Noninvasive Positive-Pressure Ventilation With Different Interfaces in Patients With Respiratory Failure After Abdominal Surgery: a Matched-Control Study

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BACKGROUND: Acute respiratory failure (ARF) is a relatively common complication after abdominal surgery. METHODS: We compared the efficacy of noninvasive positive-pressure ventilation (NPPV) delivered via helmet versus via face mask in patients with ARF after abdominal surgery in 2 intensive care units (31 beds) in the hospital affiliated with the Catholic University of Rome. Twenty-five patients with ARF after abdominal surgery were treated with NPPV via helmet, and the data from those patients were matched with 25 controls chosen from a historical group of 151 patients treated with face mask during the previous 2 years for respiratory complications after abdominal surgery. The matching was done according to age, Simplified Acute Physiology Score II, and the ratio of PaO₂ to fraction of inspired oxygen (PaO₂/FIO₂). NPPV was delivered in pressure support, starting with 10 cm H₂O, and positive end-expiratory pressure (PEEP) was increased in steps of 2–3 cm H₂O, up to a maximum of 12 cm H₂O, in order to maintain an arterial oxygen saturation over 90% with the lowest possible FIO₂. RESULTS: NPPV significantly improved PaO₂/FIO₂ in both groups. Five of 25 helmet patients (20%) and 12 of 25 mask patients (48%) were intubated (p < 0.036). The main cause for NPPV failure in both groups was intolerance (mask 32% vs helmet 12%, p = 0.6). Heart rate, systolic blood pressure, respiratory rate, duration of NPPV, level of pressure support, and PEEP presented no differences between the 2 groups, nor did intensive-care-unit or hospital mortality. Both the helmet and mask interfaces were effective in improving gas exchange and respiratory rate. The global rate of NPPV complications (mask intolerance, major leaks that caused ventilator malfunction, and ventilator-associated pneumonia) was significantly higher in the mask group than in the helmet group (19 patients vs 4 patients, p < 0.03). CONCLUSIONS: NPPV can be an alternative to conventional ventilation in patients with ARF after abdominal surgery, and helmet use is associated with a better tolerance and a lower rate of complications. Key words: noninvasive ventilation, helmet, face mask, postoperative acute respiratory failure. [Respir Care 2007;52(11):1463–1471. © 2007 Daedalus Enterprises]
Introduction

Abdominal surgery can disturb the respiratory function by causing an alteration in diaphragmatic function and contractility that leads to a reduction of pulmonary volumes and airflow, which predisposes for lower-lobe atelectasis.1–4

Moreover, postoperative pain (mainly after upper-abdominal surgery) decreases cough efficiency and thus increases the risk of respiratory infection and atelectasis.5,6 Patients with peritonitis and other abdominal infections are likely to develop secondary acute lung injury (ALI) and acute respiratory distress syndrome (ARDS).7 For all these reasons, acute respiratory failure (ARF) can be considered a relatively common complication after abdominal surgery.1

The patients who develop postoperative ARF have generally been treated with endotracheal intubation and conventional mechanical ventilation, but this technique has been associated with both early and late complications.8–10

Noninvasive positive-pressure ventilation (NPPV) (ie, the administration of mechanical ventilation, avoiding endotracheal intubation) is considered as a first-line intervention for COPD patients with exacerbation,11,12 but it has also been successfully used in patients with hypoxic respiratory failure of various origin,13–15 including postoperative ARF.16–19

In a recent prospective study19 on postoperative ARF after abdominal surgery, NPPV was associated with a low rate of endotracheal intubation, NPPV-related complications, and ICU mortality. However, only half of the patients who required intubation had early NPPV failure (ie, in the first 24 hours), which suggests that mask tolerance can play a role in the success rate.

Different interfaces have been proposed during the last decade in order to improve patient-ventilator interaction: among them, the NPPV helmet (CaStar, Starmed, Mirandola, Italy) seems to be able to reduce the face-mask adverse effects, improve gas exchange, and significantly increase patient comfort.20,21 So far, few data are known about the use of NPPV in patients with postoperative ARF, and no study has compared the efficacy and tolerance of different interfaces in delivering NPPV in postoperative ARF after abdominal surgery. The first objective of the present matched-control study was to evaluate the possibility of using face mask or helmet NPPV to prevent endotracheal intubation in a group of selected patients who developed ARF after abdominal surgery and required mechanical ventilation. A second objective was to compare the use of face mask and helmet in those patients.

