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NASAL HIGH-FLOW VERSUS VENTURI MASK OXYGEN THERAPY AFTER EXTUBATION. EFFECTS ON OXYGENATION, COMFORT, AND CLINICAL OUTCOME IN PATIENTS UNDERGOING OPEN HEART SURGERIES.

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ABSTRACT 1. This study was a randomized, controlled trial comparing NHF with the Venturi mask in critically ill patients requiring oxygen therapy after extubation, with the hypothesis that NHF could improve oxygenation.

2. Patients mechanically ventilated for more than 24 hours were screened for enrollment. Just after extubation, patients were randomized to receive oxygen through the venturi mask (control group) or the NHF (intervention group). Randomization was done. In both groups, FiO2SET was adjusted to obtain an SaO2 between 92% and 98% (88–95% in patients with compensated hypercapnia). The Venturi mask or the NHF was applied for 48 hours or up to ICU discharge. Arterial blood gases, SaO2, FiO2SET, respiratory rate, mean arterial pressure, heart rate, and patient discomfort was recorded at 1, 3, 6, 12, 24, 36, and 48 hours.

3.As compared with the venturi mask, use of the nasal high flow after extubation results in better oxygenation for the same set FiO2.

4. The use of the nasal high flow is associated with fewer episodes of interface displacement and of oxygen desaturation.

KEYWORDS : NIV, Ventilation, Face Mask, Venture Mask

INTRODUCTION

Acute respiratory failure (ARF) is the most common reason for admission in the intensive care unit (ICU), often requiring endotracheal intubation and the institution of mechanical ventilation until resolution of the underlying disease. Oxygen therapy is used to correct residual impairment in oxygenation after interruption of the ventilator support and removal of the endotracheal tube. Several devices for oxygen delivery are available in critically ill patients, such as high-concentration reservoir mask, simple face mask, venturi mask, and nasal cannula (1). The venturi mask is frequently used because it allows delivery of predetermined, nominal, FiO2 (1). The venturi mask, as all the aforementioned low-flow systems, provides oxygen at flow rates that are lower than patients' inspiratory demands; thus, when the patient's inspiratory flow exceeds the gas flow rate from the mask, room air is entrained. The final concentration of oxygen truly delivered to the patient can be lower than the set FiO2 (FiO2SET) and depends on the ventilatory demands of the patient (2)(3). The mask may also reduce patient comfort and it is more likely to be displaced by the patient than nasal cannula (4).

Breathing dry oxygen provokes dryness of the mouth, nose, throat, and respiratory tract, which may frequently result in discomfort and pain particularly in the ICU setting (5). Clinical practice guidelines recommend humidifying the oxygen when administered at flow rates exceeding 4 L/min, because the humidification provided by the nasal mucosa becomes insufficient (6). Full humidification of inspired gas may thus improve patient comfort and facilitate the elimination of secretions.

Nasal high-flow (NHF) therapy has been made available recently for adult patients. Comprehensive data about its clinical efficacy are scarce. Recently, a new device has been proposed in adult patients with ARF (7) and newborns (8): this device delivers fully humidified, high-flow oxygen (up to 60 L/min) through a nasal cannula (Optiflow; Fisher and Paykel Healthcare, Auckland, New Zealand). By delivering the gas at flow rates that exceed the patient's peak inspiratory flow rate, this high-flow system provides a constant FiO2. With this device, the final concentration of oxygen truly delivered to the patient is equivalent to the FiO2SET (2). In addition, a flow-dependent effect of continuous positive airway pressure has been documented in healthy subjects (9) and in patients (10)(11). Last, the high gas flow may generate an upper airways dead space washout effect and may create an oxygen reservoir within the upper airways (12). Through these mechanisms, the nasal high-flow (NHF) device has the potential to improve oxygenation as compared with conventional low-flow systems for oxygen therapy, such as the venturi mask (7). This study was a randomized, controlled trial comparing NHF with the Venturi mask in critically ill patients requiring oxygen therapy after extubation, with the hypothesis that NHF could improve oxygenation. This study also assessed the effects of the two devices on patient comfort, adverse events, and clinical outcome.

