The Total Face Mask Is More Comfortable than the Oronasal Mask in Noninvasive Ventilation but Is Not Associated with Improved Outcome

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Key Words

Noninvasive positive-pressure ventilation • Total face mask • Oronasal mask

Abstract

Background: Noninvasive positive-pressure ventilation (NPPV) is commonly used to improve ventilation and oxygenation and avoid endotracheal intubation and mechanical ventilation. Although clinically indicated, most patients fail to use NPPV due to mask intolerance. A total face mask was designed to increase compliance, but whether this translates into better outcome (improvement in clinical and blood gas parameters and less intubation) is unknown. **Objectives:** We compared the evolution of the clinical parameters, blood gases, levels of ventilatory support and rate of endotracheal intubation using the total face mask or the traditional oronasal mask during NPPV. **Methods:** A total of 60 patients were randomized to use either mask during NPPV. The clinical and laboratory parameters, as well as the level of ventilatory support were recorded at different intervals in both groups for up to 6 h. In addition, the tolerance for each mask and the need for endotracheal intubation were com-

pared. **Results:** Patients tolerated the total face mask significantly better ($p = 0.0010$) and used NPPV for a longer time ($p = 0.0017$) when compared with the oronasal mask. Just 1 patient switched to the total face mask because of intolerance. Although better tolerated, the rate of endotracheal intubation was similar in both groups ($p = 0.4376$), as was the clinical and laboratory evolution. **Conclusions:** The total face mask was more comfortable, allowing the patients to tolerate NPPV longer; however, these accomplishments did not translate into a better outcome. Due to its comfort, the total face mask should be available, at least as an option, in units where NPPVs are routinely applied.

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Introduction

In the last decade, there has been an increased use of noninvasive positive-pressure ventilation (NPPV) in patients with respiratory failure. There are several advantages of NPPV over endotracheal intubation and invasive ventilation, such as fewer incidences of nosocomial pneumonia and laryngeal stenosis, as well as a decrease

in the length of hospital stay and even mortality [1, 2]. The major indications of NPPV are the treatment of acute exacerbations of patients with chronic obstructive pulmonary disease or as an auxiliary method in their weaning from invasive ventilation, acute cardiogenic pulmonary edema and lung infection resulting in respiratory failure in immunosuppressed patients [3–8]. In addition, NPPV can also be helpful in hypoxemic respiratory failure, in the prevention of post-extubation respiratory failure and in selected cases of acute asthmatic attacks [9, 10]. Although clinically indicated, some patients do not tolerate the mask interface or the clinical conditions deteriorate despite its use, eventually leading to intubation. As a matter of fact, about a third of patients fail to tolerate NPPV [11, 12], and the main reasons for this intolerance are air leaks around the mask, claustrophobia and facial discomfort. To overcome these problems, new masks have been designed to increase the comfort while maintaining a tight seal necessary for this kind of ventilation. Although the nasal mask is usually considered better tolerated than the oronasal mask, the occurrence of buccal air leaks frequently precludes its use and resulted in the modification of the mask [13]. For this reason, it has been suggested that the oronasal mask should be the initial first choice in the management of acute respiratory failure [13], although this is still controversial [14, 15].

To further increase patient compliance, a total face mask that covers the whole face was developed [16] and promised to be an attractive alternative to the other masks. Surprisingly, there is a paucity of studies exploring this new mask [16, 17] and whether a more comfortable mask ultimately results in better outcomes and reduces the rate of endotracheal intubation and its consequences is still undefined.

To address these questions, we compared the outcomes of patients requiring NPPV using either the oronasal or the total face mask.

Patients and Methods

Study Population

The study was conducted at Pro-Cardíaco Hospital, a private hospital with 40 intensive or semi-intensive beds, primarily attending cardiac and pulmonary diseases. Inclusion criteria were the development of respiratory failure caused by any condition where NPPV was indicated. To be eligible, the patients had to have dyspnea and at least one of the following: tachypnea (respiratory rate $>24/\text{min}$); use of accessory muscles of respiration, paradoxal breathing; pH <7.35 with no other explanation; $\text{PaCO}_2 >45$ mm

Hg or a $\text{PaO}_2/\text{FiO}_2 <250$ at room air. Exclusion criteria were patients with altered mental status, excessive respiratory secretion, unstable coronary disease, cardiac arrhythmia leading to circulatory instability, arterial hypotension (systolic pressure <90 mm Hg or decreasing more than 40 mm Hg from baseline), abnormal coagulation (international normalized ratio >2 , platelet count $<60,000$), extensive facial lesions, facial trauma, upper airway obstruction, recent upper airway, esophagus or stomach surgery, or a medical condition requiring immediate endotracheal intubation.

