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Evaluation of patient skin breakdown and comfort with a new face mask for non-invasive ventilation: a multi-center study

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Abstract *Objective:* To evaluate patient comfort, skin breakdown and eye irritation when comparing a prototype face mask (PM) and conventional face masks (CMs) during non-invasive ventilation. *Setting and design:* Eight centers (intensive or intermediate care units). Multicenter randomized study. *Populations:* Patients with acute respiratory failure of different etiologies. *Interventions:* Patients were randomized to CMs or PM when ventilation was expected to last at least 12 consecutive hours a day for two consecutive days. Patient comfort, skin breakdown and eye irritation, assessed by means of standardized scoring systems, were measured after 24 and 48 h and before discontinuing ventilation. *Results:* Hundred ninety-four patients were randomized. Forty-seven patients were finally enrolled: PM (24) and CMs (23). Ventilator settings were similar in the two groups at the beginning of the treatment and after 24 and 48 h. Skin breakdown was significantly higher in the CMs group over the study period ($p<0.001$). Patient comfort was higher in the PM group after 24 and 48 h ($p=0.008$ and $p<0.001$, respectively). Eye irritation was absent in both groups after 24 h and did not differ significantly after 48 h ($p=0.539$). Before ventilation was discontinued skin breakdown and patient comfort were significantly higher in the CMs group, when compared to the PM group ($p<0.001$ and $p=0.003$, respectively). Eye irritation was slightly higher in the PM versus CMs group ($p=0.21$). The time on ventilation was not significantly different between the two groups ($p=0.830$). *Conclusion:* The PM significantly reduced skin breakdown while improving patient comfort, compared to the CMs.

Keywords Non-invasive mask ventilation · Face mask · Patient comfort · Skin breakdown · Eye irritation

Introduction

Several studies have shown that non-invasive mechanical ventilation (NIMV) improves gas exchange both in hypoxemic and hypercapnic respiratory failure [1]. Most non-invasive mask ventilation failures are due to technical problems such as air leaks, mask discomfort and skin lesions [2]. Among the adverse effects of mask ventilation, skin breakdown, which occurs at the site of mask contact even after only a few hours of ventilation, is a frequent complication, ranging from 2–23% [3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15]. In one study, where patients were continuously ventilated with a face mask for more than 48 h, this percentage reached 70% [16].

Hypoxemic patients generally breathe through the mouth causing unpredictable air leaks when nasal masks are used. Full face masks are therefore a better choice in these patients [13, 14]. The need for nasogastric tube insertion and the high level of pressure applied to the respiratory system during the early phase of non-invasive ventilation treatment can worsen air leaks [12, 13, 14, 15, 16]. In an attempt to reduce air leaks and improve patient-ventilator synchrony [17] masks are tightened, with the result that skin necrosis is more likely to occur and patient comfort decreases. Kramer et al. [6] reported that non-invasive ventilation fails in 18% of patients because of mask discomfort. Few studies address the impact of different devices on patient comfort and complications related to the mask [18, 19]. The ability to provide better patient comfort while reducing skin lesions might enable mask ventilation to be used successfully in a larger patient population. Recently, we tested a new face mask prototype. This prototype was specifically designed for non-invasive ventilation to allow a more comfortable patient-mask interface where the mask is in contact with the nasal bridge. Its better fit seemed to reduce air leaks. The aim of this study was to compare the effects of conventional face masks (CMs) with this prototype face mask (PM) on patient comfort, skin breakdown and eye irritation in patients with hypercapnic and hypoxemic respiratory failure.

Methods

Population

All patients were admitted to one of eight centers (intensive or intermediate care units) for evaluation and treatment of hypoxemic and/or hypercapnic respiratory failure from September 1997 to September 1999. All centers were familiar with NIMV use. The SAPS II (Simplified Acute Physiology Score) was calculated in all patients [20]. Prior to enrolment in the study all patients were tested with standard medical therapy, which consisted of supplemental oxygen, postural drainage and, depending on the underlying disease, bronchodilators and/or corticosteroids. All candidates for non-invasive ventilation fulfilled the criteria for respiratory failure according to either Antonelli or Brochard study protocols [7, 13]. Non-invasive ventilation was not considered if a patient was unconscious, hemodynamically unstable (mean arterial pressure <65 mmHg or severe arrhythmia), prone to vomiting, had undergone recent gastric or esophageal surgery, was suffering from basal skull fracture, was affected by facial skin lesions from previous mask treatment or was claustrophobic.