Patients

Twenty-five consecutive patients who developed postoperative ARF after abdominal surgery, admitted to our 13-bed surgical intensive care unit (ICU) or to our 18-bed general ICU, were prospectively included in this study and noninvasively ventilated with the CaStar helmet.

For each study patient, a matched control subject was chosen from a group of 151 patients treated for respiratory failure after abdominal surgery with face-mask NPPV in the same ICUs during the previous 2 years.

Our sample size was chosen to detect, with a 95% probability, a difference between the postulated 60% rate of intubation in the mask group (previously reported in 33 patients with hypoxemic ARF) and the 20% rate in the helmet group, which we observed in a pilot study.20

Methods

Patients

Patients were enrolled if they presented all of the following criteria:

- Clinical history compatible with ARF after abdominal surgery
- $P_{aO_2}$ lower than 60 mm Hg while breathing ambient air, or a ratio of $P_{aO_2}/FIO_2$ lower than 300 mm Hg, while breathing oxygen through an air-entrainment mask
- Presence of severe acute dyspnea, with a respiratory rate higher than 25 breaths/min and active contraction of accessory muscles of respiration or paradoxical abdominal motion

Exclusion Criteria

Patients were excluded if they met one of the following criteria:

- Need for cardiopulmonary resuscitation
- Glasgow coma score $\leq 8$
- Hemodynamic instability (defined as a systolic arterial blood pressure $< 80$ mm Hg or electrocardiographic evidence of ischemia or arrhythmias)
- Uncorrected bleeding diathesis, and cardiogenic or septic shock
- Elevated probability of surgical re-intervention in the following 48 hours
**Study Protocol**

Helmet group NPPV was delivered with the CaStar helmet, which is made of transparent latex-free polyvinyl chloride. The helmet is secured to the patient by 2 armpit braces, and connected to the ventilator by a conventional respiratory circuit. The proper helmet size (small, medium, or large) was chosen for each patient in order to avoid air leaks around the soft collar. The ventilator (300, Siemens, Uppsala, Sweden) was set in pressure-support ventilation mode, starting with 10 cm H2O of pressure support, with progressive stepwise increase of 2–3 cm H2O, according to patient comfort, to obtain a respiratory rate < 25 breaths/min and the disappearance of accessory muscle activity or paradoxical abdominal motion. Positive end-expiratory pressure (PEEP) was increased in steps of 2–3 cm H2O, up to a maximum of 12 cm H2O, in order to maintain the arterial oxygen saturation over 90% with the lowest possible FIO2. The flow trigger was set at 5 L/min, checking the absence of auto-triggering phenomena. The head of the bed was kept at a 45° angle. For 21 patients who required a nasogastric tube for surgical or nutritional reasons, a specific seal connector embedded in the helmet fixation ring was used to avoid air leaks. No humidification device was necessary.

For each patient treated with NPPV via helmet, one matched control was selected, according to the following matching criteria:

- **Cause of ARF**
- **Severity of illness on admission within 6 points of that of the treated patient (assessed via the Simplified Acute Physiology Score II)**
- **Age within 10 years**
- **P_aO2/FIO2 within 20 points of the value of the treated group**

NPPV was delivered via face mask (Vital Signs, Totowa, New Jersey, or Dar-Tyco, Mirandola, Italy). The mask was secured with head straps, avoiding a tight fit, and the head of the bed was kept elevated at a 45° angle. In all patients, a protective hydrocolloid sheet was applied over the nasal bridge. In the mask group, 19 patients required a nasogastric tube for surgical or nutritional reasons. In all mask-group patients a seal connector (Koo Europe, Buttigliera Alta, Italy) in the dome of the mask was used to minimize air leaks. All the patients were ventilated with ICU ventilators (300, Siemens, Uppsala, Sweden) set in pressure-support mode, with variable levels of PEEP. The levels of pressure support and PEEP were set as previously described for the helmet group. A heat-and-moisture exchanger (Hygrobac, Dar-Tyco, Mirandola, Italy) was used to condition the gas. In both groups the respiratory rate was continuously monitored with a cardiorespiratory monitor (Siemens-Elema, Solna, Sweden). Pain was treated in both patients groups according to our standard patient-controlled analgesia protocol, with morphine or tramadol. No patient had epidural analgesia.