Patients were randomized to receive NPPV via either an oronasal or a total face mask (Respironics Inc., Murrysville, Pa., USA). Randomization was performed in advance by a third party who tossed a coin (head – total face mask, tail – oronasal mask), then sealed and sequentially numbered all the envelopes including the mask options. The researchers were blinded to these options and only when the patients were enrolled in the study were the researchers allowed to open the envelopes. The study was approved by the local ethics committee.

NPPV Technique

NPPV was performed and monitored by a respiratory therapist under the supervision of the attending physician. NPPV was performed using the ventilator Knightstar 335 (Puritan Bennett, Pleasanton, Calif., USA). The NPPV settings were in accordance with established guidelines [18]. In general, NPPV was applied continuously for up to 6 h, starting with an inspiratory positive airway pressure (IPAP) of 4 cm H_2O and an expiratory positive airway pressure (EPAP) of 4 cm H_2O . The levels were raised 1 cm H_2O every 3 min, as necessary. Supplementary oxygen from 3 to 15 l/min was added to reach an arterial oxygen saturation (SpO_2) $>90\%$. Airtight application of the mask was achieved by elastic straps. The mask was first applied manually and then secured to the face using the straps. Skin irritation was prevented by routinely applying colloids onto the nasal bridge. All patients underwent continuous noninvasive systemic arterial blood pressure, SpO_2 and electrocardiogram monitoring. The ventilatory parameters (respiratory rate, tidal volume, flow, IPAP and EPAP, airway leak and I:E ratio) were recorded as displayed by the ventilator. The NPPV weaning process followed the guidelines described elsewhere [18].

Variables

At inclusion, epidemiological (age, gender) and clinical (blood pressure, pulse rate, respiratory rate, use of accessory muscles of respiration) data were recorded, along with noninvasive measurement of SpO_2 at room air and with supplemental oxygen. The clinical parameters were reviewed after 30 min, and then at 1-, 2-, 4- and 6-hour intervals after initiation of NPPV. During each time period, the clinical parameters, levels of ventilatory support (IPAP and EPAP) and the amount of supplemental oxygen were recorded. A visual scale of mask comfort was applied to the patients and graded as 1–5, where 1 was very comfortable and 5 was very uncomfortable. The primary end points were compliance with the mask, total time of NPPV and the requirement of endotracheal intubation within each mask group. Secondary end points were the need to switch the mask and the evolution of the clinical and arterial blood gas (ABG) parameters.

Table 1. Epidemiological, clinical and ABG parameters of both mask groups at initiation of therapy

Parameters	Oronasal mask	Total face mask	p value
Gender (M/F), %	38/62	53/47	0.1142
Age, years	79 ± 9	77 ± 11	0.2603
Respiratory rate/min	32 ± 7	31 ± 6	0.7089
Heart rate/min	91 ± 16	94 ± 23	0.6545
Use of accessory respiratory muscle, %	21 (n = 34)	19 (n = 26)	0.3570
SpO ₂ at admission, room air, %	85	83	0.5296
SpO ₂ at admission, after supplemental O ₂ , %	92	90	0.6140
ABG			
pH	7.35 ± 0.1	7.34 ± 0.10	0.3687
PCO ₂ , mm Hg	43 ± 13	43 ± 14	0.4923
PO ₂ , mm Hg	97 ± 46	91 ± 41	0.3355
HCO ₃ , mmol/l	22 ± 4	22 ± 6	0.4798
BE, mmol/l	3 ± 2	5 ± 4	0.060
Lactate, mmol/l	2.1 ± 1	1.6 ± 0.9	0.4947

M = Male; F = female; BE = base excess.

Statistical Analysis

Continuous variables were compared by the t test, and categorical variables by the χ^2 or z test (proportions), as appropriate. The adjusted mask group comparison relied on logistic regression. Results for continuous variables are presented as the mean ± SD, with ranges in parentheses. The two-sided 0.05 threshold was used for statistical significance. Analysis was performed using the statistical software XLSTAT (Addinsoft, France).