After the randomization patients were withdrawn from the study if they underwent ventilation for less than 12 consecutive hours a day for two consecutive days or needed intubation for lack of improvement in arterial blood gases or became unconscious, severely claustrophobic or affected by unremitting vomiting or were hemodynamically unstable (mean arterial pressure <65 mmHg or severe arrhythmia). Informed consent was obtained from all patients entered in the study.

Ventilator settings

All patients received non-invasive ventilation using pressure support ventilation (PSV) with positive airway pressure turbine-driven portable ventilators (BiPAP, Respironics, Murraysville, Pa.; Helia, Saime, Savigny Le Temple, France; Ony'x, Mallincrodt Puritan Bennett, Colo.) or intensive care unit ventilators (Siemens Servo 900 C or Servo 300, Uppsala, Sweden; Drager Evita 2 or 4, Lubeck, Germany). Initial ventilator settings (inspiratory and end-expiratory pressure), their titration during ventilation and the decision to discontinue mechanical ventilation were decided upon by the attending physician of each center.

Masks

Patients were randomly assigned to receive non-invasive ventilation via a CM or the PM only when mask ventilation was expected to last at least 12 consecutive hours a day for two consecutive days on the basis of diagnosis or clinical state. The face masks used in the conventional mask group were: Gibeck, Uppsala Vasby, Sweden; Respironics Murrysville, Pa., USA; King System, Noblesville, Ind., USA. Patients were randomly selected to receive one of the masks according to a random computer-generated sequence.

The prototype face mask (Koo Medical Equipment, Shanghai China) is a disposable, single size mask with the following features (Fig. 1):

1. An inflatable clear anatomical soft air cushion is mounted on a clear dome. The cushion is made of PVC and it is larger than those commercially available on other cushioned masks (Fig. 1A). This potentially allows, once the mask is secured on the patient, decrease of pressure, especially on the bridge of the nose.
   The manufacturing company made the PVC cushion as thin as possible while avoiding micro-leaks. Leaks from a fully inflated cushion were tested in vitro during a constant pressure of 40 cmH_20 over 12 h. Masks that failed to maintain pressure were discarded.
2. A stiff frame works as a mask holder with six attachment points to secure the head straps (Fig. 1B).
3. The head cap has four head straps and a quick release band to ensure immediate mask removal if needed (Fig. 1C).
4. A nasogastric tube adapter allows introduction of a feeding tube. This connector fits the mask and can be attached to the ventilator circuit (Fig. 1D). This potentially allows the reduction of leaks due to the positioning of a feeding tube between the mask and the skin.

The internal volume of the masks "in vitro" was about 220 ml and 200 ml (Gibeck mask, large and medium sizes), 240 ml and 220 ml (King mask, large and medium sizes), 350 ml and 290 ml (Respironics mask, medium and small sizes) and 235 ml (Koo