**Protocol for NPPV Application**

NPPV was administered according to the standard protocol of administration used in our ICUs for postoperative ARF patients: during the first day NPPV was maintained subcontinuously for 24 hours, depending upon patient tolerance. If the patient required NPPV discontinuation, they received oxygen through an air-entrainment mask, with an FIO2 of 0.5–0.6, for the shortest possible period. During this time, if peripheral oxygen saturation was < 90%, NPPV was immediately restored. After the first day, if oxygenation and clinical status improved, the patient was left to breathe spontaneously, with oxygen supplementation through an air-entrainment mask, for gradually increasing periods, to augment the time lag between NPPV sessions.

NPPV was definitively discontinued if the patient was clinically stable and maintained for more than 12 hours a respiratory rate < 25 breaths/min and a P_aO2/FIO2 > 200 mm Hg, and had no need of ventilatory support, absence of dyspnea, inactivation of accessory muscles, and lack of paradoxical abdominal motion.

**Criteria for Intubation**

Predetermined criteria for immediate endotracheal intubation included the inability to maintain a P_aO2/FIO2 > 140 mm Hg during NPPV, the onset of seizures or coma (Glasgow coma score ≤ 8), hemodynamic instability (systolic blood pressure < 80 mm Hg or electrocardiographic signs of ischemia or arrhythmias), intolerance of the interface, inability to manage copious secretion, inability to alleviate dyspnea, or the need for an emergency surgical procedure.

After intubation, all patients with ALI/ARDS were ventilated with the same ventilation protocol, according to the low-tidal-volume protective ventilatory strategy.7

**Definitions and Measurements**

The definitions of ALI/ARDS, nosocomial pneumonia, ventilator-associated pneumonia (VAP), sepsis, severe sepsis, and septic shock were according to published guidelines.23–27

Measurements of P_aO2, P_aCO2, pH, respiratory rate, heart rate, and systolic arterial pressure were performed at baseline, after 1 hour of NPPV treatment, when clinically required, and at the end of treatment.
End Points

Primary end points were the improvement of gas exchange and the need for endotracheal intubation at any time during the study. Improvement in gas exchange was evaluated within 1 hour after study entry (initial improvement) and over time (sustained improvement), and was defined as the ability to increase PaO2/FIO2 to > 200 mm Hg or by ≥ 100 mm Hg above baseline until mechanical ventilation was discontinued.13,27

Secondary end points were the development of NPPV-related complications (mask intolerance, major leak that caused ventilator malfunction, or VAP), ICU stay, duration of ventilation, and ICU and hospital mortality.

Ethics

Our institutional review board approved the protocol, and all patients gave their informed consent prior to participation. For the control group no written informed consent was required, as NPPV via face-mask is considered a routine clinical practice in the ICUs of our hospital. All the procedures were conducted in accordance with the ethical standards of the World Medical Association Declaration of Helsinki.

Statistics

Results are given as mean ± SD. Each group was divided into 2 subgroups, NPPV success and NPPV failure, according to the results of NPPV. Demographic and physiologic characteristics of the 2 groups were compared via Student’s t test for continuous data (separate variance estimates were used when variances were significantly different) and the Mantel-Haenszel extended chi-square test or Mann-Whitney test for categorical data. Fisher’s exact test (2-tailed) was used when appropriate (expected number of cases per cell less than 5).28 A p value < 0.05 was considered to indicate a statistically significant difference.

Results

Twenty-five patients successfully extubated after abdominal surgery, who developed postoperative ARF (Table 1) a mean 2.5 ± 1.9 days after surgery, were enrolled in the study and were treated with NPPV delivered via helmet. The helmet group was matched with a historical control group who developed ARF 2.9 ± 1.6 days after abdominal surgery and were treated with NPPV via face mask. The type of surgery and the causes of postoperative ARF were similar in the groups (see Table 1). Also, the incidence of comorbidities (congestive heart failure, COPD, and diabetes) and the time between surgery and the start of NPPV were similar.