MATERIALS AND METHODS

Study Design

1. Study type: Interventional
2. Study allocation: Randomized
3. Intervention model: Parallel Assignment
4. Masking: Open Label
5. Eligibility:

- Ages eligible for study: 18 years and older
- Genders eligible for study: Both
- Accepts healthy volunteers: No

6. Inclusion criteria:

- Mechanical ventilation > 24h
- Successful spontaneous breathing trial conducted for a period of 30-120 min.
- PaO2/FiO2 ≤ 300 at the end of the spontaneous breathing trial preceding extubation

7. Exclusion criteria

- age<18 years
- pregnancy
- tracheostomy
- need of NIV post-extubation (prophylactic NIV)

METHODOLOGY

1. The study was conducted in a tertiary care cardiothoracic center.
2. Written informed consent was obtained from all patients.
3. Patients mechanically ventilated for more than 24 hours were screened for enrollment. Patients were included if they successfully passed a spontaneous breathing trial (13), and had a PaO2/FIO2 less than or equal to 300 at the end of the spontaneous breathing trial.
4. Exclusion criteria were age less than 18, pregnancy, tracheostomy, do-not-intubate status, and planned use of noninvasive ventilation (NIV) after extubation. Planned post-extubation NIV was based on the following a priori criteria: more than three consecutive failures of the spontaneous breathing trial (14), and a PaCO2 greater than 45 mm Hg with a respiratory rate greater than 25 per minute just before the spontaneous breathing trial (15).
5. At the time of extubation, all patients were screened for normal mental status and delirium. Just after extubation, patients were randomized to receive oxygen through the venturi mask (control

group) or the NHF (intervention group). Randomization was done in a masked fashion, using opaque envelopes, with a unique computer-generated, random number sequence for both. In both groups, FiO2SET was adjusted to obtain an SaO2 between 92% and 98% (88–95% in patients with compensated hypercapnia). The Venturi mask or the NHF was applied for 48 hours or up to ICU discharge.

6. Arterial blood gases, SaO2, FiO2SET, respiratory rate, mean arterial pressure, heart rate, and patient discomfort was recorded at 1, 3, 6, 12, 24, 36, and 48 hours. Patient discomfort was assessed by asking patients to rate discomfort related both to the interface (face mask or nasal cannula) and to the symptoms of airways dryness (mouth, throat, and nose dryness; difficulty in swallowing; and throat pain) on an ICU-adapted, large-print, numerical rating scale, from 0 (no discomfort) to 10 (maximum discomfort) (16, 17).
7. Adverse events which were anticipated included (1) displacement of the oxygenation device; (2) oxygen desaturation (SaO2 < 92% or < 88% in patients with compensated hypercapnia); and (3) post-extubation ARF requiring the institution of NIV or endotracheal intubation. Decisions to apply NIV and to perform endotracheal intubation will be based on a priori criteria (15,18,19).i.e. based on the occurrence of respiratory failure, as defined by the presence of two or more of the following: 1) hypercapnia with respiratory acidosis (PaCO2 >45 mmHg with an arterial pH <7.35), 2) clinical signs suggestive of respiratory muscle fatigue or increased respiratory effort (i.e., use of accessory muscles, intercostal in-drawing, or paradoxical motion of the abdomen), 3) respiratory rate >35 breaths/min for 1h, and 4) persistent hypoxemia, defined as a SaO2 <90% or PaO2 <80 mmHg with FiO2SET >50% for more than 1h. Decision to perform endotracheal intubation was based on the presence of at least one of the following criteria: 1) hypercapnia with severe respiratory acidosis (PaCO2 >45 mmHg with arterial pH <7.25 and below the value at enrolment); 2) changes in mental status, making nursing care impossible or requiring sedation; 3) decrease in SaO2 <85% or PaO2 <45 mmHg despite oxygen therapy (with FiO2SET >50%); 4) unbearable dyspnea with respiratory muscle failure; 5) hypotension, with a systolic blood pressure <70 mmHg for more than 30-min despite adequate volume challenge, use of vasopressors, or both; or 6) unmanageable copious secretions(15, 18, 19). The final decision to reintubate the patient was made by the attending physician.