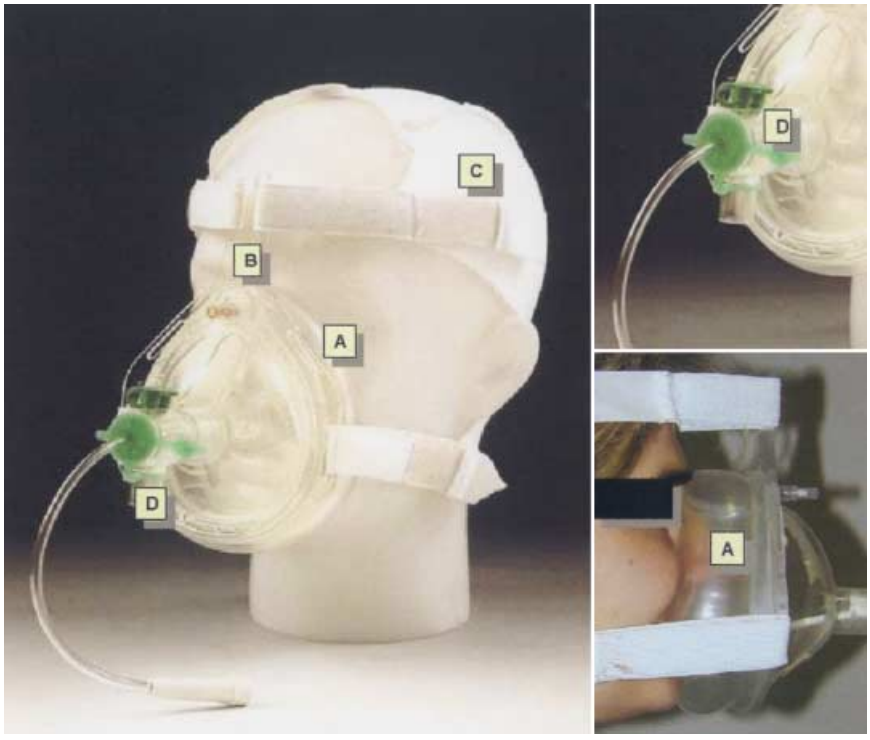

Fig. 1 The prototype face mask (*A* inflatable clear anatomical soft air cushion mounted on a clear dome, *B* mask holder that incorporates six points of attachment to secure the head straps, *C* head cap with head straps with a quick release strap to ensure immediate mask removal if needed, *D* nasogastric tube adapter to introduce the feeding tube when needed)

protoype mask, single size). The internal volume is reduced to about 140 ml and 118 ml (Gibeck mask, large and medium sizes), to 140 ml and 120 ml (King mask, large and medium sizes), to 170 ml and 140 ml (Respironics mask, medium and small sizes) and to 150 ml (Koo protoype mask, single size), taking into account reduction by a normal facial structure volume.

The masks in both groups were secured in order not to leak air while allowing enough space to pass two fingers beneath the head strap [1]. Leaks were monitored by checking the variation of inspiratory tidal volume during stable respiratory cycles or the difference between inspiratory and expiratory tidal volume when both were available on the ventilator. When leaks were detected, the masks were readjusted to minimize these.

End points and definitions

The primary end point was to determine the degree of skin lesion at comparable levels of ventilatory assistance and duration of mechanical ventilation. Other end points were the degree of patient comfort and the presence of eye irritation. The degree of skin breakdown was assessed as follows: 0= nil, 1= area of redness, 2= moderate skin breakdown, 3= skin ulcer, 4= skin necrosis. Patient's comfort was evaluated by means of a standardized scoring system modified from Calderini et al. [17] as follows: 1= very poor, 2= poor, 3= sufficient, 4= good and 5= very good. The presence of eye irritation was evaluated and scored as follows: 0= absent, 1= present.

Improvement in blood gases was not an end point of our study. Therefore no comparison of this between the two groups was included in the outcome analysis.

Measurements of patient discomfort, skin breakdown, eye irritation and arterial blood gases

An attending physician not involved in the study was present daily to assess the degree of patient discomfort, skin breakdown and eye irritation. Patients were asked to report their level of comfort by pointing to a number on a board and chose the appropriate score answering the question: "How comfortable is this kind of ventilation?". Patient discomfort, skin breakdown, eye irritation scores and ventilatory parameters were assessed after 24 and 48 h on ventilation and when mechanical support was discontinued. Blood gases were measured before the initiation of mechanical ventilation, after 24 h and at 48 h.

Statistical analysis

The results are expressed as means ± standard deviation (SD). For baseline and follow-up comparisons between the two groups Student's *t*-test was applied; as was ANOVA for continuous data and χ^2 test with Yates' correction for non-linear data. A p value less than 0.05 was considered statistically significant.