In the mask group, the failure patients were older and had a higher severity of illness and a lower PaO2/FIO2 (Table 2) than the success patients, but these differences were not statistically significant, probably because of an insufficient sample size. In the helmet group the failure patients were significantly sicker, as shown by the higher Simplified Acute Physiologic Score II (p = 0.01), whereas age was higher and baseline PaO2/FIO2 was lower, but these differences were not statistically significant (see Table 2).

Heart rate, systolic pressure, respiratory rate, pH, and PaCO2 were similar in the mask and helmet groups during the whole course of the study (Table 3).

The applied PEEP (6.2 ± 2.1 cm H2O vs 6.3 ± 1.9 cm H2O, p = 0.7), pressure support (13.4 ± 2.6 cm H2O vs 14.5 ± 3.6 cm H2O, p = 0.4), and duration of NPPV (25.9 ± 25 h vs 31.8 ± 19.6 h, p = 0.36) were also similar.

Eighteen (72%) of the 25 patients in the mask group and 14 (56%) of the 25 patients in the helmet group showed an initial improvement in PaO2/FIO2 (Fig. 1). According to the definitions, a sustained improvement was achieved in 18 patients (72%) in the mask group and in 16 patients (64%) in the helmet group (see Table 3). Twelve patients (48%) in the mask group and 5 (20%) in the helmet group failed NPPV (p = 0.036) despite an initial improvement, and
were intubated after a mean 32.1 ± 31.1 h and 45 ± 24.9 h, respectively (p = 0.4). The reasons for failure were:

- Intolerance: 8 patients (32%) in the mask group and 3 patients (12%) in the helmet group (p = 0.06)
- Lack of response: 3 patients and 1 patient, respectively (p = 0.67)
- Severe skin necrosis: one patient per group (p = 0.51)

The main cause for the higher rate of failure in the mask group was intolerance due to pressure-related pain in the nasal region. Despite the use of nasal skin protection and accurate nursing, 8 mask patients (32%) had superficial nasal abrasions (which spontaneously healed in 7–10 d).

VAP occurred in 8 patients (7 in the mask group and 1 in the helmet group) several days after failure of NPPV and endotracheal intubation. Only 1 patient (4%) in the helmet group developed skin necrosis in the axillary region, related to the arm-pit braces. Concerning the global rate of NPPV complications in the 2 groups (mask intolerance, major leaks that caused ventilator malfunction, or VAP), the incidence was significantly higher in the mask group than in the helmet group (19 patients vs 4 patients, p < 0.03).

In 16 patients (8 per group), ARDS was the cause of postoperative ARF. The failure rate in this subgroup of patients was 50%; however, only 2 (25%) of the 8 patients in the helmet group were intubated, versus 7 (87.5%) of the 8 patients in the mask group (p = 0.04) (see Table 2).

The ICU mortality was similar in the groups: 7 patients (28%) died in the mask group, versus 5 patients (20%) in the helmet group (see Table 3). In both groups the ICU mortality rate was significantly higher in the failure group than in the success group (p < 0.05). In the mask group, 6 patients died of sepsis and multiple-organ failure, and one died of cardiogenic shock. In the helmet group, 4 patients died of sepsis and multiple organ failure, and one died of cardiogenic shock. The hospital mortality was similar (see Table 3).

### Discussion

Our results show that in patients with postoperative ARF, NPPV delivered via face-mask or helmet can significantly improve PaO2/FIO2 and respiratory rate, but patients treated with the helmet had a significantly lower rate of NPPV failure, probably because of better tolerance of the interface.
Surgical patients may experience ARF in the early postoperative period, especially after upper-abdominal surgery. ARF genesis is multifactorial and partly related to intraoperative atelectasis, due to collapsed alveoli, blood displacement into the abdomen, and reduction of thoracic diameter with diaphragmatic displacement and dysfunction. The reduction in chest wall compliance, due to increased abdominal pressure and postoperative pain, may cause a prolonged and sometime severe reduction of functional residual capacity, PaO2, and forced vital capacity. NPPV can rapidly reverse these phenomena through the combined positive effects of PEEP and inspiratory pressure support, which increase lung ventilation, reopen atelectatic alveoli, and improve gas exchange. Surprisingly, few studies have investigated the clinical application of NPPV in patients with ARF subsequent to abdominal surgery.