Primary endpoint was oxygenation (i.e., the PaO2/FiO2SET at 24 h). Secondary endpoints were patient discomfort, episodes of device displacement, episodes of oxygen desaturation, occurrence of post-extubation ARF requiring any form of ventilator support, and reintubation.

Statistics

The Venturi mask is an oxygenation device delivering low gas flow, such as the nasal cannula and the simple mask. For the sample size calculation, three publications were referred comparing the effects of any low-flow systems and NHF on oxygenation(7, 10,21). With a type 1 error of 0.05 and a power of 80% we calculated a sample size of 104 patients (52 patients in each arm). Data were analyzed with an intention-to-treat approach. Categorical variables were reported as percentages and continuous variables as mean and SD. Comparisons of continuous variables between groups were performed using analysis of variance. Comparisons between categorical variables were performed using the chi-square test. P less than 0.05 was considered statistically significant. In the present study, only the primary endpoint (PaO2/FIO2SET at 24 h) was rigorously tested at a 5% type 1 error level: all other tests on secondary endpoints were merely exploratory in nature, and no multiple inference corrections were applied.

RESULTS

- Between November 2014 and March 2016, 104 patients were enrolled in the study, 52 in the control group (venturi mask) and 52 patients in the intervention group (nasal high flow).

Patient characteristics at inclusion were as follows:

Age (yr.)	Venturi group (n= 52)	Nasal high flow (n= 52)	p value
Male sex	30	33	0.413
Female sex	22	19	0.372
Type of admission	Surgical	Surgical	
PaO2, mm Hg	95.408 ± 10.417	93.827 ± 9.139	0.413
PaCO2, mm Hg	38.208 ± 3.152	37.596 ± 3.780	0.372
SaO2, %	97.042 ± 1.106	95.462 ± 0.727	0.0001
FIO2, %	40	40	0.322
PaO2/FIO2, mm Hg	237.3423 ± 24.157	234.5769 ± 22.838	0.550
Respiratory rate, breaths/min	18.50 ± 1.553	17.56 ± 1.461	0.002
Heart rate, beats/min	85.54 ± 8.842	83.87 ± 7.423	0.298
Mean arterial pressure, mm Hg	84.37 ± 6.259	81.40 ± 5.191	0.010

PaO2/FiO2

PaO2/FiO2 :The PaO2/FiO2 ratio was significantly higher with nasal high flow as depicted in the table below :

Therapy		N	Mean	SD	SE of Mean	Significance
paO2/FiO2	Venturi Mask	52	237.3423	24.157	3.350	.550
	NHF	52	234.5769	22.838	3.167	
(paO2/FiO2)1	Venturi Mask	52	235.8163	27.496	3.813	<.0001
	NHF	52	259.6154	30.544	4.236	
(paO2/FiO2)3	Venturi Mask	51	237.6402	31.954	4.474	<.0001
	NHF	52	281.7308	37.673	5.224	
(paO2/FiO2)6	Venturi Mask	51	243.6353	38.429	5.381	<.0001
	NHF	52	299.4615	43.260	5.999	
(paO2/FiO2)12	Venturi Mask	51	250.6059	40.135	5.620	<.0001
	NHF	52	315.7212	48.387	6.710	
(paO2/FiO2)24	Venturi Mask	50	258.080	44.765	6.331	<.0001
	NHF	52	337.644	47.747	6.621	
(paO2/FiO2)36	Venturi Mask	48	263.4479	48.188	6.955	<.0001
	NHF	52	356.8942	46.079	6.390	
(paO2/FiO2)48	Venturi Mask	37	273.5905	57.849	9.510	<.0001
	NHF	49	370.0510	44.857	6.408	

DISCUSSION

The conclusions and results which can be drawn from the present study can be summarized as follows:

1. as compared with the venturi mask, use of the nasal high flow after extubation results in better oxygenation for the same set FiO2.
2. the nasal high flow decreases respiratory rate and improves patient discomfort both related to the interface and to symptoms of airways dryness.
3. use of the nasal high flow is associated with fewer episodes of interface displacement and of oxygen desaturation.