Results

Hundred ninety-four eligible patients were randomized between September 1997 and September 1999 (Fig. 2). Hundred forty-seven patients were withdrawn from the study. Sixty-four patients (33%) were intubated within 12 h because of lack of improvement in arterial blood gases or for other reasons; 50 patients (25.8%) did not undergo non-invasive ventilation for at least 12 consecutive hours a day for two consecutive days and all avoided intubation; 33 patients (17%) did not fulfil the study protocol criteria for other reasons (25 patients had to be transferred to other departments or hospitals; 8 patients complained of claustrophobia and were switched to nasal

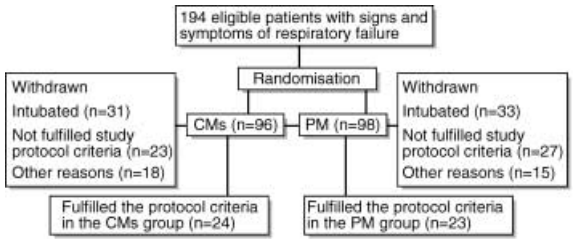

Fig. 2 Trial profile (*CMs* conventional masks group, *PM* prototype mask group)

Table 1 Patients' characteristics (*CMs* conventional masks, *PM* prototype mask, *SAPS II* Simplified Acute Physiology Score, *ARF* acute respiratory failure)

	CMs group *n*=24	PM group *n*=23	*p* value
Sex (male), *n* (%)	5 (21)	4 (17)	0.5
Age (years) mean ± SD	58 (18)	56 (18)	0.6
SAPS II mean ± SD	31 (10)	29 (5)	0.3
Weight (kg)	71 (13)	71 (13)	0.9
Hypoxemic ARF, *n* (%)	9 (37)	12 (52)	0.23
Hypercapnic ARF, *n* (%)	15 (72)	11 (48)	0.24

Table 2 Types of ventilator used in the two groups (*CMs* conventional masks, *PM* prototype mask)

Ventilators	CMs group *n*=24	PM group *n*=23
ICU ventilator		
Servio 900c or 300	9	9
Drager Evita 2 or 4	7	8
Turbine driven ventilator		
Respirinics BiPAP	3	4
Saime Helia	3	1
Puritan Bennet ONY'X	2	1

masks. Of these eight patients, four avoided intubation and four were intubated). Forty-seven patients (24.2%) were finally enrolled; 23 patients received the PM and 24 patients the CMs. Differences between the two groups were found in the number of patients who were intubated within 12 h.

In the CMs group seven patients received the Respironics mask; seven the King mask and ten the Gibeck one. Eight patients assigned to the PM group and 15 patients of the CMs group had pre-existing restrictive or obstructive lung disease. Patient characteristics are shown in Table 1. Table 2 lists the different types of ventilator used in the study.

Eight patients (34.7%) in the CMs group and seven in the PM group (29.1%) had nasogastric tubes inserted through their noses for other reasons than to prevent or to treat gastric distension. Ten patient had the nasogastric tubes already inserted because of feeding problems and five because they had undergone major surgery.

Table 3 Arterial blood gases in the two groups (*CMs* conventional masks, *PM* prototype mask)

Parameters	CMs group *n*=24	PM group *n*=23	*p* value
Baseline			
pH	7.35±0.09	7.37±0.1	0.42
PaO_2/FIO_2	145.5±55.4	160.2±72.3	0.43
$PaCO_2$ (mmHg)	54.5±18.4	46.3±22.1	0.17
After 24 h			
pH	7.40±0.05*	7.41±0.04*	0.17
PaO_2/FIO_2	215.4±17.6*	278.2±92.3*	0.008
$PaCO_2$ (mmHg)	48.7±10.8	42.7±13.1	0.10
After 48 h			
pH	7.40±0.04*	7.42±0.04*	0.06
PaO_2/FIO_2	207.8±56.8*	279.2±90.6*	0.002
$PaCO_2$ (mmHg)	47.8±9.5	40.7±9.6	0.01