Pennock et al investigated the effects of nasal bi-level positive airway pressure in a group of 31 patients (including 22 patients with postoperative ARF) and found significant improvement in gas exchange and a dramatic reduction in respiratory rate after 1 hour of treatment, with a success rate of 67%. These results were confirmed by the same authors in a study with 110 patients affected by ARF (in 80% postoperative) and treated with nasal bi-level positive airway pressure.

The efficacy of face-mask NPPV, in comparison to nasal CPAP, was investigated by Pankow et al in a group of postoperative patients affected by the obesity-hypventilation syndrome. Pankow et al concluded that face-mask

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<tr>
<th>Table 3. Outcomes After 1 Hour of NPPV and at the End of Treatment</th>
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<tbody>
<tr>
<td><strong>Mask Group</strong></td>
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<td>(n = 25)</td>
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<td><strong>Systolic Blood Pressure (mean ± SD mm Hg)</strong></td>
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<td>Before NPPV</td>
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<td>After 1 hour of NPPV</td>
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<td>At end of NPPV</td>
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<td><strong>Heart Rate (mean ± SD beats/min)</strong></td>
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<td><strong>Respiratory Rate (mean ± SD breaths/min)</strong></td>
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<td><strong>pH (mean ± SD)</strong></td>
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<td><strong>PaO2/FIO2 (mean ± SD mm Hg)</strong></td>
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<td><strong>PaCO2 (mean ± SD mm Hg)</strong></td>
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<td><strong>Initial PaO2/FIO2 improvement after 1 h of NPPV (n, %)</strong></td>
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<td><strong>Sustained PaO2/FIO2 improvement (n, %)</strong></td>
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<td>18 (72)</td>
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<td><strong>Duration of NPPV (mean ± SD h)</strong></td>
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<td><strong>Duration of mechanical ventilation + NPPV (mean ± SD d)</strong></td>
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<td><strong>Endotracheal intubation (n, %)</strong></td>
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<td><strong>ICU stay (mean ± SD d)</strong></td>
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<td><strong>Hospital mortality (n, %)</strong></td>
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*Sustained improvement was defined as a PaO2/FIO2 increase of ≥ 200 mm Hg or a PaO2/FIO2 increase of ≥ 100 mm Hg above baseline until discontinuation of mechanical ventilation.

FIO2 = fraction of inspired oxygen
NPPV = noninvasive positive-pressure ventilation
ICU = intensive care unit
NPPV Interfaces in Postoperative Acute Respiratory Failure

NPPV is more efficient than nasal CPAP in correcting gas-exchange abnormalities.

Varon et al\textsuperscript{18} prospectively investigated the efficacy of NPPV in a group of 60 patients affected by cancer (25 of them gastrointestinal cancers) who developed postoperative ARF. Their results confirmed that NPPV can be considered effective in cancer patients, avoiding intubation in 70\% of the patients.

Very recently, Jaber et al\textsuperscript{19} prospectively evaluated (in the only study that enrolled only abdominal surgery patients) the use of NPPV in 72 patients affected by established ARF. Forty-eight patients (72\%) were successfully treated and avoided endotracheal intubation. The nonintubated patients had significantly shorter ICU stay and lower mortality rate. Apparently our results show a higher intubation rate in the mask group patients (48\% vs 28\%), but this can be explained by the different patient population. In the study by Jaber et al, only 42\% of the patients had hypoxemia and bilateral lung infiltrates, whereas in the present study 64\% of the patients in the mask group had ALI/ARDS or pneumonia as the cause of postoperative ARF. Interestingly, the rate of failure reported by Jaber and colleagues in that specific subgroup of patients was 67\%.

