our study also revealed that oxygenation parameters (PaO_2) and carbondioxide ($PaCO_2$) clearance were improved in both the groups. The difference was not statistically significant. This is perhaps due to the fact that difference in interface has no bearing on the natural course of disease but it can influence the requirement of intubation. Similar results were observed in another clinical review by Rodriguez et al, out of 9 original articles 8 studies showed similar oxygenation rates, while the incidence of intubation was lower with use of helmet in 4 studies [8].

Effective delivery of high levels of PEEP partly explains significant reduction in the intubation rate. The unique ability to provide neck seal allows the delivery of higher airway pressures without substantial air leak. This could, perhaps, translate into reduced respiratory rate, higher oxygen saturation levels and reduced number of intubations (9). High fresh gas flow rates (100 to 120 L/min) decreased the risk of CO_2 rebreathing in the helmet [9]. Thus, PEEP and fresh gas flow effects of helmet NIV appear to have improved oxygenation and work of breathing. Also, expired humidified gases combine with dry fresh gas flow, thereby, enhancing humidification and improving patient comfort. Use of helmet NIV shifts tidal volume to higher compliance point on pressure-volume curve, which improves patient- ventilator synchrony.

Similar results were obtained by Tonnelier et al [10], in his pilot study in patients with respiratory failure due to ACPE reported that there was a significant reduction in respiratory rate and heart rate in both helmet and mask groups. Improved oxygenation was found in both groups but helmet allowed a longer period of CPAP without any adverse event and better tolerance than the mask. Hence, helmet was considered a better alternative to facemask showing better patient compliance.

However, our study had several limitations. Firstly, it was a single centre trial conducted in a small group of selected patient population. The findings of this study cannot be generalized to all patient subgroups. Also, the sample size was small. Further studies are required in this direction to provide deeper insights.

Conclusion

Helmet is superior over face mask in terms of reduced number of intubations and better success rate. However, both interfaces were comparable in terms of oxygenation and carbon-dioxide clearance parameters.

Conflicts of interest

Authors declare no conflicts of interest.

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