*$p<0.05$ versus baseline

Initial ventilatory settings were similar in the two groups at the beginning of the ventilatory treatment: maximal inspiratory pressure (Pmax) was 16.7±4.1 cmH_2O and positive end-expiratory pressure (PEEP) was 5.2±2.6 cmH_2O in the PM group versus Pmax (15.6±6.8 cmH_2O) and PEEP (4.7±2.2 cmH_2O) in the CMs group (p=0.510 and p=0.485, respectively). The number of hours of continuous use of mechanical ventilation and parameters set on the ventilator did not differ between the two groups after 24 h (18.5±3.5 h in the PM group versus 19.5±3.2 h in the CMs group, p=0.28; Pmax 16.6±3.8 cmH_2O and PEEP 5.3±2.6 cmH_2O in the PM group versus Pmax 15.1±6.2 cmH_2O and PEEP 4.7±2.1 cmH_2O in the CMs group, p=0.328 and p=0.394, respectively). For these pressure values, skin breakdown scores were significantly higher in the CMs group after 24 h on non-invasive ventilation when compared to the PM group (1.75±0.9 in the CMs group versus 0.39±0.7 in the PM group, $p<0.001$). Twenty patients (86.9%) in the PM group and 24 patients (100%) in the CMs group were still in the study after 48 h. Non-invasive ventilation was successful in the remaining three patients (13.1%) of the PM group and they avoided intubation. Parameters set on the ventilator did not differ between the two groups after 48 h: Pmax 16.9±4.2 cmH_2O and PEEP 5.5±2.9 cmH_2O in the PM group versus 14.7±6.2 cmH_2O and PEEP 4.5±1.8 cmH_2O in the CMs group (p=0.166 and p=0.167, respectively). For these pressure values, the skin breakdown scores were significantly higher in the CMs group after 48 h on ventilation when compared to the PM group (2.1±0.9 in the CMs group versus 0.47±0.6 in the PM group, $p<0.001$ at any time).

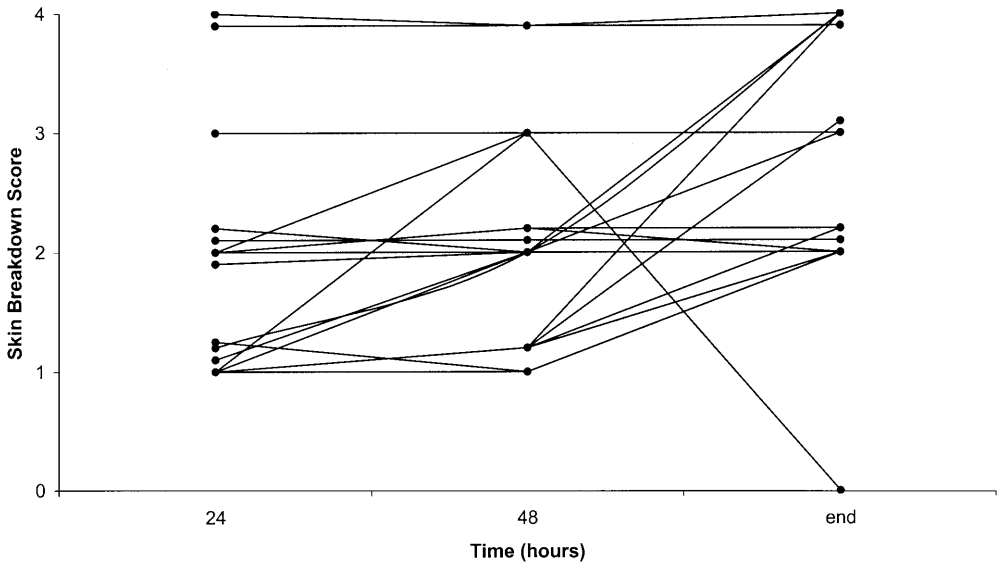

Fig. 3 Trend of skin breakdown score in the conventional masks group (● conventional mask group patients). Skin breakdown score: 0= nil, 1= area of redness, 2= moderate skin breakdown, 3= skin ulcer, 4= skin necrosis