So far, no randomized controlled study has evaluated the efficacy of NPPV in patients with established ARF after abdominal surgery; however, one recent randomized controlled study\textsuperscript{31} evaluated the prophylactic use of CPAP delivered via helmet in this kind of patient. In that study the authors compared the rate of prevention from endotracheal intubation observed with an early, preventive application of helmet CPAP to standard oxygen air-entrainment mask in a group of patients who developed hypoxemia after major abdominal surgery. They found that helmet CPAP significantly reduced the cumulative probability of intubation, compared to the standard approach (p < 0.05); only one patient in the helmet CPAP group, versus 10 patients in the standard oxygen group, was intubated (p = 0.05). Helmet CPAP significantly reduced the incidence of infection (p = 0.03), pneumonia (p = 0.03), and sepsis (p = 0.03), and this interface was well tolerated, which suggests a possible interest also for its application to deliver NPPV.

The aim of our matched-control study was to compare NPPV, delivered via helmet or face-mask, in preventing intubation during episodes of established ARF following abdominal surgery.

Our results suggest that, despite the efficacy of both interfaces in improving gas exchange in the short term, the relatively common development of intolerance phenomena is still an important cause of mask NPPV discontinuation, above all if used with a standard ICU ventilator without a specific NPPV algorithm. In that situation the helmet seems to offer some real advantages in terms of comfort and tolerance, by allowing prolonged continuous application of NPPV. However, it is also important to emphasize that the helmet can be used only with ICU ventilators that have a double circuit, and it has never been validated with turbine ventilators. Moreover, the helmet is not designed for use with ventilator CPAP or free-flow CPAP that applies flow of < 35 L/min.\textsuperscript{32}

The patients in the helmet and mask groups had a similar response to NPPV during the first hour, with a significant improvement in P\(_{\text{aO}_2}/\text{FIO}_2\). However, 12 patients in the mask group, versus only 5 in the helmet group (p = 0.04), were intubated. This result can probably be explained by considering the causes of ARF: patients with atelectasis, cardiogenic pulmonary edema, or ALI showed a sustained improvement, compared to the patients affected by ARDS or pneumonia, who often worsened after an initial improvement. This result is in accordance with the data reported by authors who evaluated NPPV in ARDS patients.\textsuperscript{33}

The rate of intubation (higher than 50\%) in this subgroup of patients suggests a prudent approach: limiting NPPV application only to patients in whom NPPV failure can be immediately treated by a prompt intubation. However, in our study, especially in the subgroup of patients who had ARDS as the cause of postoperative ARF, we found that the choice of the interface can significantly improve the success rate: 7 of the 8 patients in the mask group, versus only one of the 8 patients in the helmet group, were intubated (p = 0.036). However, considering the small number of patients and the consequent possibility of a type 2 error, we cannot make a conclusion about the efficacy of the helmet in ARDS patients, and larger randomized controlled studies are necessary to address the effectiveness of helmet NPPV in that kind of patient.
The present study has other important limitations related to its design (matched-control study, in which the historical comparison of 2 populations can favor the group treated with the new method). We are also aware of the possibility of a learning-curve effect that could have influenced our results; however, we consider this possibility unlikely, because mask NPPV was widely used in our ICUs for more than 10 years, but we also have extensive experience with the helmet in our ICUs, and both interfaces have similar instrumentation and are used by the same caregivers.

It is also important to emphasize that our results were obtained in 2 ICUs that have extensive NPPV experience (more than 500 patients were treated in the last 3 years), and therefore cannot be generalized to less experienced centers. Another possible limitation is our use of the Servo 300 ventilator, which does not have a specific NPPV algorithm, and cycles to expiration when the inspiratory flow decreases to the 5% of the peak flow. The Servo 300 requires great attention to minimizing air leaks when used for NPPV. Because air leaks are generally absent or minimal with the helmet, this subgroup of patients can be favored by the increased incidence of intolerance in the face mask group. The absence of a comparison of interface comfort between the 2 groups, and also the lack of evaluation of a time-consuming procedure for nurses, are also limitations of the present study.

Conclusions

The results of this matched-control study confirm that NPPV may be an alternative to conventional ventilation in patients with postoperative ARF after major abdominal surgery and suggest that helmet NPPV is a valid alternative to face mask, which reduces the intolerance phenomena and increases the NPPV success rate. It is worth keeping in mind that the generalization of the present results remains to be proven by large randomized controlled studies.

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