Effect of Nasal high flow on oxygenation

With a high-flow system, the ventilatory demand of the patient is completely met by the gas flow delivered by the device. In contrast, the oxygenation device is classified as a low-flow system when it fails to meet the ventilator demand of the patient. The flow rate delivered by the system should not be confused with the oxygen concentration. Indeed, a high-flow system, such as the nasal high flow, can deliver low FiO2, whereas a low-flow system, such as the venturi mask, can deliver FiO2 as high as 60%(3).

In the present study as compared with the venturi mask, nasal high flow results in better oxygenation for the same set FiO2. Several mechanisms could explain this effect. First, by delivering the gas at flow rates that exceed the patient's peak inspiratory flow rate, this device provides a constant FiO2. As a result, the final concentration of oxygen truly delivered to the patient is equivalent to the FiO2(20). Several authors have shown that the delivered FiO2 is greater with high-flow oxygenation devices than with the standard systems supplying low gas flow rates(20)(21). With these latter devices, the delivered FiO2 can decrease considerably when the patient's inspiratory flow is high, as it is often the case in critically ill patients(1)(20)(22). Several studies have suggested that NHF may improve oxygenation compared with low-oxygen flow devices(7)(10)(12)(26). In line with these studies, the present study also found that oxygenation, for the same set FiO2, was improved by the nasal high flow.

Effect of Nasal high flow on other respiratory parameters

The contemporary decrease in the respiratory rate and in the PaCO2 suggests that dead space was reduced with the nasal high flow. There are two main mechanisms through which nasal high flow may decrease dead space: increase in tidal volume and improvement in inspiratory

air-flow dynamics(27). Alternatively, nasal high flow could have washed out the nasopharyngeal dead space volume, thus producing a sort of unidirectional breathing that is known to reduce inspired dead space volume(28). The increase in tidal volume decreases the anatomic dead space and improves breathing efficiency, thus explaining the reduction in PaCO2 with nasal high flow(27). The slower and deeper breathing can also decrease the work of breathing(29) and can relieve dyspnea through a neural pathway including the activation of central and reflex mechanisms(30). The lower respiratory rate observed with the nasal high flow can be explained by a decreased patient inspiratory effort,(31) although this remains a speculation because this was not measured in the present study.

Effect of Nasal high flow on patient comfort

In the present study, the nasal high flow reduced patient discomfort related both to the interface and to the symptoms of airways dryness. Other studies in critically ill patients also suggested that the nasal cannula improves comfort as compared with the face mask(7)(10)(32)(33)(34). In the present study discomfort related to the interface was lower with the nasal high flow, particularly after the first 12 hours. In addition, the nasal high flow system decreased the discomfort related to symptoms of airways dryness as compared with the venturi mask. A better gas humidification obtained with the nasal high flow may explain this finding. Indeed, several investigators have reported that improving the humidification of the inspired gas ameliorates patient comfort(2)(5)(35)(36).

Effect of Nasal high flow on Adverse Events and Weaning Outcome

The nasal high flow reduced the incidence of adverse events, such as interface displacement and oxygen desaturation. The improved comfort with the nasal high flow may explain finding that the use of this device was associated with less displacement of the interface. In turn, it can be speculated that the better tolerance and the fewer interface dislodgements may have reduced the episodes of oxygen desaturation with the nasal high flow, as opposed to the venture mask. This finding is in line with the results of a previous study showing that the use of nasal cannulae was associated with fewer oxygen desaturations as compared with the face mask in patients undergoing high-flow oxygen therapy(34).

With the use of nasal high flow there was improvement in oxygenation, comfort, and compliance with the therapy together with the improved patient ability to clear secretions, along with a decreased patient inspiratory effort and abetter lung recruitment.

CONCLUSION

- As compared with the Venturi mask, the use of the NHF system in the post extubation period results in better oxygenation for the same set FIO2.
- In addition, the NHF decreases PaCO2 and the respiratory rate, while improving patient comfort and reducing episodes of interface dislodgement and oxygen desaturation.

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