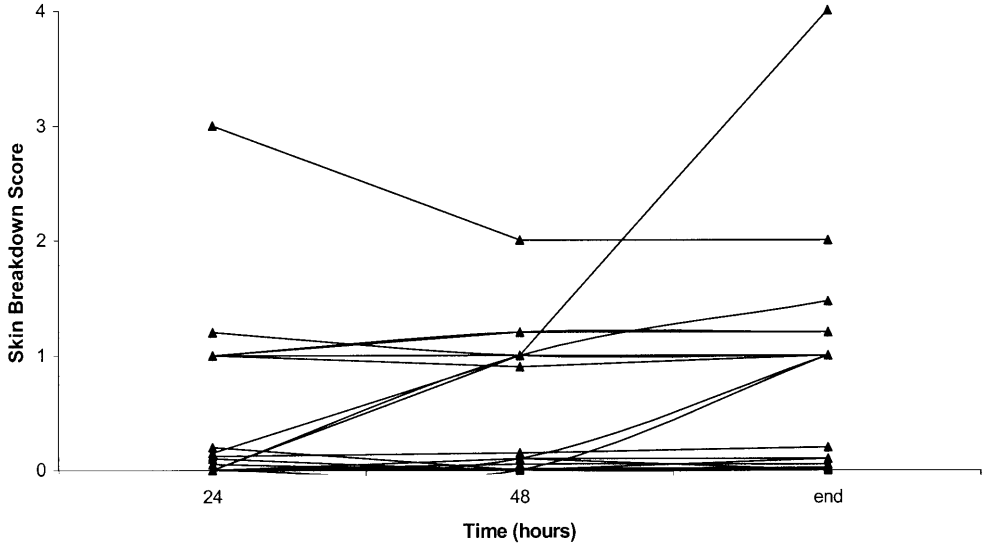

Fig. 4 Trend of skin breakdown score in the prototype mask group (black triangle = prototype mask group patients) Skin breakdown score: 0= nil, 1= area of redness, 2= moderate skin breakdown, 3= skin ulcer, 4= skin necrosis

The patient comfort score was higher in the PM group when compared to the CMs group after 24 h (3.52±0.7 in the PM group versus 2.9±0.7 in the CMs group, p=0.008) and 48 h (3.56±0.8 in the PM group versus 2.7±0.7 in the CM group, p<0.001). The eye irritation scores were nil in both groups after 24 h and did not significantly differ at 48 h (0.04±0.02 in the CMs group versus 0.08±0.2 in the PM group, p=0.539). The proportion of patients who developed skin breakdown over the study period was lower in the PM group [10 (43%) patients versus 24 (100%) in the control group; p<0.01]. Arterial blood gases in the CMs group and in the PM group over time are shown in Table 3. The PaO_2/FIO_2 ratio was significantly greater in the PM group when compared to CMs group after 24 and 48 h.

Ventilatory settings were also similar before discontinuing non-invasive ventilation (Pmax 12.9±5 cmH_2O and PEEP 4±1.9 cmH_2O in the PM group versus Pmax 13.5±5.5 cmH_2O and PEEP 4.5±2.1 cmH_2O in the CMs group, p=0.697 and p=0.396, respectively). At the end of ventilation, the skin breakdown score was significantly higher in the CMs group when compared to the PM group (2.79±1 in the CMs group versus 0.69±0.9 in the PM group, p=0.00). Patient comfort score was also significantly higher in the PM group (3.52±0.8 versus 2.8±0.8 in the CMs group, p=0.003). The eye irritation score was significantly higher in the PM group (0.21±0.4 versus 0.08±0.2 in the CMs group, p=0.000). Skin breakdown score trends over time are reported in Figs. 3 and 4. The overall time spent on ventilation was not signifi-

cantly different between the PM and CMs groups (90.6±62.4 h in the PM group versus 87.1±47.1 h in the CMs group, p=0.830). Two patients were intubated in the PM group and six in the CMs group. Two patients in each group were enrolled into a program of home care ventilation.

Discussion

This study showed that skin breakdown and patient comfort can be improved by using a new prototype mask (PM).

Respiratory failure patients' preference for mouth breathing probably explains why most studies on non-invasive mask ventilation in hypoxemic and hypercapnic respiratory failure published in the last 10 years were performed using face masks [1]. Of these studies eight used a mask specifically designed for non-invasive ventilation [7, 11, 12, 13, 14, 15, 16, 17]. In most of these studies, masks were fitted tightly in order to reduce air leaks, which often caused skin lesions. The development of skin lesions was more likely to occur on the nasal bridge [1], where the skin lies upon very little subcutaneous tissue on the nasal bone. Factors contributing to skin breakdown include pressure, lesions due to contact with stiff parts of the mask frame and tissue hypoxia [1] due to impaired blood capillary perfusion of the skin. Only the Total Face Mask (Respironics, Pittsburgh, Pa.) can be positioned without irritating the junction between nose and forehead [18].

The incidence of skin necrosis in the group of patients with the new PM was lower than in patients treated with conventional full face masks. Although there was no difference in the total duration of ventilation between the two groups, we took into account the number of continuous daily hours for each patient only at the beginning of the treatment. However, the duration of mask ventilation and the level of pressure applied did not seem to influence the occurrence of skin lesions [9].