Results

A total of 60 consecutive patients with respiratory failure were included, 34 in the oronasal mask group and 26 in the total face mask group. At admission, both groups were comparable in relation to age, gender and severity of respiratory failure according to clinical and ABG parameters (table 1). The total face mask was significantly more tolerated, with 87% of the patients compliant with the mask, as compared to 46% in the oronasal mask group ($p = 0.0010$). This was also expressed by a significantly longer time of NPPV use with the total face mask as compared with the oronasal mask (288 and 178 min, respectively; $p = 0.0017$) (table 2). Just 1 patient switched from the oronasal mask to the total face mask because of intolerance. All but 6 patients had the ABG parameters

Table 2. Comparison of compliance, total time of NPPV use and need of tracheal intubation with both masks

Parameters	Oronasal mask	Total face mask	p value
Compliance, % of users	46	87	0.0010
Total time, min	178 ± 141	288 ± 126	0.0017
Need of tracheal intubation, %	17	19	0.4376

Table 3. ABG parameters after 1 h of NPPV in both mask groups

	Oronasal mask	p value	Total face mask	p value
pH	7.37 ± 0.04	0.0864	7.38 ± 0.05	0.0516
PCO ₂ , mm Hg	41 ± 11	0.2892	39 ± 10	0.1478
PO ₂ , mm Hg	115 ± 69	0.1626	110 ± 52	0.1023
HCO ₃ , mmol/l	21 ± 6	0.2946	23 ± 5	0.3755
BE, mmol/l	5 ± 5	0.0886	3 ± 3	0.0764

Statistical analysis comparing the evolution of the blood gases before initiation of therapy and 1 h after therapy was implemented in each mask group. BE = base excess.

collected at admission. Measurement of ABG was repeated after 1 h of NPPV in 66% of patients ($n = 40$). Despite better toleration and longer NPPV use in the total face mask group, the decrease in the respiratory and heart rates and the amount of pressure support (IPAP and EPAP) were similar in both groups as was the improvement in ABG (table 3). In relation to endotracheal intubation, 4 patients (15% of total) in the total face mask group were eventually intubated due to the worsening of the medical condition, compared to 6 patients (17% of total) in the oronasal mask group, and this difference was not statistically significant ($p = 0.4376$). Interestingly, all patients that needed endotracheal intubation in the total face mask group tolerated the mask during the whole time, compared with only 2 out of the 6 patients in the oronasal mask group.

Discussion

NPPV has become an important instrument in the emergency and intensive care wards, giving respiratory support, while other therapies are implemented to reverse respiratory failure. With this approach, patients are spared intubation and mechanical ventilation. In

some situations, its role as first-line support ventilation is solid whereas in others, a trial may be worthwhile before proceeding to tracheal intubation, as long as there is no contraindication. Although widely available, NPPV is underused even among patients with chronic obstructive pulmonary disease exacerbations and cardiogenic pulmonary edema, the 2 best and widely accepted indications [19]. One of the main reasons for NPPV failure is intolerance of the mask, and for this reason, new masks were designed to overcome this problem, including the total face mask and the helmet. Both are recommended for patients with claustrophobia, and additionally allow the patient to talk and read while decreasing some complications such as eye irritation and skin necrosis [20, 21]. Although an interesting interface, the helmet is more difficult for the physical therapist or other health care providers to handle, may accumulate carbon dioxide and may cause hearing damage due to the noise exposure inside the helmet [21–23]. Some of these drawbacks are not shared by the total face mask. Furthermore, the helmet was associated with worse patient-ventilator synchrony and inspiratory effort when compared with the oronasal mask [21]. For these reasons, the total face mask is probably the best tolerated mask and may be an attractive alternative in cases where mask intolerance is the primary reason for failing to comply with NPPV. This is in accordance with our results which showed that the total face mask was more

comfortable for the patients, resulting in longer use of NPPV, when compared with the oronasal mask. As it is believed that patients who have a favorable response to NPPV usually improve within the first 2 h [24, 25], it is extremely important that patients tolerate the mask as long as necessary to correct the respiratory failure while specific therapies are being implemented. For this reason, the better tolerated total face mask might theoretically be an advantage and results in less intubation, when compared with the (less pleasant) oronasal mask. However, our results did not show any difference in the clinical and ABG results or in the rate of intubation. One possible explanation is that an even larger population would be necessary to show any statistical difference. Another explanation is that there is really no difference at all, and the use of different masks is only a matter of patient comfort and costs. As all patients in the total face mask group who were eventually intubated tolerated the mask while most in the oronasal mask group did not, it seems suitable as a first option. We hope that more studies are conducted with an even larger population. In conclusion, the total face mask is an attractive mask that increases compliance and should be available, at least as an option, in units where NPPV is routinely applied. Although not established to improve the final outcome, its comfort and easy use are at least very positive for both the patients and health professionals.

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