One patient in the CMs group had a skin ulcer after 24 h of ventilation. It had completely healed after 6 days. This very fast recovery can be explained by the fact that the face mask (Gibeck, Uppsala Vasby, Sweden) was repositioned: as with the prototype mask, the point of head strap attachment on this mask can be changed. Altering the points of contact between face and mask facilitated faster recovery. Meduri et al. recommend using a patch of wound care dressing on the nasal bridge to reduce skin lesions [1]. We did not implement this suggestion to avoid confounding variables. The routine use of patches might have yielded different results, particularly in the CMs group. However, not using artificial skin or padding could also explain the high rate (100%) of skin breakdown in this group.

With mask ventilation, skin breakdown is independent of the level of pressure [9]. During mask CPAP only, however, air leaks are a minor problem, because the pressure applied to the respiratory system is constant and does not require a tight-fitting mask. In contrast, during pressure support ventilation, pressure applied to the airway opening switches from a high level (maximal pressure) to a lower level that can be ZEEP or PEEP. Air leaks are more likely to occur with poor patient-ventilator synchrony during intermittent positive pressure ventilation [17].

A potential explanation for the reduction in skin lesions, while using the PM mask, was the larger cushion surface that permitted a better seal between skin and mask at the level of the nasal bridge. This potentially allowed fewer air leaks with less tightening of the mask and avoided the harmful contact between the mask frame and the skin. In addition, the six head points of attachments on the mask holder made it possible to fix the mask in a more stable and secure manner, thus reducing mask displacement and pressure. In the CMs group insertion of the feeding tube increased the number of leaks that made further tightening of the mask necessary. In the PM group use of the nasogastric tube adapter reduced the need for mask readjustment to achieve an adequate seal. This suggests that since the study protocol imposed tightening the head strap for leak reduction, the major difference in patient comfort and skin breakdown scores between the two groups was due to differences in mask tightening because of air leaks.

Eye irritation is another problem related to mask ventilation, although somewhat less important than skin breakdown [1]. In our study the incidence of eye irritation was low in both groups with a slight, but not significant, increase in irritation score in the prototype group at the end of the study. The prototype mask comes in one size with a larger cushion. Even though the mask did not come in contact with the eyes, the cushion surface could have slightly hampered lid movements, thus irritating the conjunctiva.

Improvement of gases exchanges was not a primary end point of our study. However, both the groups had a significant improvement in PaO_2:FIO_2 over time with a significantly greater PaO_2/FIO_2 ratio in the prototype group, when compared to CMs group, after 24 and 48 h. This should not be explained by differences between the two groups, because of too different patient etiologies enrolled in the study. Howevermore comfort and less pain due to the lower degree in skin breakdown could lead to improved patient's psychological well-being while reducing agitation and high respiratory frequency, thus ameliorating the PaO_2:FIO_2 ratio. Intubation rate was also not an end point of our study. Therefore considerations about the number of intubated patients cannot be drawn from our results.

Parameters set on the ventilators decreased during the course of the study. This was due to the attending physician's modification in the ventilator setting for clinical

reasons. Nursing care time between the two groups was not taken into account. The design of the study, which included both intensive and intermediate care units, with a different nurse-patient ratio, did not allow an exact comparison. However, a face mask that is more comfortable for the patient could possibly reduce the time spent by nurses or respiratory therapists on re-adjustments.

A major limitation of the study is that it was not blinded to the type of mask. Therefore bias on the part of investigators, care-givers or even patients can not be entirely eliminated. We also used multiple different masks and ventilators with patients randomized into only two groups. Ideally it should have been a four-group study with patients randomized in order to have a different type of mask for each group. In addition, because of nonspecificity of the question answered by the patients regarding the comfort score, they might have had different interpretations. We did not measure mask comfort per se, but rather a composite comfort score.

In conclusion, our study has demonstrated that noninvasive ventilation via the prototype mask significantly reduced skin breakdown while improving patient comfort compared to conventional masks. Extensive studies are required to correct problems with face mask ventilation and optimize tools to ensure maximum patient comfort.

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